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Datasheet for the decision of 29 September 2022

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Language of the proceedings: EN

Title of invention:
A preparation for use of aspartate for regulating glucose levels in blood

Patent Proprietor:
N.V. Nutricia

Opponent:
Fresenius Kabi Deutschland GmbH

Headword:
Aspartate for regulating glucose/NUTRICIA

Relevant legal provisions:
EPC Art. 56
RPBA 2020 Art. 13(1), 13(2)

Keyword:
Main request, auxiliary requests 1 and 2 - Inventive step - (no)
Auxiliary requests - admitted (no)

Decisions cited:
T 0939/92, T 0197/10

Catchword:

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Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1150/20 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 29 September 2022

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)
Respondent: (Opponent)	Fresenius Kabi Deutschland GmbH Else-Krömer-Strasse 1 61352 Bad Homburg (DE)
Representative:	Fresenius Kabi Deutschland GmbH Patent Department Pharmaceuticals Division Borkenberg 14 61440 Oberursel (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 9 March 2020 revoking European patent No. 2705849 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Chakravarty
Members:	D. Luis Alves
	R. Romandini

Summary of Facts and Submissions

I. European patent EP 2 705 849, entitled "*A preparation for use of aspartate for regulating glucose levels in blood*", was granted on European patent application No. 13 152 810.1.

II. The patent was opposed under Article 100(a) EPC, on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC), insufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).

III. The opposition division revoked the patent.

IV. The patent proprietor (appellant) filed an appeal against that decision. The opponent is respondent to this appeal.

V. In their statement setting out the grounds of appeal, the appellant contested the reasoning of the opposition division and maintained the main request (patent as granted), auxiliary request 1 as filed on 28 May 2019, and auxiliary requests 2 to 20 as filed on 12 December 2019.

VI. The respondent submitted arguments with a letter of reply.

VII. With a letter dated 19 January 2022, the appellant filed sets of claims of auxiliary claim requests 1A to 3A, 5A, 7A to 9A, 11A, 13A to 15A and 17A ("Series A"), 13B to 20B ("Series B")and 13C to 15C and 17C ("Series C").

VIII. The board appointed oral proceedings and in a communication pursuant to Article 15(1) RPBA, informed the parties of its preliminary opinion, *inter alia*, on claim construction and the formulation of the objective technical problem with regard to claim 1 of then auxiliary request 2.

IX. Oral proceedings took place as scheduled. At the oral proceedings the appellant withdrew the main request and auxiliary requests 1 to 6, 8 to 12, 14 to 18 and 20, and filed an auxiliary request 21. Auxiliary request 7 became the main request, auxiliary request 13 became auxiliary request 1, auxiliary request 19 became auxiliary request 2 and auxiliary request 21 became auxiliary request 3. Auxiliary requests "Series A", "Series B" and "Series C", all filed 19 January 2022, were maintained. At the end of the oral proceedings, the chair announced the board's decision.

X. Claim 1 of the main request and of auxiliary requests 1 to 3 is reproduced below, with the differences to the main request underlined by the board.

Claim 1 of the **main request** reads:

"1. A liquid nutritional or pharmaceutical composition containing a protein fraction comprising 12.0 - 40 wt% aspartate equivalents, based on the weight of the protein fraction, wherein the protein fraction comprises soy protein and alpha-lactalbumin enriched whey protein."

Claim 1 of **auxiliary request 1** reads:

"1. A liquid nutritional or pharmaceutical composition containing a protein fraction comprising 12.8 - 30 wt%

aspartate equivalents, based on the weight of the protein fraction, wherein the protein fraction comprises soy protein and alpha-lactalbumin enriched whey protein."

Claim 1 of **auxiliary request 2** is identical to claim 1 of auxiliary request 1.

Claim 1 of **auxiliary request 3** reads:

"1. A liquid nutritional or pharmaceutical composition containing a protein fraction comprising 12.8 – 30 wt% aspartate equivalents, based on the weight of the protein fraction, wherein the protein fraction comprises soy protein and alpha-lactalbumin enriched whey protein, and wherein the composition is a complete nutrition comprising 18 – 22 en% protein.

