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**Datasheet for the decision
of 11 December 2017**

Case Number: T 1471/14 - 3.3.09

Application Number: 06737520.4

Publication Number: 1871182

IPC: A23L1/29

Language of the proceedings: EN

Title of invention:

CONCENTRATED LIQUID HUMAN MILK FORTIFIER (HMF)

Patent Proprietor:

ABBOTT LABORATORIES

Opponents:

Nestec S.A.
N.V. Nutricia

Headword:

Relevant legal provisions:

EPC Art. 54, 83, 123(2), 123(3)

Keyword:

Admittance of documents, arguments and claim requests
Novelty
Sufficiency of disclosure
Amendments - added matter - extension of scope in view of
change from product to use claim
Remittal

Decisions cited:

G 0002/88, T 0401/95, T 0282/09

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 1471/14 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 11 December 2017

Appellant: ABBOTT LABORATORIES
(Patent Proprietor) 100 Abbott Park Road
Abbott Park, IL 60064-3500 (US)

Representative: Boulton Wade Tennant
Verulam Gardens
70 Gray's Inn Road
London WC1X 8BT (GB)

Respondent: Nestec S.A.
(Opponent 1) Avenue Nestlé 55
1800 Vevey (CH)

Representative: Santarelli
49, avenue des Champs-Élysées
75008 Paris (FR)

Respondent: N.V. Nutricia
(Opponent 2) Eerste Stationsstraat 186
2712 HM Zoetermeer (NL)

Representative: Wohlfahrt, Jan Günther
Gleiss Große Schrell und Partner mbB
Patentanwälte Rechtsanwälte
Leitzstraße 45
70469 Stuttgart (DE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 19 May 2014
revoking European patent No. 1871182 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman	W. Sieber
Members:	M. O. Müller
	F. Blumer

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the proprietor of European patent No. 1 871 182 against the decision of the opposition division to revoke it. Opponent 2 also appealed this decision, said appeal later having been withdrawn.

II. With the notice of opposition opponents 1 and 2 had requested revocation of the patent in its entirety on the grounds under Article 100(a) (lack of novelty and inventive step), 100(b) and 100(c) EPC.

The documents submitted during the opposition proceedings included:

D1: US 2002/0142025 A1; and

D17: C. J. Klein, The Journal Of Nutrition, volume 132, 2002, pages 1395S, 1461S to 1467S;

III. The opposition division's decision was based on a main request and three auxiliary requests.

Claim 1 of the main request and second auxiliary request were identical and read as follows:

"1. A liquid human milk fortifier composition comprising from 15% to 45% by weight of protein, on a dry weight basis, and having a caloric density of from 1.25 kcal/ml to 6.0 kcal/ml, wherein the liquid composition is intended to be added to human milk in a volume-volume ratio of from 1:3 to 1:9."

Claim 1 of the first and third auxiliary requests were also identical and differed from claim 1 of the main

request in that the lower limit for the protein amount had been increased to 20% by weight.

The main request and the first to third auxiliary requests were found not to be allowable since the subject-matter of claim 1 of all requests lacked novelty over example 4 of D1.

IV. This decision was appealed by the proprietor and opponent 2.

The proprietor's statement of grounds of appeal contained a main request and first to ninth auxiliary requests as well as

D17a: pages 1492S to 1498S of D17; and

D36: European commission decision 2005/580/EC dated 25 July 2005, 1 page.

V. With its letter dated 17 September 2014, opponent 2 filed its grounds of appeal. In a subsequent letter dated 29 January 2015, it filed:

D36a: European Public Assessment Report (EPATR), EMEA/H/C/678, Cystadane, EPAR summary for the public, 2 pages;

D36b: Cystadane[®], distributed by Orphan Medical, Inc., revision date November 2005, 6 pages; and

D37: Set of claims filed by the proprietor on 13 November 2014 in the parallel US application 11/370,610 and front page of the corresponding application.

VI. With its letter of 10 February 2015 opponent 1 filed its response, which included:

D38: Publication of HighBeam Research, 1 March 2004, 1 page.

VII. With communication dated 26 April 2017, the board communicated its preliminary opinion to the parties.

VIII. With its letter dated 10 October 2017, the proprietor filed a revised main request and revised first to ninth auxiliary requests.

IX. On 11 December 2017, oral proceedings took place before the board, during which opponent 2 withdrew its appeal. Since, from this point on, the proprietor was the sole appellant, and opponent 2 gained the status of a respondent, the parties will be referred to hereinafter as the appellant and respondent 1 and 2, respectively.

After the board had announced its conclusion that the first auxiliary request did not meet the requirements of Article 123(3) EPC, the appellant replaced this request by a new first auxiliary request.

