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**Datasheet for the decision  
of 24 February 2021**

**Case Number:** T 0149/18 - 3.3.09

**Application Number:** 13159400.4

**Publication Number:** 2612561

**IPC:** A23C1/04, A61P3/02, A23L33/00,  
A23L33/19, A23L33/17

**Language of the proceedings:** EN

**Title of invention:**  
High protein liquid enteral nutritional composition

**Patent Proprietor:**  
N.V. Nutricia

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

**Headword:**  
Enteral composition comprising globular proteins/NUTRICIA

**Relevant legal provisions:**  
EPC Art. 100(c), 76

**Keyword:**

Main request and auxiliary requests: Amendments meeting the "gold standard" according to G 2/10 (no) - Added subject-matter - (yes)

**Decisions cited:**

G 0002/10, T 1621/16

**Catchword:**



**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 0149/18 - 3.3.09

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.09**  
**of 24 February 2021**

**Appellant:**  
(Patent Proprietor)

N.V. Nutricia  
Eerste Stationsstraat 186  
2712 HM Zoetermeer (NL)

**Representative:**

Nederlandsch Octrooibureau  
P.O. Box 29720  
2502 LS The Hague (NL)

**Appellant:**  
(Opponent 1)

Société des Produits Nestlé S.A.  
Entre-deux-Villes  
1800 Vevey (CH)

**Representative:**

D Young & Co LLP  
120 Holborn  
London EC1N 2DY (GB)

**Appellant:**  
(Opponent 2)

Fresenius Kabi Deutschland GmbH  
Else-Kröner-Str. 1  
61352 Bad Homburg (DE)

**Representative:**

Fresenius Kabi Deutschland GmbH  
Patent Department  
Borkenberg 14  
61440 Oberursel (DE)

**Decision under appeal:**

**Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
17 November 2017 concerning maintenance of the  
European Patent No. 2612561 in amended form.**

**Composition of the Board:**

**Chairman**            A. Haderlein  
**Members:**            A. Veronese  
                              D. Rogers

## **Summary of Facts and Submissions**

- I. This decision concerns the appeals filed by the two opponents and the patent proprietor against the decision of the opposition division finding that European patent No. 2 612 561 as amended meets the requirements of the EPC. The patent is based on European patent application 13159400, filed as divisional application based on European patent application 09718670 ("parent application").
- II. With their notices of opposition, the opponents had requested revocation of the patent in its entirety, *inter alia*, on the ground under 100(c) EPC.
- III. In its decision, the opposition division found, *inter alia*, that auxiliary request 2 met the requirements of the EPC, in particular those of Article 76(1) EPC.
- IV. Since both the patent proprietor and the two opponents are appellants in these appeal proceedings, for simplicity the board will continue to refer to them as the patent proprietor and the opponents.
- V. During the appeal proceedings, the patent proprietor filed the following requests, under cover of a letter dated 11 August 2020: main request, auxiliary requests 1 to 7 and auxiliary requests 1A to 6A. Auxiliary request 1 corresponds to the auxiliary request 2 found allowable by the opposition division.
- VI. Claim 1 of the main request reads as follows:

"A packaged, sterilized or pasteurized liquid enteral nutritional composition having a pH of 4 to 8 and comprising 10-20 g of non-hydrolysed globular protein per 100 ml of the composition, wherein said globular protein is selected from the group consisting of whey protein, pea protein, soy protein, and any mixture thereof, said composition obtainable by heat-treatment comprising the consecutive steps of:

- a) adjusting the pH of an aqueous composition comprising non-hydrolysed globular proteins to a value of between 4 and 8;
- b) converting the composition of non-hydrolysed globular proteins obtained in step a) into an aerosol;
- c) subjecting the aerosol obtained in step b) to a temperature of 100 to 190 °C during a time of 30 to 300 milliseconds;
- d) flash-cooling the heat-treated aerosol obtained in step c) to a temperature below 85°C to obtain an aqueous solution comprising heat-treated globular proteins."

VII. Claim 1 of auxiliary requests 1 to 6 and 1A to 6A contains, as claim 1 of the main request does, the features characterising the pH and the amount of protein of the nutritional composition, and the pH of step a). It differs from claim 1 of the main request in that, *inter alia*, in step c) the temperature is 110 to 180°C, and the time is 40 to 200 ms. In claim 1 of auxiliary request 7, the pH of the composition is 4 to 7, and the time is 40 to 150 ms.

VIII. The opponents' arguments relevant for the decision were as follows:

None of the requests, with exception of auxiliary request 1, should be admitted into the appeal.

Claim 1 of the main request contained subject-matter extending beyond the content of the parent application as filed. The combination of the following features was not disclosed in that application: 10 to 20 g of protein per 100/ml of nutritional composition, a pH of 4 to 8 for the nutritional composition and a pH of 4 to 8 for pH adjustment step a) of the heating process.