XI. Claim 1 of each of the sets of claims in **"Series A"**, is identical to claim 1 of the correspondingly numbered auxiliary request referred to in the statement setting out the grounds of appeal.

Similarly, claim 1 of each of the sets of claims **"Series B"** and **"Series C"** reads as claim 1 of the correspondingly numbered auxiliary request underlying the decision under appeal, and maintained with the statement setting out the grounds of appeal, except that it additionally includes the following wording:

"and further comprising 10 to 30 en% protein based on the energy content of the liquid nutritional or pharmaceutical composition".

XII. The following documents are referred to in this decision:

D2: US 6,743,770 B2

D4: Crespillo *et al.*, Clinical Nutrition 22(5), 2003, pp. 483-487

D7: Hageman *et al.*, The Journal of Nutrition 138, 2008, pp. 1634-1640

D11: Experimental report filed by the patent proprietor, pp. 3/7-7/7

XIII. The appellant's arguments, relevant to this decision, are summarised as follows:

Main request - claim 1
Claim construction

The claim was directed to a nutritional composition, defined *inter alia* by the percentage (in weight) of aspartate equivalents in the protein fraction. The claim did not define how much protein fraction was present in the overall composition. That being said, the skilled person with a mind willing to understand and taking the whole content of the patent into account, would not interpret the claim so as to encompass a composition with a very low protein content, see e.g. paragraph [0102] which indicated that the composition could be a nutritionally complete formula. Furthermore, in view of the technical effect of aspartate on the regulation of blood glucose levels, the skilled person would understand that the composition had to comprise a "substantial amount" of aspartate equivalents.

Inventive step - Article 56 EPC

Composition DD, disclosed in document D4, represented the closest prior art. It contained soy protein as the only source of protein. Soy protein contained 11.8% aspartate (see Table 2 of document D4).

Two aspects distinguished the claimed composition from this closest prior art: the percentage of aspartate in the protein fraction was at least 12.0%, instead of 11.8% in composition DD, and the protein fraction in the claimed composition contained α-lactalbumin-enriched whey protein in addition to soy protein.

The patent showed that rats presented a reduction in post-prandial blood glucose levels when the meal contained an increased level of aspartate (see Example 7). This effect was confirmed by the experimental results in documents D7 and D11. Thus the technical effect associated with increased aspartate level was an improved regulation of blood glucose levels.

In view of this technical effect, the objective technical problem was the provision of a composition for further improving the regulation of blood glucose levels.

Even if the objective technical problem were formulated as the provision of an alternative composition for the regulation of glucose levels, the claimed solution was not obvious.

The skilled person would have had no motivation to provide a composition with an increased aspartate

level. Furthermore, the skilled person reading document D4 would have found no incentive to modify the protein fraction of composition DD. In particular, they would have found nothing in document D4 which motivated them to remove soy protein and replace it with whey protein enriched in α-lactalbumin because soy protein was disclosed as being important in glucose metabolism (see page 486, right-hand column, third paragraph). Furthermore, the skilled person would not have consulted document D2 when seeking to solve the objective technical problem because this document was concerned with treating different conditions, namely stress conditions. Moreover, it did not disclose the aspartate content of whey enriched in α-lactalbumin, so there was no disclosure that this protein source contained higher levels of aspartate than soy.

Auxiliary request 1 - claim 1
Inventive step - Article 56 EPC

The claimed compositions comprised at least 12.8 wt% aspartate equivalents in the protein fraction and were thus further distinguished from composition DD disclosed in document D4, which had only 11.8 wt% aspartate equivalents in the protein fraction.

Auxiliary request 2 - claim 1
Inventive step - Article 56 EPC

No arguments specific to this claim request were provided.

Auxiliary requests "series A", "Series B" and "Series C" - Admittance into the appeal proceedings

The requests in "Series A" addressed objections under Article 83 EPC. They had not been filed in the proceedings before the opposition division because the opposition division held that these requirements were met.

