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Datasheet for the decision of 7 June 2018

Case Number: T 0181/17 - 3.3.09

Application Number: 09743961.6

Publication Number: 2346356

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Title of invention:
LIQUID HIGH-FAT PROTEIN COMPOSITION

Patent Proprietor:
N.V. Nutricia

Opponent:
Nestec S.A.

Headword:

Relevant legal provisions:
EPC Art. 100(c), 100(b), 54, 56

Keyword:
Inventive step attack based on new closest prior art - not admitted
Main request - allowed

Decisions cited:
T 0304/08

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

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Case Number: T 0181/17 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 7 June 2018

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)	Nestec S.A. Avenue Nestlé 55 1800 Vevey (CH)
Representative:	Mitscherlich PartmbB Patent- und Rechtsanwälte Sonnenstraße 33 80331 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 28 November 2016 concerning maintenance of the European Patent No. 2346356 in amended form.**

Composition of the Board:

Chairman	W. Sieber
Members:	F. Rinaldi
	C. Heath

Summary of Facts and Submissions

I. This decision concerns the appeals filed by both the opponent and the patent proprietor against the interlocutory decision of the opposition division that European patent No. 2 346 356 as amended met the requirements of the EPC.

II. With the notice of opposition, the opponent had requested revocation of the patent based on Article 100(a) (lack of novelty and lack of inventive step), Article 100(b) and Article 100(c) EPC.

The documents cited during opposition proceedings included:

D1: EP 0 953 289 A2
D2: J.M.M. Cruijsen, "Physical stability of caseinate stabilized emulsions during heating", 14 pages, 1996
D4: US 2003/0104033 A1
D17: Y.H. Hui, "Handbook of Food Products Manufacturing", John Wiley & Sons, Inc., 2007, 723-747
D18: Expert's declaration, Kirstine Mette Sveje
D19: Expert's declaration, Kirstine Mette Sveje
D20: A.W.M. Sweetsur et al., Journal of the Society of Dairy Technology 33(3), 1980, 101-105.

III. The opposition division's decision was based on a main request and auxiliary request 1 and can be summarised as follows:

Late-filed documents D17 to D20 were not admitted into the proceedings.

Main request:

Claims 1, 21 and 22 of the main request were identical to claims 1, 21 and 22 as granted and read as follows:

"1. *Shelf-stable liquid aqueous nutritional composition comprising non-micellar casein and more than 30 g fat per 100 ml of said composition, wherein the composition further comprises a heat stabilisation system.*"

"*21. Composition according to any one of claims 1 to 19 for use in the management of conditions in malnourished persons or persons at risk of becoming malnourished, and which are in need of liquid oral nutrition.*"

"*22. Composition according to claim 21 for use in the treatment of malnourished persons, persons at risk of malnourishment, metabolically stressed people, and elderly.*"

The opposition division held that the invention underlying claim 1 was sufficiently disclosed having regard to the term "shelf-stable" and the open-ended range of fat content. The invention was also sufficiently disclosed as regards the therapeutic uses referred to in claims 21 and 22. However, the subject-matter of claim 1 of the main request lacked novelty over D1.

As regards method claim 20, the patent proprietor noted during oral proceedings that the claim contained an unintentional error that made it broader in scope than the granted claim. The patent proprietor then tried to introduce a main request that had been amended

accordingly. However, this request was not admitted into the proceedings, because the subject-matter of claim 1 still lacked novelty over D1.

Auxiliary request 1:

Auxiliary request 1 was held to meet the requirements of the EPC, in particular those of Articles 123(2), 84, 54 and 56 EPC.

Claim 1 of this request differed from claim 1 of the main request in that the composition was sterilised and had a final pH between 6.5 and 7.2.

Method claim 20 was identical to granted claim 20 (the heat stabilisation system was again mandatory, and not optional, as in claim 20 of the main request). It read as follows:

> "*20. Method for the production of a composition according to any one of the preceding claims, comprising the steps of:*
> *(i) preparing an aqueous composition by dissolving into water the casein source and the emulsifier, a heat stabilisation system, and optionally other ingredients such as a precipitation stabiliser, other proteins, carbohydrates and minerals;*
> *(ii) adjusting the pH to between 6.5 and 7.2;*
> *(iii) adding the fat source to the composition obtained by step (ii);*
> *(iv) homogenising the composition obtained by step (iii) and subjecting it to one or more heat treatments.*"

Claims 21 and 22 were identical to those of the main request.