Each of these features was selected among others disclosed in the parent application and/or resulted from a combination of different originally disclosed ranges and values. In particular, the pH range for pH adjustment step a) resulted from a combination of a range disclosed on page 9 with the specific value of 4. This was mentioned on page 10 but not as the lowest value of a range. Such a combination was not allowable in accordance with the case law, and other pH values were disclosed on page 10. Furthermore, page 10 and the examples taught to select a pH of 4 for step a) when low temperatures were used and a pH of 7 when high temperatures were used. The criteria for selecting the pH during step a) did not apply for selecting the pH of the final composition. Separate steps were required to adjust the pH of the aqueous composition during step a) and that of the final product.

These objections applied to all requests. In the case of auxiliary request 7, a different temperature range and heating time were also selected.

IX. The proprietor's arguments relevant for the decision were as follows:

Basis for the claimed subject-matter was found in the following parts of the parent application as filed:

- claim 1 option ii), disclosing a nutritional composition comprising 10 to 20 g of globular protein per 100 ml
- claim 5, disclosing a nutritional composition having a pH in the range of 2 to 8 and preferably of 4 to 7
- page 9 and claim 12 in combination with page 10, lines 3 to 8, 16 to 18, and page 8, lines 28 to 31, disclosing a method for treating globular proteins and its use to prepare the nutritional composition
- Page 11, lines 14 to 16, showed that there was no close association between the pH and the heat-treatment time and temperature. As in case T 1621/16, the claimed subject-matter was "based on combinations of more and less preferred options of lists of converging alternatives" but did not contain added subject-matter because the pH and the concentration of the compositions in the examples of the parent application was a pointer toward the claimed combination of features.

X. The requests

The proprietor requested that the decision under appeal be set aside and that the patent be maintained upon the basis of the main request or, alternatively, upon the basis of auxiliary requests 1 to 7 or 1A to 6A, all filed under cover of the letter dated 11 August 2020.

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



## Reasons for the Decision

### Main request

1. The opponents requested that the main request not be admitted into the appeal proceedings. In view of the following findings of the board, there is no need to discuss the issue of admissibility.

2. *Subject-matter extending beyond the content of the parent application as filed (Article 76 EPC)*

2.1 Claim 1 is drafted as a product-by-process claim and comprises a twofold definition of the claimed enteral nutritional composition. On the one hand, it specifies features characterising the final nutritional compositions, which include:

- an amount of globular protein in the range of 10 to 20 g per 100 ml of the composition
- a pH in the range of 4 to 8

On the other hand, it specifies features characterising the process carried out for preparing this composition. These include, *inter alia*, a step a), which involves:

- adjusting the pH of an aqueous composition comprising the protein to a value of 4 to 8, before carrying out the following heating steps.

2.2 The parent application as filed does not contain a product-by-process claim. Claim 1 and the passage bridging pages 4 and 5 ("summary of the invention") disclose a nutritional composition comprising non-

hydrolysed globular proteins. Claim 22 and page 9, lines 18-27, disclose a method for heat-treating these proteins. Claim 1 of the main request is obtained by combining features disclosed in these different parts of the parent application.

2.3 The amount of whey protein contained in the nutritional composition claimed in the main request is the second among three possible alternatives disclosed in claim 1 of the parent application, namely:

i) 9 to 20 g of non-hydrolysed globular protein per 100 ml of the composition having a pH > 3 and  $\leq 8$

ii) 10 to 20 g of non-hydrolysed globular protein per 100 ml of the composition

iii) 9 to 20 g of non-hydrolysed globular protein per 100 ml of the composition, with the proviso that a UHT-sterilized composition comprising 9.2 weight% whey protein having a pH=3 is excluded

2.4 The range defining the pH of the nutritional composition has been obtained by combining the upper limit of a broad range of 2 to 8 disclosed in claim 5 of the parent application with the lower limit of a narrower preferred range of 4 to 7 disclosed in that claim.

2.5 The pH range of 4 to 8 of the composition prepared in pH adjustment step a) has been obtained by limiting the range of 2 to 8 disclosed on page 9, line 21, and in claim 22 of the parent application, with the specific value "4", disclosed on page 10, line 5. However, pH=4, which is not disclosed as the lowest value of a range, is only one among the options shown on page 10, namely:

>3 and  $\leq 8$ , 2 to 5, 6 to 8 and the specific value 7. Thus, the limitation to a pH of 4 to 8 is only one of those available relying on the teaching of page 10.