The requests "Series B" and "Series C" included a limitation of the amount of protein present in the composition. They were a response to the respondent's argumentation presented for the first time in the reply to the statement of grounds of appeal that the claimed compositions could comprise as little as 1% of protein (see reply to the appeal, page 14, second full paragraph). This justification had already been given in the letter accompanying these requests.

Auxiliary request 3
Admittance into the appeal proceedings - Article 13(2) RPBA 2020

This claim request was filed in reaction to board's preliminary opinion, which set out for the first time a particular interpretation of claim 1, making a distinction between the aspartate level in the protein fraction and in the composition as a whole, and according to which the claim was interpreted to encompass compositions comprising as little as 1% of protein.

Claim 1 of this request was directed to the most preferred compositions and thus complied with the requirements of Article 123(2) EPC. The meaning of

"complete nutrition" was clear to the skilled person (Article 84 EPC).

XIV. The respondent's arguments, relevant to this decision, are summarised as follows:

Main request - claim 1
Claim construction

The claim was clear and therefore it should be interpreted at face value. It defined the percentage (in weight) of aspartate equivalents in the protein fraction without defining a minimum amount of protein in the composition. Interpreting the claim as implying any specific lower limit on the amount of protein in the composition did not find any support in the description. On the contrary, paragraph [0102] of the patent referred to supplemental compositions and sip feeding of patients. Different purposes implied a wide range of energy densities for the composition and therefore a "substantial amount" of protein was not implied, contrary to the appellant's argument. Moreover, it was not clear how much protein a "substantial amount" was, nor could a limitation be implied from the use in regulation of glucose levels, since this use was not a feature of the claim.

Inventive step - Article 56 EPC

Composition DD, disclosed in document D4, comprised soy protein having 11.8 wt% aspartate equivalents in the protein fraction. It could be considered to represent the closest prior art. The claimed composition differed from this composition in (i) the percentage of aspartate in the protein fraction and (ii) the presence

of whey protein enriched in α-lactalbumin in addition to the soy protein.

As there was no synergy between the technical effects caused by the two distinguishing features, two partial technical problems should be formulated, one based on each of the above mentioned differences.

With regard to difference (i), there was no evidence that the minor difference of between 12.0 and 11.8 wt% aspartate equivalents was associated with any technical effect. Moreover, when assessing the technical effect associated with this difference, a distinction should be made between the percentage of aspartate equivalents relative to the total composition and the percentage in relation to the protein fraction only. Claim 1 encompassed compositions with a protein content as low as 1% relative to the composition as a whole. However, the experimental data in Example 7 of the patent and documents D11 and D7 was for compositions with much higher total protein content. Furthermore, the compositions tested in Example 7 and documents D11 and D7 differed from those defined in the claim in several other respects, so that the experimental results could not show that any technical effect was due to the aspartate level alone. Thus, claim 1 encompassed embodiments for which the technical effect (an improved regulation of blood glucose) allegedly caused by difference (i) was not present. In fact, by not being limited in the total amount of protein, the claim encompassed compositions that would even have a detrimental effect in the blood glucose levels.

Since the alleged technical effect was not present over the whole range claimed, the partial objective

technical problem should be formulated as the provision of an alternative composition.

The provision of a composition with increased levels of aspartate equivalents in the protein fraction was an arbitrary solution to this problem.

Furthermore, whey protein enriched in α-lactalbumin was commonly known to the skilled person as a protein source for nutritional and pharmaceutical compositions. Document D2 for example disclosed the use of this protein source in compositions for diabetic patients (see claims, column 5, lines 55 to 64 and column 9, lines 15 to 21). Selecting one of the possible solutions available to the skilled person (adding whey protein enriched in α-lactalbumin) required no inventive skill. No motivation or pointer was necessary since these protein sources were well known.

With regard to difference (ii), the claim defined no lower limit for the amount of α-lactalbumin-enriched whey protein. Furthermore, no technical effect had been shown to be associated with the presence of α-lactalbumin-enriched whey protein. Thus, the partial objective technical problem was the provision of an alternative composition. The claimed solution was obvious for the same reasons as for the other formulated partial problem.

