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**Datasheet for the decision  
of 23 February 2022**

**Case Number:** T 0616/19 - 3.3.09

**Application Number:** 13818523.6

**Publication Number:** 2938211

**IPC:** A23L2/52, A23L33/19, A23L33/125

**Language of the proceedings:** EN

**Title of invention:**

METHOD FOR THE PREPARATION OF A LIQUID ENTERAL NUTRITIONAL  
COMPOSITION COMPRISING MICELLAR CASEIN

**Patent Proprietor:**

N.V. Nutricia

**Opponents:**

FrieslandCampina Nederland B.V.  
Fresenius Kabi Deutschland GmbH  
Société des Produits Nestlé S.A.

**Headword:**

Method for producing a nutritional composition/NUTRICIA

**Relevant legal provisions:**

EPC Art. 56  
EPC R. 103(4) (a)

**Keyword:**

Inventive step - (no)

Reimbursement of appeal fee at 25% - (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

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**Case Number: T 0616/19 - 3.3.09**

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.09**  
**of 23 February 2022**

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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
8 January 2019 concerning maintenance of the  
European Patent No. 2938211 in amended form.

**Composition of the Board:**

**Chairman** A. Haderlein  
**Members:** M. Ansorge  
D. Rogers

## Summary of Facts and Submissions

- I. Appeals were filed by the proprietor and opponents 2 and 3 against the opposition division's interlocutory decision holding the then auxiliary request 2 allowable. For simplicity, the board will continue to refer to the parties as the proprietor and opponents 1 to 3.
- II. With their notices of opposition, the opponents had requested that the patent be revoked, in particular on the ground for opposition under Article 100(a) EPC (lack of inventive step).
- III. In the present decision, reference is made to the following documents:
- D18: US 2012/0142587 A1  
D26: Experimental report filed by the proprietor  
(3 October 2019)
- IV. The opposition division decided, *inter alia*, that the then auxiliary request 2 was allowable, in particular that the claimed method of producing a liquid nutritional composition involved an inventive step in view of D18 as the closest prior art.
- V. Claim 1 of the then auxiliary request 2 before the opposition division, which is identical to claim 1 of the main request and all the auxiliary requests on appeal, reads as follows:
- "A method of producing a liquid nutritional composition for enteral use comprising a protein fraction, a carbohydrate fraction and a fat fraction, wherein the

composition comprises 8 to 20 g/100 ml micellar casein, 10 to 40 g/100 ml digestible carbohydrates, 5 to 15 g/100 ml dietary fat and has an energy density of at least 1.6 kcal/ml, the method comprising the steps of:

- a) mixing a dry blend of micellar casein and digestible carbohydrate with water having a temperature of between 30°C and 90°C,
- b) dissolving the blend of micellar casein and digestible carbohydrate in the water,
- c) de-aerating the composition of step b), preferably until the amount of air in the composition reaches a value below 20 % (v/v),
- d) mixing dietary fat into the composition of step c), and
- e) heat-treating, preferably by heat-sterilization or pasteurization, the nutritional composition obtained in step d), optionally followed by aseptically filling of the heat-treated composition in a suitable container."

VI. Before the debate was closed and the decision was announced in the oral proceedings before the board, the proprietor withdrew its appeal.

VII. The parties' relevant arguments, submitted in writing and during the oral proceedings, are reflected in the reasons for the decision set out below.

VIII. Requests

The proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request, filed with the grounds of appeal, or alternatively on the basis of one of auxiliary requests 1 to 5, or according to auxiliary

request 6, this being the request which the opposition division held allowable. Auxiliary requests 1 and 2 were filed with the grounds of appeal, and auxiliary requests 3 to 5 were filed under cover of a letter dated 12 December 2019.

Opponents 2 and 3 requested that the decision be set aside and that the patent be revoked in its entirety.

## Reasons for the Decision

### MAIN REQUEST

1. Inventive step
  - 1.1 It was common ground between the parties that D18 is the closest prior-art document for assessing inventive step in this case; however, the parties disagreed on the embodiment in D18 which represented the closest prior art. While opponents 2 and 3 considered the method of producing preparation A from D18 to be the closest prior art, the proprietor was of the opinion that the method of producing preparation B from D18 was to be chosen.
  - 1.2 The methods of producing preparations A and B from D18 exemplify ways of producing a heat-treated liquid enteral nutritional composition comprising 10 to 20 g of protein per 100 ml of the composition, in which at least 70 weight % of the protein comprises micellar casein, and in which the total amount of monovalent metal ions in the composition is less than 25 mg/g of protein (see claim 1).
  - 1.3 For the following reasons, the method of producing preparation A from D18 is an appropriate starting point in the assessment of inventive step.
    - 1.3.1 Paragraph [0102] of D18 explicitly mentions that the liquid enteral nutritional composition according to the invention can be prepared as indicated in the examples, which clearly includes the method of producing preparation A. Likewise, it is mentioned in paragraph [0115] of D18 that "the compositions



according to the invention have been prepared as follows", which clearly includes the method of producing preparation A referred to in the following paragraph, paragraph [0116], as well.