IV. Both the opponent and the patent proprietor appealed this decision.

As both the opponent and the patent proprietor are appellant and respondent in these proceedings, for simplicity the board will continue to refer to them as the opponent and the patent proprietor.

V. The opponent requested that the opposition division's decision be set aside and that the patent be revoked in its entirety. It also requested that D17 to 20, which had not been admitted by the opposition division, be admitted into the proceedings. Furthermore, the following documents were filed with the statement setting out the grounds of appeal:

D21: US 2001/0007878 A1
D22: WO 98/21953 A1
D23: Experimental report
D23a: Experimental report (identical to D23, better visibility of figures)

Reference was also made to:

https://en.wikipedia.org/wiki/Malnutrition
https://en.oxforddictionaries.com/definition/malnutrition

VI. The patent proprietor requested that the opposition division's decision be set aside and that the patent be maintained based on the main request or auxiliary requests 1 to 6, all requests filed with its statement setting out the grounds of appeal dated 28 March 2017. Furthermore, the following documents were filed with the statement setting out the grounds of appeal:

D24: P. Walstra et al., "Dairy Science and Technology", 2nd ed. CRC Press, 2005, 447-451

D25: Da-Wen Sun "Handbook of Food Safety Engineering", Wiley-Blackwell, 2012, 28 pages

D25a: Enlarged copy of paragraph 14.2 of D25.

VII. Further submissions were filed by the opponent by letters of 9 August 2017 and 28 September 2017, and by the patent proprietor by letter of 17 August 2017, including a screenshot of:

http://dictionary.cambridge.org/dictionary/english/malnourished.

VIII. In preparation for the oral proceedings, the board issued a communication dated 28 March 2018.

IX. With a letter dated 9 April 2018, the patent proprietor filed new auxiliary requests 1-4 and renumbered former auxiliary requests 2-6 as auxiliary requests 5-9. The opponent made submissions by letter of 3 May 2018.

X. At the beginning of the oral proceedings, which were held on 7 June 2018, the requests of the parties were as follows:

The **patent proprietor** requested

- that the opposition division's decision be set aside and that the patent be maintained in amended form based on:
  - the main request filed by letter of 28 March 2017, or

- auxiliary requests 1 to 4 filed by letter of 9 April 2018; or
- auxiliary request 5 to 9, which were filed as auxiliary request 2 to 6 by letter of 28 March 2017 and renumbered by letter dated 9 April 2018; and

- that documents D17 to D23/D23a not be admitted into the proceedings.

The **opponent** requested

- that the decision of the opposition division be set aside and that the patent be revoked;

- that the main request and auxiliary requests 1 to 4 not be admitted into the proceedings;

- that documents D17 to D23/23a but not documents D24 and D25 and D25a be admitted into the proceedings.

XI. In the course of the oral proceedings, the patent proprietor withdrew its request that D17 not be admitted and the opponent withdrew its request that D24 not be admitted into the proceedings.

XII. The claims of the main request, the only relevant request in the present decision, correspond to the claims of the patent as granted, except that granted claim 23 has been deleted. Claims 1, 21 and 22 are identical to claims 1, 21 and 22 of the main request before the opposition division, and claim 20 is identical to claim 20 of auxiliary request 1 allowed by the opposition division (for the wording of these claims, see point III. above).

XIII. The opponent's arguments which are relevant to the present decision may be summarised as follows:

- Admissibility of documents:

  The opposition division had been wrong in not admitting late-filed documents D18 to D20 into the proceedings. They should be admitted because their disclosure was *prima facie* relevant. The same reasoning applied to D21 to D23/D23a. D25, however, had been published well after the filing date of the application from which the opposed patent stems.

- Admissibility of the main request

  The main request was not admissible, since it essentially reinstalled the claims of the patent as granted. However, in view of proprietor's filing of a new main request in opposition proceedings, the granted claims had to be regarded as withdrawn or abandoned.

- Added subject-matter:

  The feature "for use in the management of conditions in malnourished persons" in claim 21 had no basis in the application as filed.

- Sufficiency of disclosure:

  With respect to the subject-matter of claim 1, objections were raised to (i) the feature "shelf-stable", (ii) the feature "heat stabilisation system" and (iii) the open-ended concentration range for the amount of fat.

  With regard to (i), there was no evidence that shelf-stability was indeed achieved and could be

measured. Therefore, there was only a weak presumption that the invention was enabled.