Auxiliary request 1 - claim 1
Inventive step - Article 56 EPC

The claimed subject-matter did not involve an inventive step for the same reasons as given for claim 1 of the main request.

Auxiliary request 2 - claim 1
Inventive step - Article 56 EPC

No arguments specific to this claim request were provided.

Auxiliary requests "series A", "Series B" and "Series C" - Admittance into the appeal proceedings

These requests should not be admitted into the appeal proceedings because they were not suitable to address the objections raised against the higher ranking claim requests and further in view of the need for procedural economy.

The requests in "Series A" were according to the appellant intended to deal with the issue of insufficient disclosure. However, this issue had already been raised in the notice of opposition. Moreover, the amendment made in these requests was not suitable to overcome the problem under Article 83 EPC set out in the decision under appeal.

The claim requests in "Series B" should not be admitted either. Even if it had not been explicitly mentioned in the opposition proceedings that a composition with 1% protein was encompassed by the claim, the underlying issue had. This issue was that there was a mismatch between the examples in the patent and the subject-matter claimed. Claim 1 did not give any definition of the carbohydrate or protein content of composition. The "Series B" requests had not been filed as a response to the respondent's reply to the appeal because they were not filed in direct reply to this but much later. The amendments made in this series of claim requests did not overcome the issues arising from the

breadth of the claim in relation to the prior art and to the examples in the patent. Indeed, the lower limit of 10 en% protein introduced into the claims still defined a much lower protein content than present in the relevant prior art (the protein content was 17% in document D4 and 25% in document D6).

Auxiliary request 3
Admittance into the appeal proceedings - Article 13(2) RPBA 2020

This request should not be admitted into the proceedings because there was no justification for its filing at the oral proceedings. The objection that claim 1 lacked any definition of the amount of protein, had been made in the reply to the appeal. The example of a composition comprising only 1% of protein was merely illustrative of this argument. Furthermore, the request raised several complex issues: the requirements of Article 123(2)EPC were not met because claim 1 included a combination of multiple selections, and the meaning of "complete nutrition" was not clear.

Moreover, there were no exceptional circumstances (Article 13(2) RPBA 2020).

XV. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims of the main request, filed as auxiliary request 7 on 12 December 2019, or on the basis of the claims of any of auxiliary request 1, filed as auxiliary request 13 on 12 December 2019, auxiliary request 2, filed as auxiliary request 19 on 12 December 2019, auxiliary request 3, filed as auxiliary request 21 at the oral proceedings before the

board or auxiliary requests "Series A", "Series B" or "Series C", all filed on 19 January 2022; that the board review the decision of the opposition division to admit documents D13 to D15 into the opposition proceedings and that the board not admit these documents into the appeal proceedings; and, that the board not admit the respondent's line of argument based on the disclosure in document D6 as representing the closest prior art.

The respondent requested that auxiliary claim requests Series A, B and C filed on 19 January 2022 not be admitted into the proceedings and that the appeal be dismissed.

Reasons for the Decision

Main request - Claim 1

Claim construction

1. Claim 1 is directed to a liquid nutritional or pharmaceutical composition containing a protein fraction which comprises soy protein and α-lactalbumin-enriched whey protein, wherein this protein fraction is characterised as comprising 12.0 to 40 wt% aspartate equivalents (see section X.).

2. In the board's view, due to the use of the terms "containing", "comprising" and "comprises", the claim does not define the overall amount of protein in the composition, only the weight percentage of aspartate equivalents in the protein fraction which comprises soy protein and alpha-lactalbumin enriched whey protein.

The claim does not define a minimum weight percent aspartate equivalents relative to the composition as a whole. Thus, the level of aspartate equivalents in the composition as a whole is not defined, meaning that the composition claimed may have a significantly lower level of aspartate equivalents than 12.0 wt%.