X. The only independent claim, i.e. claim 1, of the main request is identical to claim 1 of the main request before the opposition division (see point III above).

Claim 1 of the relevant auxiliary requests reads as follows (amendments with regard to claim 1 of the main request have been highlighted by the board):

(New) first auxiliary request:

"1. **Use of a** A liquid human milk fortifier composition comprising from 15% to 45% by weight of protein, on a dry weight basis, and having a caloric density of from 1.25 kcal/ml to 6.0 kcal/ml, **as a human milk fortifier for providing nutrition to preterm infants, wherein in use** wherein the liquid composition is intended to be added to human milk in a volume-volume ratio of from 1:3 to 1:9."

Second auxiliary request:

"1. A liquid human milk fortifier composition comprising from 15% to 45% by weight of protein, on a dry weight basis, **and a water-insoluble calcium component, said water-insoluble calcium component representing from 50% to 100% of the total calcium in the composition, said composition** and having a caloric density of from 1.25 kcal/ml to 6.0 kcal/ml, wherein the liquid composition is intended to be added to human milk in a volume-volume ratio of from 1:3 to 1:9."

Third auxiliary request:

"1. A liquid human milk fortifier composition comprising from 15% to 45% by weight of protein, on a dry weight basis, **and a water-insoluble calcium component, said water-insoluble calcium component being selected from the group consisting of calcium phosphate dibasic, calcium phosphate tribasic, calcium carbonate, calcium citrate, and combinations thereof, and said water-insoluble calcium component representing from 50% to 100% of**

the total calcium in the composition, said composition and having a caloric density of from 1.25 kcal/ml to 6.0 kcal/ml, wherein the liquid composition is intended to be added to human milk in a volume-volume ratio of from 1:3 to 1:9."

Fourth auxiliary request:

"1. A liquid human milk fortifier composition **which is aseptically packaged, said composition** comprising from 15% to 45% by weight of protein, on a dry weight basis, and having a caloric density of from 1.25 kcal/ml to 6.0 kcal/ml, wherein the liquid composition is intended to be added to human milk in a volume-volume ratio of from 1:3 to 1:9."

The fifth to ninth auxiliary requests are not relevant to the present decision.

XI. So far as relevant to the present decision, the appellant's arguments can be summarised as follows:

D17a and D36 should be admitted into the proceedings, since they had been filed at the earliest possible time during the appeal proceedings, constituted a reaction to the opposition division's decision and were a follow-up of arguments presented throughout the opposition proceedings.

The invention as defined in the main request was sufficiently disclosed. As set out in the board's preliminary opinion, it was common general knowledge to add further components if the caloric density required by claim 1 could not be achieved with protein alone.

The subject-matter of claim 1 of the main request was novel over the supplement disclosed in example 4 of D1. This document neither disclosed that the supplement was intended to be added to human milk in a volume ratio as required by claim 1, nor was it packaged or labelled as a human milk fortifier. It was in fact not suitable as a human milk fortifier in view of its calcium, phosphorus and manganese amounts and the presence of betaine. Lastly, it was not in a liquid form.

The first to fourth auxiliary requests should be admitted into the proceedings since they were filed at the earliest possible time during the appeal proceedings, constituted a reaction to the opposition division's decision and represented a follow up of arguments presented throughout the opposition proceedings.

Contrary to the respondents' arguments, claim 1 of the first auxiliary request did not violate Article 123(3) EPC since its scope was not broader than that of claim 1 and claim 18 as granted.

Also the omission of the type of percentage of the insoluble-calcium amount in claim 1 of the second and third auxiliary requests did not add matter.

The feature of aseptic packaging in claim 1 of the fourth auxiliary request met the requirements of Article 123(2) EPC, since it was disclosed on pages 10 and 11 of the application as filed. The subject-matter of claim 1 was also novel, since example 4 of D1 did not disclose aseptic packaging.

Inventive step should not be discussed before the board but the case should be remitted to the opposition

division. It was not true that by not filing the fourth auxiliary request before the opposition division the appellant had neglected its procedural duties.

Furthermore, the discussion of inventive step was a complex issue and should therefore be discussed before the opposition division first.

XII. So far as relevant to the present decision, the respondents' arguments can be summarised as follows:

D17a and D36 should not be admitted into the proceedings since they should have already been filed before the opposition division.

The invention defined in claim 1 of the main request was insufficiently disclosed, since it was not possible to obtain caloric densities as required by claim 1 with the amount of protein stipulated in this claim.