As for (ii), the feature was defined in functional terms and placed an undue burden on the skilled person attempting to rework the invention.

As for (iii), there was no evidence in the opposed patent that the invention was enabled when high concentrations of fat were used. The test results in D23/D23a showed experimentally that it was not in fact possible to obtain shelf-stable compositions at high-fat concentrations such as 60 g or 70 g per 100 ml. The compositions tested in D23/D23a had been prepared as described in the opposed patent and had been heated at a temperature typical for pasteurisation.

The combination of all three objections amplified the lack of sufficiency.

Furthermore, the subject-matter of claims 21 and 22 was directed to the treatment of malnourished patients. However, it had not been demonstrated or at least rendered credible that the high-fat compositions as described in claim 1 could be used to treat all conditions of malnourishment, for instance obese persons, which clearly fell under the patient group of "malnourished" persons.

- Novelty:

The subject-matter of claims 1 and of claims 21 and 22, in so far as it related to the non-medical treatment of malnourished persons, was anticipated by D1 and by D17.

The product of example 1 of D1 (paragraphs [0036] to [0038]) had to be regarded as inherently shelf-stable, because it comprised the same ingredients as the subject-matter of claim 1.

Document D17 in section 32.7.5 disclosed cream liqueur products having the same ingredients as the subject-matter of claim 1. In particular, the high-fat concentration of 40% had to be understood as meaning that the composition had a fat content of more than 30 g per 100 ml.

The subject-matter of the method claim 20 lacked novelty over D1, D2, D21 and D22. Claim 20 had to be interpreted as being merely suitable to provide the composition of claim 1. The cited prior-art documents included all process steps (a) to (d) of claim 20.

- Admissibility of the attack based on D17 as the closest prior art:

  It should be possible to develop an inventive-step attack using D17 as the closest prior art, because this document was already relevant for assessing novelty.

- Inventive step:

  After the board's decision not to admit the new attack based on D17 into the proceedings, lack of inventive step was eventually argued using only D4 as the closest prior art. Example 1 of D4 disclosed all features of the subject-matter of independent claims 1, 20 and 21, with the exception of the fat content. The technical problem was the provision of a high caloric composition. The solution was obvious to the person skilled in the art who was

aware that high-fat compositions existed in the art and that additives for stabilising such compositions were known in the art.

XIV. The patent proprietor's arguments which are relevant to the present decision may be summarised as follows:

- Admissibility of documents:
  The opposition division had been right in not admitting D18 to D20 into the proceedings. Documents D21 and D22 should not be admitted, since they essentially had the same content as D4. D23/ D23a should not be admitted, since it could and should have been filed earlier, namely already during the opposition proceedings.

- Admissibility of the main request:
  The main request filed on appeal corresponded to the claims of the granted patent, except that granted claim 23 had been deleted. Basically, such a set of claims had been filed as the main request in opposition proceedings, except that this main request had contained an unintentional error in claim 20: the (broader) wording of claim 20 as filed had been used, according to which the heat stabilisation system was optional. However, the patent proprietor's intention to retain granted claims 1 to 22, i.e. including granted method claim 20, had always been clear.

- Added subject-matter:
  There was a basis for the amendment "for use in the management of conditions in malnourished persons [...]" on page 1, line 9 to 11, of the original application.

- Sufficiency of disclosure:

  In view of the ample guidance in the application as filed, the invention was sufficiently disclosed. The skilled person had no difficulty in producing shelf-stable compositions and in applying a heat stabilisation system. In this context, reference was made to paragraphs [0017], [0044] and [0045] of the opposed patent. The examples disclosed in paragraphs [0072] to [0081] were shelf-stable. The tests in D23/D23a were not a genuine attempt to work within the disclosure of the opposed patent: the preparation method used in D23/D23a did not include a pasteurisation step.

  With regard to the objections to claims 21 and 22, the person skilled in the art had no difficulty in identifying the appropriate patient group for the composition of the opposed patent. The skilled person would not use the term "malnourishment" in applications which would not make any sense in the context of high-fat compositions.

- Novelty:

  D1 did not disclose shelf-stable liquid compositions including more than 30 g fat per 100 ml. In the light of the patent specification "shelf-stable" had to be understood as meaning sterilised.

  D17 disclosed in section 32.7.5 only a composition including 40% solid matter, of which 40% was fat. Thus, the fat content disclosed in this section was of 16%, which was the typical fat content of cream liqueur compositions.