3. The appellant argued that, the skilled person with a mind willing to understand, would read the claim as relating to a composition comprising a substantial amount of protein.

4. It is however established in the case law of the boards of appeal that terms are to be given the broadest technically sensible meaning they have for the reader skilled in the technical field (see decisions cited in Case Law of the Boards of Appeal of the EPO, 9th edn. 2019, II.A.6.1). Accordingly, the board holds that the skilled person reading claim 1 would not interpret "protein fraction" to necessarily define any minimum amount of protein in the claimed composition.

5. The appellant further argued that the skilled person reading the claim would take the whole content of the patent into account. Paragraph [0102], in particular made it clear that the claim would not be construed as encompassing compositions with a very low protein content.

6. However, it is established case law of the boards that when a claim is clear there is no need to interpret the claim in the light of the description (see decision T 197/10). There have been no submissions in the appeal that the claim lacks clarity nor had the board identified any terms in the claim that would need interpreting in the light of the description.

Notwithstanding these considerations, the board is of the view that paragraph [0102] of the patent in any case does not support the appellant's view but rather confirms the board's interpretation of the claim. The appellant's assertion that the nutritional composition must contain a "substantial amount" of protein relies on its intended use as a complete nutritional formula. However, while paragraph [0102] mentions that the composition may be a complete nutritional formula, it also mentions that it may be a supplemental formula. Thus, even the intended uses recited in the description do not imply any particular amount of protein in the composition.

Inventive step - Article 56 EPC
Closest prior art

7. The appellant submitted that the closest prior art was represented by composition DD disclosed in document D4. The board sees no reason why this composition may not serve as a starting point for the assessment of inventive step.

8. Document D4 concerns the metabolic effects of enteral nutritional compositions in patients with diabetes and in particular aims to achieve "acceptable glycaemic and lipid metabolic control" (see page 483, right-hand column, first paragraph, last sentence). It discloses a study comparing three compositions differing in the type and content of dietary fibre, carbohydrate, fat and protein (see title, abstract and page 486, left-hand column, first to third paragraphs). Composition DD was designed for diabetes patients and contained 45% carbohydrates, 38% lipids and 16% soy protein. This corresponded to 11.8 wt% aspartic acid in

the protein fraction (according to Table 2). Composition DD achieved the lowest postprandial glycaemic levels (see "Results" and "Conclusions" on page 483). The authors suggest a number of factors which could be responsible for this result, including the type of carbohydrate, type of fat, content and type of dietary fibre, and type of protein (see page 486, right-hand column, first and second paragraph).

9. The parties were in agreement that the claimed composition differed from composition DD disclosed in document D4 on two accounts: (i) the percentage of aspartate in the protein fraction and (ii) the presence of whey protein enriched in α-lactalbumin in addition to soy protein. The technical effect of these differences was, however, disputed.

10. When determining the technical effect that may be attributed to these two distinguishing features, the board will consider each separately. Indeed, it has not been argued that these features are functionally interdependent, and the board has no reason to consider this to be the case.

First partial problem: Technical effect and objective technical problem associated with the percentage of aspartate in the protein fraction

11. According to the established case law of the boards of appeal, a technical effect should be achieved by substantially all embodiments claimed for it to be taken into account when formulating the objective technical problem (see decision T 939/92 (OJ EPO 1996, 309), Reasons 2.5.4 and 2.6 and the further decisions cited in Case Law of the Boards of Appeal of the European Patent Office, 9th edn. 2019, I.D.4.3.).

12. The patent, in paragraph [0132], asserts that a technical effect that may be attributed to "the relatively high amount of rapidly available aspartate" in the protein fraction in a nutritional composition is a decrease in postprandial glucose levels in the subjects fed with the nutritional composition. However, the patent does not provide any evidence that this technical effect is actually achieved by all the claimed compositions. The claim does not define the amount of protein and there are no experimental results showing a technical effect linked to 12.0 wt% aspartate equivalents relative to the protein fraction, irrespective of the percentage of aspartate equivalents relative to the composition as a whole.