- 1.3.2 In this context, the board does not share the proprietor's view that the method of producing preparation A does not fall under the general teaching of D18 and that it does not form an appropriate starting point for the skilled person. As outlined in point 1.3.1, D18 undoubtedly discloses that the method of producing preparation A is suitable for producing the nutritional composition claimed in D18, and therefore the method of producing preparation A is a valid starting point. It is unconvincing that preparation B could be the only valid starting point in the assessment of inventive step over D18.

As admitted by the proprietor, the method of producing preparation A has more features in common with the claimed method than preparation B from D18; however, having the most relevant features in common and requiring the minimum quantity of structural modifications is one of the criteria to be taken into account when selecting the closest prior art, thus supporting the position of opponents 2 and 3.

In view of the above, the board is convinced that the method of producing preparation A from D18 is a valid starting point in the assessment of inventive step.

- 1.4 The method of producing a liquid nutritional composition from claim 1 of the main request differs from the method for producing preparation A from D18 in that the latter does not clearly and unambiguously disclose that the micellar casein and digestible

carbohydrate are mixed as a dry blend with water. This was common ground between the parties. The proprietor did not invoke any other difference over preparation A from D18.

- 1.5 The proprietor submitted that an improvement did result from this single difference, i.e. a reduction in viscosity as evidenced by the examples in the patent and D26, whereas opponents 2 and 3 contested that an improvement was demonstrated over D18.
- 1.6 For the following reasons, no effect was demonstrated over the method of producing preparation A from D18.
  - 1.6.1 The comparative examples mentioned in the patent, i.e. Example 1, Trial 1-2, and Example 2, Trial 2-1, are not representative of the method of obtaining preparation A from D18.

In the method of producing preparation A from D18 (Examples 1 to 6) it is not mentioned that the micellar casein isolate (MCI) needs to be added as a separate ingredient, as in Example 1, Trial 1-2, of the patent. The passage "Next, the different amount of powder proteins (MCI, MPI, Calcium caseinate), and maltodextrine (glucose syrup 47DE, about 2.2kg) was added to the solution" (see preparation A from D18) is ambiguous with respect to the way in which MCI and maltodextrine are to be added. Nevertheless, it cannot be interpreted as disclosing adding MCI followed by a combination of digestible carbohydrate and caseinates, as in Example 1, Trial 1-2, of the patent. The same applies to Example 2, Trial 2-1, of the patent. Also, in these trials, maltodextrin having a dextrose equivalent (DE) of 19 was used, whereas in D18 maltodextrin having a DE of 47 was used, the DE value

having an influence on the viscosity, as evidenced by the penultimate sentence of paragraph [0069] of D18.

Therefore, the comparative examples Trial 1-2 and Trial 2-1 of the patent do not constitute a comparison with the closest prior art, i.e. the method of producing preparation A from D18.

- 1.6.2 In addition, the comparative experiment according to Trial A from D26 does not reproduce preparation A from D18 either.

In both the method of producing preparation A from D18 and Trial A from D26, sucrose is added first. Next, as literally mentioned in the method of producing preparation A, "the different amount of powder proteins (MCI, MPI, Calcium caseinate), and maltodextrine (glucose syrup 47DE, about 2.2 kg) was added to the solution". It cannot be derived from this information that maltodextrin was added before the protein powders and that calcium caseinate was added last. In addition, maltodextrin 47DE is used in preparation A from D18, but a low-DE maltodextrin (19DE) is used in D26. Furthermore, calcium caseinate is used in preparation A from D18, whereas D26 only mentions caseinates in general. Finally, no fat is used in Trial A from D26, whereas preparation A from D18 applies rapeseed oil as a fat ingredient.

- 1.6.3 The proprietor argued that it was not mandatory for the method of producing preparation A from D18 to be explicitly reworked. What mattered was that it was credibly demonstrated that the effect results from the difference over D18. In its view, the experimental evidence provided demonstrated an improved viscosity over the method of producing preparation A from D18.