The subject-matter of claim 20 was directed to a manufacturing method providing the subject-matter of claim 1. The products disclosed in D1, D2, D21 and D22 were either too low in fat content or not shelf-stable.

- Admissibility of the attack based on D17 as the closest prior art:
  The attack should not be admitted, since it had not been presented until the oral proceedings.

- Inventive step:
  D4 was the closest prior art. The technical problem was how to provide a shelf-stable liquid aqueous nutritional composition. The problem was solved. There was nothing in the prior art to suggest this solution: in D4 only low-fat concentrations were used, and paragraph [0011] of D4 taught away from using caseinate. Documents D17 and D24 emphasised that there were many difficulties in stabilising high-fat compositions.

Reasons for the Decision

1. Admissibility of documents

1.1 Admitted documents:

1.1.1 D17 and D24: In the course of the oral proceedings before the board, both parties relied on D17 and D24. Consequently, the opponent eventually withdrew its request that D24 not be admitted and the patent proprietor its request that D17 not be admitted into

the proceedings. The board thus saw no reason not to admit these two documents into the proceedings.

1.1.2 D21 and D22: These documents were used to attack method claim 20. The core issue for assessing patentability of this claim is how to interpret its scope. In this specific situation, the board decided to admit these documents in view of procedural economy.

1.1.3 D23/D23a: The opponent filed this experimental report to demonstrate that, in view of the open-ended range in claim 1 ("more than 30 g fat per 100 ml"), the invention was not enabled over the entire scope claimed. The patent proprietor argued that such tests could and should have been filed earlier, because the lack of experimental evidence had already been highlighted during the opposition proceedings. Nevertheless, the board considers that the filing of D23/D23a with the statement setting out the grounds of appeal, i.e. at the earliest possible stage in the appeal proceedings, is an acceptable reaction, occasioned at least in part by the opposition division's decision. Thus, the board decided to admit D23/D23a into the proceedings.

1.2 Non-admitted documents:

1.2.1 D18 and D19: These two documents had been filed late during opposition proceedings and the opposition division had exercised its discretion not to admit them into the proceedings for their lack of *prima facie* relevance. As these documents were not used during the oral proceedings before the board, the board saw no reason to overrule the opposition division's decision on this issue.

1.2.2 D20: This document had also been filed late during opposition proceedings, and the opposition division had exercised its discretion not to admit it for lack of relevance to the present case. The opponent argued that D20 underlined that heat stability was a complicated technical problem which was not easily solved and that the difficulties were mainly caused by the protein which is present in skim milk. This argument does not convince the board. D20 deals with heat stability of skim milk products, i.e. low-fat products. Technical problems that occur with a low-fat product are simply not the same as those that occur with a high-fat composition, since fat globules do interact with casein. This is confirmed by handbooks D24 (page 448) and D17 (page 727). Thus, the board saw no reason to overrule the opposition division's decision on this issue.

1.2.3 D25: In view of the fact that this document was published in 2012, i.e. some four years after the date of filing of the opposed patent, it was not admitted.

2. Admissibility of the main request

2.1 The opponent requested that the main request not be admitted into the proceedings because the appealed decision was not based on this request. It alleged that the patent proprietor was trying to re-install the claims as granted, which had been replaced by a new main request before the opposition division. This implied that the former main request (i.e. the claims as granted) had been withdrawn. A request which had been abandoned or withdrawn could not be the subject of an appeal.

2.2 First of all, the board notes that the main request does not re-install the claims as granted. Claim 23 as granted is deleted from the main request. Besides, it is evident from the course of events in the present case that the patent proprietor never intended to abandon or withdraw a request worded like the present main request.

2.2.1 In opposition proceedings, the patent proprietor had filed a new main request from which granted claim 23 had been deleted in a genuine attempt to overcome objections of added subject-matter raised by the opposition division in its preliminary opinion accompanying the summons. It was only during oral proceedings before the opposition division that the proprietor realised that claim 20 of the then main request was broader in scope than claim 20 as granted. It explained that an unintentional error had occurred in claim 20 when filing the then new request (see minutes, point 3.3.2). Subsequently, the patent proprietor tried to introduce an amended main request in which only the unintentional error in claim 20 was amended (see minutes, point 4.1). Such a set of claims would have been identical to the present main request. However, the request was not admitted into the proceedings because such a set of claims contained an unaltered claim 1, the subject-matter of which was still not novel over D1.