12.1 Example 7 of the patent shows blood glucose levels in rats that had been fed with compositions containing a constant amount of protein and carbohydrate and differing only in the protein source, such that they contained either caseinate (7.8 wt% aspartate equivalents), soy (10.8 wt% aspartate equivalents) or soy enriched with aspartate (aspartate level not reported) (see Figure 1). In a fourth composition, the protein component consisted of soy hydrolysate, α-lactalbumin and methionine (see Figure 2). The experimental results thus allow a comparison of blood glucose levels after consumption of a composition with 7.8wt% and 10.8wt% aspartate equivalents. As to the fourth composition, although the level of aspartate equivalents is not reported, it is concluded in Example 7 that this composition had a beneficial effect on blood glucose levels.

12.2 However, Example 7 does not report any experimental results obtained with compositions differing in the

amount of protein relative to the composition as a whole, for instance compositions having an overall lower aspartate content than composition DD, despite having 12 wt% or higher aspartate content relative to the one or more protein fractions. Thus, no conclusion can be drawn from Example 7 as to any effect on blood glucose levels related to aspartate equivalents relative to one of the protein fractions in the composition, irrespective of the amount of aspartate relative to the the composition as a whole.

13. The appellant referred to the disclosure in documents D11 and D7 to support the view that that an effect on blood glucose levels is attributable to the percentage of aspartate equivalents in the protein fraction. These documents provided experimental results showing that increasing percentage aspartate in the feed resulted in improved glycaemic parameters.

14. However, the disclosure in neither document supports the appellant's case. Document D7 is an experimental report comparing the effect of three types of nutritional compositions, differing only in the protein fraction, on glycaemic parameters. Document D11 reports the postprandial glucose levels for various compositions, including two compositions differing solely in the protein source. Neither document D11 or D7 discloses experimental results for claimed compositions in which the protein fraction comprises 12.0 wt% of aspartate equivalents. From the disclosure in document D11, a comparison can only be made between 12.5 and 6.6 wt%; from document D7, only a comparison between 13.6 and 11.8 wt% can be made. In addition, the appellant has not pointed to experimental results obtained with compositions having an overall lower aspartate content despite having 12 wt% or higher

aspartate content relative to the protein fraction. Nevertheless, it is not disputed by the appellant that claim 1 encompasses compositions having a lower aspartate content, relative to the composition as a whole, than composition DD.

15. Consequently, the board considers that no technical effect beyond the effects known for the composition disclosed in document D4, namely control of post-prandial glucose levels, can be attributed to substantially all embodiments claimed.

16. In accordance with the case law of the boards of appeal, alleged advantages or improvements over the state of the art which are merely referred to without evidence to support a comparison with the closest prior art cannot be considered in determining the objective technical problem underlying the invention (see also the decisions cited in Case Law of the Boards of Appeal of the European Patent Office, 9th edn. 2019, I.D. 4.2.).

17. Hence, the objective technical problem solved by all claimed compositions is formulated as the provision of an alternative liquid nutritional composition for glycaemic control.

Obviousness

18. The question to be answered in assessing the obviousness of the claimed subject-matter is whether or not the skilled person, starting from composition DD disclosed in document D4 representing the closest prior art and faced with the above formulated objective technical problem (see point 17.), would have provided

a composition with increased aspartate in the protein fraction.

19. Document D2 concerns nutritional compositions for managing stress symptoms and preventing related secondary effects such as the development of diabetes and discloses protein sources commonly used in nutritional compositions: "*Sources of protein can be any suitable protein utilized in nutritional formulations and can include whey protein, whey protein concentrate, whey powder, egg, soy protein, soy protein isolate, caseinate (e.g., sodium caseinate, sodium calcium caseinate, calcium caseinate, potassium caseinate), animal and vegetable protein and mixtures thereof. The preferred protein is alpha lactalbumin-enriched whey protein used alone or in combination with other protein (e.g., whey, casein, soy, milk, egg)* [...]" (column 5, lines 55 to 63; emphasis added by the board).