The board is not convinced. As outlined in points 1.6.1 and 1.6.2, too many modifications have been made to the proprietor's comparative experiments over the method of producing preparation A from D18. Therefore, the proprietor's comparative examples are not representative of the method of producing preparation A from D18. For this reason alone, an effect over D18 cannot be acknowledged.

- 1.6.4 Even when assuming, for the sake of argument, that the proprietor's comparative experiments, i.e. Example 1, Trial 1-2, of the patent, Example 2, Trial 2-1, of the patent or Trial A from D26, were representative of the method of producing preparation A from D18, no improved viscosity over the method of producing preparation A from D18 was demonstrated.

On the contrary, the viscosity of the nutritional composition obtained by the method of producing preparation A from D18 is even lower compared with the examples in line with claim 1 of the main request.

As can be understood from Example 6 of preparation A from D18 the final viscosity of the nutritional composition is 116 mPa•s (see viscosity 4 in Table 2 of D18).

As demonstrated in the following, the viscosities of the nutritional compositions in line with claim 1 of the main request are higher:

- Example 1, Trial 1-1, of the patent: 140 mPa•s (see page 6, lines 6 to 11 from the bottom of the proprietor's grounds of appeal);
- Example 2, Trial 2-2, of the patent: 270 mPa•s; and

- Trial B from D26: 285 mPa•s.

Under these circumstances, it is neither derivable nor credible that an improved viscosity might be the result of applying a dry blend of micellar casein and digestible carbohydrate (in line with claim 1 of the main request) instead of following the mixing procedure mentioned in preparation A from D18.

1.6.5 Finally, the proprietor also submitted that preparation A from D18 related to a pilot-scale trial, whereas the alleged effect became apparent on an industrial scale. This argument is not convincing since claim 1 also covers methods carried out on a pilot scale, as admitted by the proprietor.

In view of the above, no improvement over the method of producing preparation A from D18 can be acknowledged.

1.7 As a consequence, the objective technical problem to be solved is to provide an alternative method of producing a liquid nutritional composition for enteral use.

1.8 With respect to the question of obviousness, the board draws the following conclusion.

1.8.1 In the method of producing preparation A from D18, sucrose was dissolved in water first (as in Example 1, Trial 1-1, and Example 2, Trial 2-2, of the patent and Trial B from D26). Next, it is mentioned in the method of producing preparation A from D18 that a different amount of powder proteins (MCI, MPI, calcium caseinate) and maltodextrin was added to the solution, without explicitly mentioning whether the powder proteins and maltodextrin were added simultaneously as a dry blend,

or simultaneously in unblended form, or sequentially, i.e. one after the other.

1.8.2 D18 does not literally mention that micellar casein and a digestible carbohydrate were mixed as a dry blend with water; however, in view of the least ambitious problem, i.e. to provide an alternative method, the board considers this mode of adding these ingredients to be obvious to a skilled person and to fall within the teaching of D18.

1.8.3 In view of this least ambitious problem, a skilled person having knowledge of D18 would consider using a dry blend of micellar casein and digestible carbohydrate to be a routine mode of addition. There are no passages in D18 which would discourage the skilled person from adding these ingredients in the form of a dry blend. In preparation A from D18 it is mentioned that powder proteins (MCI, MPI, calcium caseinate) and maltodextrin were added to the solution. Mixing a dry blend of micellar casein and carbohydrate with water is not excluded in the method of producing preparation A from D18. Instead, it is encompassed by the formulation given in preparation A, as also confirmed by the proprietor. Mixing a dry blend of micellar casein and carbohydrate with water is thus considered to be an obvious alternative in view of the teaching provided in D18.

In view of the above, the method from claim 1 of the main request does not involve an inventive step in view of D18 as the closest prior art.

AUXILIARY REQUESTS

2. Claim 1 of the main request is identical to claim 1 of all the auxiliary requests on appeal (see point V. above). Therefore, for the same reasons as outlined above for the main request, none of the auxiliary requests is allowable.

3. Partial refund of the proprietor's appeal fee

Before the debate was closed and the decision was announced during the oral proceedings, the proprietor withdrew its appeal. According to Rule 103(4) (a) EPC, the proprietor's appeal fee is reimbursed at 25%.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.
3. The proprietor's appeal fee is reimbursed at 25%.

The Registrar:

The Chairman:



A. Nielsen-Hannerup

A. Haderlein

Decision electronically authenticated