2.2.2 Thus, rather than abandoning a request worded like the present main request, the patent proprietor had attempted during oral proceedings to introduce a request identical to that main request.

2.3 In view of this, the opponent's request that the main request not be admitted is not justified.

3. Main request - added subject-matter:

The amendment in claim 21 "for use in the management of conditions in malnourished persons..." is based on claims 1 and 10 (further comprising a heat stabilisation system) as filed in conjunction with the first paragraph of the application as filed, in particular in lines 9 to 11. It is specified there that the "nutritional composition according to the invention is especially suitable for malnourished persons or persons at risk of becoming malnourished, and in need of liquid oral nutrition". The board cannot see that the slightly reworded expression "management of conditions" in claim 21 results in any added subject-matter. The ground under Article 100(c) EPC does not prejudice the maintenance of the patent in the form of the main request.

4. Main request - lack of sufficiency of disclosure

4.1 The opponent regarded several features in claim 1 as leading to insufficient disclosure, namely:

(i) the feature "shelf-stable";
(ii) the feature "heat stabilisation system"; and
(iii) the open-ended concentration range for the amount of fat.

4.2 As a first remark, the board notes that the opposed patent contains sufficient information for the person skilled in the art to carry out the invention. The patent specification includes a definition of what "shelf-stable" means (paragraph [0017]), a definition of "heat stabilisation system" and compounds to be used as heat stabilisation system (paragraph [0044] and

[0045]). Furthermore, the patent contains a rather detailed description of the process for preparing the shelf-stable liquid nutritional composition together with formulation examples (paragraphs [0072] to [0081]). Although no tests have been carried out with the exemplified compositions, it is plausible that no sedimentation occurs.

4.3 More specifically, as regards objection (i), the expression "shelf-stable" is defined in paragraph [0017]. The last two sentences of this paragraph read:

> "*To serve and qualify as a commercial nutritional product, [...] the product according to the invention should be able to withstand sterilisation [...]. To further ensure a long shelf live, the product should be shelf-stable, meaning that no sedimentation, segregation, aggregation, flocculation or gelation of the individual components should occur after the heat treatment.*" (emphasis added by the board)

The first sentence specifies that the product of the invention, i.e. the liquid nutritional composition, should be able to withstand sterilisation. The next sentence specifies that the shelf-stable product shows no sedimentation, segregation, aggregation, flocculation or gelation of the individual components after *the* heat treatment. The antecedent for "*the* heat treatment" in this sentence can only be the sterilisation mentioned in the previous sentence because it is actually the only process step mentioned in the paragraph which qualifies as a heat treatment. In other words, "shelf-stable" is defined in the opposed patent as meaning that the composition has undergone sterilisation and that the product does not

show inhomogeneity such as sedimentation. Moreover, the patent specification contains instructions on how to prepare the shelf-stable compositions. The board therefore does not accept that there is only a weak presumption that the invention is enabled and that the burden of proof has actually shifted. At best, there may be a lack of clarity as to the intended duration of the product's shelf life. But this is not an issue of lack of sufficiency of disclosure.

4.4 Equally, as for objection (ii), the instructions given in the opposed patent, together with the examples of compounds useful for achieving stabilisation given in paragraphs [0044] and [0045], are in the present case sufficient to enable the reworking of the invention and even to find further suitable heat stabilisation systems. In fact, when formulating novelty attacks, the opponent had no difficulty in identifying heat stabilisation systems in the cited prior-art documents (e.g. dipotassium phosphate in D1).

4.5 Finally, as regards objection (iii), the board's view is as follows:

4.5.1 The fact that the subject-matter of claim 1 encompasses an open-ended range ("more than 30 g fat per 100 ml") does not necessarily lead to the conclusion that the opposed patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by the skilled person. In fact, the patent contains examples containing between 38.7 to 41.5 g fat per 100 ml.

4.5.2 The test results provided in D23/D23a were filed to demonstrate that the open-ended range "more than 30 g fat per 100 ml" in claim 1 embraced embodiments which

could not be made, thus leading to a lack of sufficiency. These tests demonstrated that compositions including 60 or 70 g of fat per 100 ml, i.e. fat contents falling within the open-ended range showed phase separation and segregation. In other words, the compositions were not shelf-stable.