20. It can be taken from the above cited passage that the authors of document D2 considered that whey protein enriched in α-lactalbumin, as well as its mixtures with other proteins, such as soy, were protein sources commonly used in nutritional compositions.

21. The board is of the view that the skilled person, starting from the composition DD and seeking an alternative, would have turned to any of the protein sources commonly available for nutritional compositions for addition to the composition DD. These protein sources included α-lactalbumin-enriched whey. Using α-lactalbumin-enriched whey as the protein source, the skilled person would have obtained compositions comprising at least 12.0 wt% aspartate equivalents, as encompassed by the claim because α-lactalbumin-enriched

whey protein contains 12.4 wt% or 13-13.5 wt% aspartate equivalents (see the patent, Table 2), a fact which was not disputed by the appellant. Compositions including α-lactalbumin-enriched whey protein would be suitable alternatives for achieving glycemic control, since the level of aspartate equivalents is comparable to that in composition DD.

22. According to the appellant, the skilled person would not have arrived at the claimed composition because document D2 did not disclose the aspartate content of α-lactalbumin-enriched whey protein. However, it is irrelevant for this conclusion whether or not document D2 disclosed the content of aspartate in the protein sources, since the skilled person's motivation to use protein sources alternative to those in composition DD does not depend on their aspartate content.

23. According to the appellant, the claimed alternative was also not obvious because the skilled person would not have replaced the soy protein in composition DD with alpha-lactalbumin since it was, according to document D4, a beneficial protein source for the purposes of regulating blood glucose levels.

24. However, the claim requires the presence of soy and the skilled person knew from document D2 that mixtures of proteins sources were commonly used for nutritional compositions. Moreover, while there might be circumstances where a skilled person would not have modified a particular component because it was presented as essential to achieve a given technical effect, no such situation is present in the case at hand. Indeed, soy protein is not disclosed in document D4 as being essential. The document presents a number of possible explanations for the advantageous

glycaemic control achieved with composition DD, soy protein being just one of them (see summary in point 8. above). Therefore, in the board's view, the skilled person would not have been deterred from adding to the prior art composition further protein sources, such as α-lactalbumin-enriched whey, when seeking to provide an alternative composition for glycaemic control.

25. The appellant further argued that the skilled person would not have taken document D2 into account because it was not concerned with glycemic control but with different diseases, namely with managing stress symptoms.

26. The board disagrees. The objective technical problem formulated above is addressed to a person skilled in nutritional compositions in general. Their expertise is not limited to nutritional compositions suitable for treating a particular disease.

Second partial problem: Technical effect and objective technical problem associated with the presence of α-lactalbumin-enriched whey protein in addition to soy

27. The board could not identify any technical effect related to this difference and none was put forward by the appellant. In the absence of any technical effect going beyond those known for the composition disclosed in document D4, the objective technical problem solved by the claimed composition is identical to the technical problem formulated for the other distinguishing feature, i.e. the provision of an alternative liquid nutritional composition for glycaemic control (see point 17.).

Obviousness

28. The board considers the solution for this second partial problem to be obvious in view of the disclosure of α-lactalbumin-enriched whey protein as a preferred source of protein, for example in document D2, for the same reasons as set out in points 18. to 26. above.

Conclusion

29. In view of the above considerations on both partial problems, the claimed subject-matter does not involve an inventive step.

Auxiliary request 1 - claim 1
Inventive step - Article 56 EPC

30. The difference between the composition defined in claim 1 and the composition considered above in the context of the main request lies in the range for the content in aspartate equivalents, defined as 12.8-30 wt% of a protein fraction in the composition, whereas it was defined as 12.0-40 wt% in claim 1 of the main request.