2.6 The narrower preferred pH range of 4 to 8 of the nutritional composition, given in claim 5, does not correspond to the narrower pH ranges given for step a) on page 10, namely: 2 to 5 and preferably 4 or, alternatively, 6 to 8 and preferably 7. This indicates that according to the parent application the pH of the composition prepared during step a) is not necessarily that of the final nutritional composition and that these pH values are independent from each other. This is confirmed by figures 1 and 4, which show that a second pH adjustment step is carried out after the cooking step. It is also confirmed by the fact that according to the embodiments on page 10, lines 24 to 31, a pH of 4 is selected when the temperature of the heating step is low, e.g. 110°C, and a pH of 7 is selected when the temperature is high, e.g. 170°C. This correlation between the pH and the temperature concerns the aqueous composition of step a) but not the final nutritional composition. The passage on page 11, lines 14 to 16, mentioned by the proprietor, teaching that the pH, temperature and time of the process steps can be "combined in an intelligent manner", does not contradict this conclusion. Rather, it confirms it because it links once more the pH and the temperature chosen for step a).

2.7 The proprietor has argued that the claimed subject-matter was based on a combination of originally disclosed converging alternatives and that the criteria developed in T 1621/16 had to be applied in the case at issue for assessing added subject-matter. Reference was made to point 2 of the headnote and to point 1.7.3 of

this decision. These state, essentially, that a claim amended on the basis of multiple selections from lists of converging alternatives does not add subject-matter if the resulting combination is not associated with an undisclosed technical contribution and the application as filed includes a pointer to the combination of features resulting from the multiple selections.

2.8 According to the proprietor, the examples of the parent application, which mention pH values of 4, 4.1 and 7.5, and a protein concentration of 12 and 16 g/100 ml, provided a pointer toward the combination of the originally disclosed alternatives. Thus, in view of T 1621/12, although it resulted from multiple selections, the claimed combination did not create new subject-matter.

2.9 The board is not persuaded by the proprietor's arguments. The presence of "pointers" represented, for instance, by examples may well become relevant for determining the disclosure of an application as originally filed. However, when assessing added subject-matter, it is the "gold standard" defined in G 2/10, points 4.2 and 4.3, that is decisive. This requires that any amendment to the parts of a European patent application or patent relating to the disclosure can only be made within the limits of what a skilled person would derive directly and unambiguously from the whole of these documents as filed.

2.10 The board considers that the gold standard is not met in the case at issue. As mentioned above, the claimed subject-matter results from multiple selections. As far as the alleged presence of a "pointer" in the parent application is concerned, the following is to be considered: the pH values of the composition prepared

in step a) according to the examples of the parent application fall within the newly created range of 4 to 8. However, they also fall within the originally disclosed range of  $>3$  and  $\leq 8$  shown on page 10, line 2. The two close pH values 4 and 4.1 fall within the preferred range of 2 to 5 shown on page 10 lines 3-4, and the value of 7 within the range of 6 to 8, shown on page 10 lines 6 to 8. The amounts of protein in the examples fall within all embodiments of claim 1. Thus, other combinations of values and ranges can be envisaged relying on the examples and the teaching of page 10, in addition to that suggested by the proprietor. Furthermore, as already mentioned above, the specific pH values of step a) mentioned in the examples are associated with a specific choice of temperature, reflecting the teaching of page 10, lines 24 to 31. Simply referring to the pH values shown in the examples ignores this teaching. Therefore, the parent application does not disclose a clear, unequivocal pointer to the claimed combination of features.

2.11 For these reasons, by selecting the following features from the parent application, subject-matter has been created, that is not directly and unambiguously disclosed and extends beyond the content of the parent application as filed:

- an amount of 10 to 20 g of globular protein per 100 ml of nutritional composition, among the options in claim 1
  
- a pH in the range of 4 to 8 for the above composition, this range resulting from the combination of the ranges disclosed in claim 5, and

- a pH in the range of 4 to 8 for pH adjustment step a), this range resulting from the combination of the range shown on page 9, line 21, with the specific value 4 on page 10, line 5.

2.12 It is concluded that the main request does not comply with the requirements of Article 76(1) EPC.

**Auxiliary requests 1 to 7 and 1A to 6A**

3. *Subject-matter extending beyond the content of the parent application as filed (Article 76 EPC)*

3.1 Claim 1 of all auxiliary requests, except auxiliary request 7, contains the combination of features which has been found to add subject-matter when dealing with the main request. Thus, the same conclusions apply.

3.2 Claim 1 of auxiliary request 7 differs from claim 1 of the main request in that the pH of the nutritional composition is from 4 to 7 and that a temperature of 110 to 180°C and a time of 40 to 150 milliseconds are selected for step c). These conditions are selected among numerous others mentioned on page 10, line 10 to 23 of the parent application. Thus, for the same reasons discussed above when dealing with the main request, the claimed combination of features in auxiliary request 7 adds new subject-matter.

3.3 For these reasons, none of the auxiliary requests complies with the requirement of Article 76(1) EPC.

3.4 In view of these conclusions, it is not necessary to discuss the issue of admissibility of the auxiliary requests.

## 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:



A. Nielsen-Hannerup

A. Haderlein

Decision electronically authenticated