4.5.3 The opposed patent gives, in the section "Method of preparation" in paragraphs [0072] to [0081], a rather detailed description of how the liquid nutritional compositions according to the invention can be prepared. As pointed out by the patent proprietor, the compositions tested in D23/D23a were not prepared as set out in these paragraphs; in particular, no pasteurisation step was carried out. Heating the mixture at 75°C in a water bath as cited in D23/D23a cannot be considered a pasteurisation step.

4.5.4 The opponent argued that the temperature of 75°C described in D23/D23a was a typical pasteurisation temperature. However, D23/D23a does not disclose any duration for the heat treatment at 75°C, which is also an important element of the pasteurisation process. Thus, the board cannot identify in D23/D23a a step corresponding to the pasteurisation step disclosed in paragraph [0076] of the opposed patent as part of the procedure for preparing the liquid nutritional compositions according to the invention. The board notes in this context that a sterilisation step is explicitly mentioned in D23/D23a (as in paragraph [0078] of the opposed patent) and the sterilisation conditions (temperature *and* time) are also explicitly stated, whereas there is no reference to pasteurisation and the conditions thereof (temperature *and* time).

4.5.5 In view of these considerations, there is no valid evidence on file demonstrating that the invention is not enabled over its entire scope. Since the patent in suit furthermore contains examples containing between 38.7 to 41.5 g fat per 100 ml, and these fat contents are considerably above the lower limit of 30 g fat per 100 ml, the board considers that the invention as claimed in claim 1 is sufficiently disclosed. Also the opponent's argument that objections (i), (ii) and (iii) in combination amplifies the lack of sufficiency cannot alter the board's conclusion in this respect.

4.6 The opponent also considered that the medical use defined in claims 21 and 22 was not enabled. Although these claims were directed to the treatment of malnourished patients, it was not plausible that the high-fat compositions as described in claim 1 could be used to treat obesity, which is a condition of malnourishment by overnutrition.

4.6.1 The board agrees with the opponent that "malnourished" is a very broad expression, and, in fact, encompasses both therapeutic and non-therapeutic aspects. The board also agrees with the opponent that the therapeutic aspects of malnourishment *in principle* cover the treatment of, for instance, obesity.

4.6.2 However, it should be kept in mind that claim 1 defines compositions that are particularly rich in fat, namely containing more than 30 g of fat per 100 ml. The subject-matter of claims 21 and 22, which is directed to the treatment (or management) of malnourishment refers back to the high-fat composition of claim 1. Under these specific circumstances, it is immediately clear to the skilled reader - on the basis of the claims alone - that the compositions claimed are

intended to treat malnourished persons requiring a high intake of fat based calories. Conversely, persons not needing a fat-rich nutrition (such as obese patients) should not consume such a composition.

4.6.3 In this context, the board notes that the patent specification is in line with this interpretation. As pointed out in paragraphs [0002] to [0004], the high-fat compositions are intended for people in need of high-energy liquid nutritional compositions such as severely-ill persons that are hardly capable of orally taking in nutrition and/or fluids to maintain an adequate nutritional level, or for sportsmen, the elderly or any person in need of high-energy and/or high-fat nutrition. In other words, the description of the opposed patent is also not misleading the person skilled in the art. Thus, in the present case, the skilled reader would rule out the interpretation suggested by the opponent.

4.7 It follows from this that none of the objections raised under Article 100(b) EPC compromise the maintenance of the patent in amended form.

5. Novelty of claims 1, 21 and 22

5.1 Novelty of claims 1, 21 and 22 vs. D1

5.1.1 The opponent considered the intermediate product disclosed in paragraphs [0036] to [0038] of example 1 of D1 to be novelty-destroying. According to this passage, a slurry is produced with water (63.5 kg), non-micellar casein (sodium caseinate, 6.8 kg), palm oil (45.4 kg), dipotassium phosphate (341 g), which according to the patent in suit is a heat stabiliser,

and emulsifiers (2.388 kg). To 19.1 kg of this slurry, 2.2 kg of sweet whey protein is added and the resulting slurry is homogenised. The opponent calculated that an emulsion was produced including 34.9 g fat per 100 ml of the composition. This calculation was not contested by the patent proprietor.

5.1.2 The crucial issue is whether this intermediate product is a shelf-stable composition. As explained in detail in point 4.3 above, the expression "shelf-stable" is defined in the opposed patent as meaning, among other things, that the product has undergone a sterilisation step.

5.1.3 Due to the fact that the intermediate composition of example 1 is not sterilised, the subject-matter of claim 1 is novel over D1. Analogously, the subject-matter of claims 21 and 22 - in so far as it relates to the non-medical aspect of malnourishment - is also novel over D1.