31. The lower limit of aspartate equivalents in the protein fraction of 12.8 wt% does not change the claim construction under point 2. above. Accordingly, claim 1 of this claim request is also directed to a liquid nutritional or pharmaceutical composition containing a protein fraction for which the content in aspartate equivalents is defined with respect to the protein but not to the composition as a whole, since the protein content of the composition is not defined. Moreover, as was the case for claim 1 of the main request, no

technical effect, beyond that obtained with the prior art composition DD, can be acknowledged for substantially all claimed embodiments. Thus, the objective technical problem, solved by the claimed invention remains the same as that solved by claim 1 of the main request. Because the problem solved by the claimed composition is still the provision of an alternative liquid nutritional composition for glycaemic control, the conclusions on obviousness reached for the main request apply equally.

Auxiliary request 2

32. Claim 1 of this request is identical to claim 1 of auxiliary request 1, so that the conclusion that the claimed subject-matter does not involve an inventive step applies equally here.

Admittance of auxiliary requests "Series A", "Series B" and "Series C" into the appeal proceedings

33. These requests were filed with the letter dated 19 January 2022, after the respondent's reply to the appeal. They represent an amendment to the appellant's case. Thus, admission and consideration of these requests is at the board's discretion, in accordance with Article 13(1) RPBA. The board exercises discretion taking into account, *inter alia*, the current state of the proceedings, the suitability of the amendment to resolve the issues which were admissibly raised by another party in the appeal proceedings or which were raised by the Board, whether the amendment is detrimental to procedural economy, and whether the party has demonstrated that the amendment, *prima facie*, overcomes the issues raised by another party in the

appeal proceedings or by the Board and does not give rise to new objections.

34. Claim 1 of each of auxiliary requests 1A to 3A, 5A, 7A to 9A, 11A, 13A to 15A and 17A ("Series A"), is identical to claim 1 of the correspondingly numbered auxiliary request referred to in the statement of grounds of appeal. Since claim 1 of each request does not define the protein content of the composition, the conclusion reached for claim 1 of the main request, that the claimed subject-matter does not involve an inventive step, applies equally here.

35. Claim 1 of auxiliary requests "Series B" and "Series C", includes a definition of the contribution of the protein fraction to the total energetic content of the composition. In view of the objections in opposition proceedings relating to the absence, in the claimed composition, of features present in the compositions used in the experiments, the board considers that these claim requests could and should have been filed in the opposition proceedings.

36. Accordingly the board decided to not admit these requests into the appeal proceedings (Article 13(1) RPBA 2020).

Admittance of auxiliary request 3 into the appeal proceedings

37. In addition to the features in claim 1 of auxiliary requests 1 and 2, the composition defined in claim 1 of this request is a complete nutritional composition and the protein fraction represents 18-22 en% of the composition.

38. This claim request was filed at the oral proceedings before the board and is therefore an amendment to the respondent's case. Such amendments are governed by Article 13(2) RPBA 2020 and they are, in principle, not taken into account unless there are exceptional circumstances, justified by cogent reasons.

39. The appellant submitted that the claim construction, set out in the board's preliminary opinion for the first time, constituted exceptional circumstances which justified late the filing of the claim request.

40. However, the claim construction set out by the board in its communication under Article 15(1) RPBA was based on submissions made by the respondent in its reply to the statement of grounds of appeal (see reply to the appeal, page 14, second full paragraph).

41. Thus the claim construction provided in the communication under Article 15(1) RPBA does not represent an exceptional circumstance within the meaning of Article 13(2) RPBA. Furthermore, in accordance with Article 13(1) RPBA, the amendment should not give rise to new objections. In that regard the board shares the respondent's view that a claim including the expression "complete nutrition" would need to be assessed for clarity. For these reasons the board did not admit this request into the proceedings.

Appellant's request to review the opposition division's decision to admit documents D13, D14 and D15 into the opposition proceedings

42. The opposition division decided to admit these documents (see point 3 of the decision under appeal)

and the appellant requested that the board review this decision. Since the board did not rely on these documents to reach a decision on inventive step, there is no need to rule on this point.

43. In view of the foregoing, none of the claim requests forming part of the appeal proceedings meets the requirements of the EPC. Accordingly, the patent cannot be maintained on the basis of any of these requests.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

The Registrar: The Chairman:

I. Aperribay A. Chakravarty

Decision electronically authenticated