5.2 Novelty of claims 1, 21 and 22 vs. D17

5.2.1 In the statement setting out the grounds of appeal, the opponent cited D17 as novelty destroying. The opponent cited various passages of this document allegedly disclosing the features of claim 1. In its communication, the board informed the parties that separate items of D17 had to be combined in order to read a novelty-destroying disclosure into the document.

5.2.2 At the oral proceedings, the opponent relied only on section 32.7.5 of D17, on page 742, which reads as follows:

32.7.5 Cream Liqueur

The basic principles involved in the manufacture of cream liqueurs are illustrated in the flow diagram in Figure 32.10, adapted from Banks and others (1982). The final composition of a cream liqueur is 14% ethanol and 40% solids. Ionic conditions, pH, and the type of caseinate will affect the structure of cream liqueurs. A reduction in pH below 6.4 results in increasing flocculation of fat globules (Dickinson and others 1989). Sodium chloride will increase the viscosity of sodium-caseinate-stabilized emulsions in cream liqueurs (Lynch and Mulvihill 1997). Addition of cream liqueur to coffee will mix into the beverage rather than form a cream layer above the coffee. By adding trisodium citrate to sequester calcium, and at a high fat content of 40%, a stable cream liqueur can be produced that floats on top of hot coffee (Muir 1988).

5.2.3 However, this passage also does not unambiguously disclose the combination of features of present claim 1. In fact, it consists of a summary of four different scientific publications. For the board, it is not clear what precisely this document discloses.

5.2.4 A first possible reading of this passage would be that each scientific publication is a different, stand-alone disclosure, meaning that the summaries of these publications cannot be straightforwardly combined.

5.2.5 A second reading would be that the entire passage must be understood as single, new disclosure. However, such a reading inevitably leads, again, to different ways of reading the document:

(a) The patent proprietor's way of reading this passage is that the cream liqueur composition contains about 40% solids, of which 40% are fat, thus resulting in a fat content of 16%. Fat contents within this range are in fact typical for cream liqueur beverages.

(b) According to the opponent, D17 disclosed all ingredients disclosed in claim 1, and the "the high-fat content of 40%" had to be understood as meaning that the composition had a fat content of more than 30 g per 100 ml.

5.2.6 From all this, the board can only conclude that D17 does not - directly and unambiguously - disclose a shelf-stable composition comprising more than 30 g fat per 100 ml of said composition, wherein the composition further comprises a heat stabilisation system and non-micellar casein. Consequently, the subject-matter of claims 1, 21 and 22 is novel over D17.

6. Novelty of method claim 20

6.1 Claim 20 relates to a "[m]ethod for the production of a composition according to any one of the preceding claims, comprising the steps of: [...]". The opponent argued, citing T 304/08, that such a claim must be read as being directed to a process *suitable for* the production of one of the claimed composition.

6.2 In decision T 304/08, the board examined a claim directed to a "*method for reducing malodor associated with a disposable absorbent product intended for the absorption of body fluids, said method comprising the steps of: [...]*". The intention of such a claim was to protect a specific purpose (namely, reducing malodor associated with a disposable absorbent product intended for the absorption of body fluids). To sum up, the activity claim examined in T 304/08 was aimed at *achieving an effect* and not at *producing a product.*

6.3 However, claim 20 is directed to a different type of activity claim, namely to the production of a product. In particular, claim 20 relates to a production process resulting in the product of claim 1 (and its dependent claims 2 to 19). Thus, a product having the features of claim 1 must be the result of the method of claim 20, which means that not only the features of steps (i) to (iv) but also the features of the product of claim 1

are features limiting the subject-matter of method claim 20.

6.4 The opponent also cited D2, D21 and D22 against the novelty of the subject-matter of claim 20. However, none of these documents discloses compositions comprising 30 g fat (or more) per 100 ml. Consequently, these documents do not disclose the method of claim 20, which is a method for manufacturing a shelf-stable liquid aqueous nutritional composition comprising, among other things, more than 30 g fat per 100 ml of the composition.

6.5 D1 was also cited against the novelty of the subject-matter of claim 20. However, D1 does not disclose the preparation of a sterilised composition comprising more than 30 g of fat per 100 ml.

6.6 Thus, the subject-matter of claim 20 is also novel over the cited prior art.

7. Admissibility of the attack using D17 as the closest prior

7.1 At the oral proceedings, the opponent stated - for the first time in the appeal proceedings - that it would present an inventive-step attack based on D17 as the closest prior art. The patent proprietor objected to this new attack.

7.2 The board notes that, over the course of the appeal proceedings, the opponent has submitted four substantive written submissions, all of which referred to D17, but only in the context of novelty.

7.3 Introducing an attack based on D17 as the closest prior art at such a late stage in the proceedings confronts both the board and the patent proprietor with a completely new case.

7.4 The opponent argued that, since D17 had been used to attack novelty, it could have been expected that this document would also be used for an inventive-step attack. This does not convince the board. In view of the duty of a party to present its complete case, there is no obligation on the board (or on the patent proprietor) to speculate on other attacks. Novelty and inventive step are different grounds of opposition, and documents useful in attacking novelty are not necessarily the same as those that qualify as the closest prior art.

7.5 Thus, the attack based on D17 as the closest prior art is not admitted into the proceedings in accordance with Article 13(1) Rules of Procedure of the Boards of Appeal.

8. Inventive step

8.1 The invention relates to a liquid aqueous nutritional composition comprising at least non-micellar casein, having more than 30 g fat per 100 ml of said liquid aqueous nutritional composition, and a heat stabilisation system. The product is shelf-stable, meaning that after sterilisation no sedimentation, segregation, aggregation, flocculation or gelation of the individual components should occur.

8.2 Closest prior art:

8.2.1 In its communication, the board informed the parties that it regarded document D4 as the closest prior art, as was the case in the appealed decision. At the oral proceedings, the opponent likewise used only D4 as the closest prior art.

8.2.2 D4 relates to an enteral formula having a protein system that contains a stabilising protein and caseinate. As regards the composition's stability, D4 makes no distinction between micellar and non-micellar casein. In fact, it is stated in D4 that "caseinate actually destabilizes the enteral formula by promoting phase separation" (see paragraph [0011]). The formula exhibits a reduced rate of creaming and an enhanced shelf life (D4, paragraph [0001]).

8.2.3 An embodiment of such a formula is described in its example 1. It is undisputed that this example discloses non-micellar casein as one of its ingredients and a heat stabilisation system. Furthermore, the composition is sterilised. The patent proprietor calculated a fat content of 3.4 g per 100 ml for this composition. The opponent did not contest this. The fat content is the only distinguishing feature.

8.3 The technical problem and its solution:

Starting from D4, the objective technical problem is to provide an alternative high-caloric, shelf-stable liquid aqueous nutritional composition. The opponent contested that the technical problem of providing shelf-stable compositions was indeed solved. However, as discussed in detail above, and also in view of the disclosure of the examples disclosed in

paragraph [0072] and following, the board considers it credible that the objective technical problem is indeed solved.

8.4 Obviousness:

8.4.1 To arrive at the subject-matter claimed, a *nine-fold* increase of the fat content is necessary. This cannot be considered an obvious modification of the composition of the closest prior art.

8.4.2 Starting from the teaching of example 1 of D4, the board simply cannot see that the skilled person would consider it obvious to envisage - with a reasonable expectation of success - a nine-fold increase of the fat content to solve the technical problem. In this context, the disclosure regarding the destabilising role of the caseinate discussed in paragraph [0011] of the closest prior art cannot be disregarded. Moreover, the fact that compositions including more than 30 g fat are *per se* known (e.g. from D1, paragraph [0038], or possibly from D17) would not prompt the person skilled in the art starting from example 1 of D4 to arrive at the subject-matter of claim 1.

8.4.3 The disclosure of D17 and D24 was discussed by the parties at the oral proceedings. For the board, these documents demonstrate that the stability of sterilised high-fat compositions is indeed a technical issue and that there may be ways to stabilise high-fat compositions (by adjusting the pH and by using stabilisers). However, there is simply no incentive for the person skilled in the art to combine the teaching of these documents with the closest prior art, example 1 of D4, in order to solve the objective technical problem.

8.5 It follows from this that the subject-matter of claim 1, and by the same token of claims 20 to 22, involves an inventive step (Article 56 EPC).

9. In view of this conclusion, there is no need to discuss the auxiliary requests.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of claims 1 to 22 of the main request as filed with letter dated 28 March 2017 and a description to be adapted thereto, if required.

The Registrar: The Chairman:

M. Cañueto Carbajo W. Sieber

Decision electronically authenticated