The subject-matter of claim 1 of the main request lacked novelty over the supplement of example 4 of D1. Claim 1 was neither restricted by the intention expressed in this claim of adding the human milk fortifier in a certain volume ratio, nor by any specific type of packaging or labelling. Furthermore, in view of the description of the opposed patent, and contrary to the appellant's argument, it could not be assumed that a generally accepted definition of human milk fortifiers existed that restricted the amount of calcium, phosphorus and manganese such that the supplement of example 4 of D1 could not be regarded as being suitable as a human milk fortifier. The same applied to the presence of betaine, which was not excluded by the opposed patent. Lastly in view of the reference to millilitre and litre in example 4 of D1,

it had to be assumed that the supplement of this example was in liquid form.

The first to fourth auxiliary requests should not be admitted into the proceedings, since they should have already been filed before the opposition division.

Claim 1 of the first auxiliary request did not meet the requirements of Article 123(3) EPC. Unlike claim 1 as granted, it covered fortified human milk and unlike claim 18 as granted, it covered uses without any administration of the fortified human milk to a preterm infant.

Claim 1 of the second and third auxiliary requests contained added matter, since, unlike in the application as filed, the percentage of insoluble calcium component relative to total calcium was not expressed as a weight percentage.

Claim 1 of the fourth auxiliary request did not meet the requirements of Article 123(2) EPC, since the application as filed disclosed aseptic packaging only in combination with specific amounts of fat and carbohydrate. Furthermore, this claim did not meet the requirements of Article 123(3) EPC, since unlike granted claim 7, it was not restricted to specific amounts of carbohydrate and fat. Lastly, the subject-matter of claim 1 lacked novelty over example 4 of D1, since this example referred to a food for clinical or dietary use, which was inherently aseptically packaged. Furthermore, aseptic packaging was the only type of packaging disclosed in D1.

Respondent 2 requested that the case be remitted to the opposition division. Respondent 1 requested that the

case not be remitted but that inventive step be decided by the board itself. It would have been the appellant's procedural duty to file the fourth auxiliary request already before the opposition division. In this case the opposition division could have decided inventive step so that no remittal would have been necessary.

XIII. The appellant requested that the appealed decision be set aside and the case be remitted to the opposition division for further consideration of the main request, or, if the main request was not considered acceptable, that the case be remitted to the opposition division for further consideration on the basis of any of the first to ninth auxiliary requests, the first auxiliary request as filed during oral proceedings before the board, the main request and the second to ninth auxiliary requests as filed with letter dated 10 October 2017. The appellant clarified that it requested remittal for consideration under Article 56 EPC only, assuming that all other objections had been dealt with in the present appeal proceedings.

XIV. Respondent 2 requested that

- the patent stay revoked, implying that the patent proprietor's appeal be dismissed;
- D36a, D36b and D37 be admitted into the proceedings;
- D17a and D36 and arguments related thereto not be admitted into the proceedings;
- the first to ninth auxiliary requests (the first auxiliary request as filed during oral proceedings before the board, the second to ninth auxiliary

requests as filed with letter dated 10 October 2017) not be admitted into the proceedings;

- if the board came to the opinion that the main request or any of the first to ninth auxiliary requests fulfilled the requirements of Rule 80 EPC and Articles 123(2), 123(3), 83 and 54(2) EPC, the case be remitted to the opposition division.

XV. Respondent 1 requested that

- the patent proprietor's appeal be dismissed;
- D17a and D36 and related arguments not be admitted into the proceedings;
- D38 be admitted in the event that D36 was admitted
- the first to ninth auxiliary requests (the first auxiliary request as filed during oral proceedings before the board, the second to ninth auxiliary requests as filed with letter dated 10 October 2017) not be admitted into the proceedings;
- in case the main request or any of the first to ninth auxiliary requests, if admitted, was considered to be novel with respect to document D1, that the board study the ground of lack of inventive step without remitting the case to the opposition division.

Reasons for the Decision

Main request

1. Novelty
 - 1.1 Admissibility of documents and arguments
 - 1.1.1 Respondents 1 and 2 requested that D17a and D36 and the novelty arguments related thereto not be admitted into the proceedings.

The appellant had filed D17a and D36 with its statement of grounds of appeal. It argued that these documents showed that the supplement of example 4 of D1 was not suitable as a human milk fortifier, since it contained betaine and an amount of manganese that was too high. The supplement did thus not anticipate the feature "human milk fortifier" of claim 1.

The board does not see any reasons for not admitting documents D17a, D36 and the arguments related thereto. They were filed at the earliest possible time during the appeal proceedings, namely with the statement of grounds of appeal. Furthermore, these documents and arguments merely constitute a follow-up of what the appellant had argued throughout the opposition proceedings, namely that the supplement of example 4 of D1 was not suitable as a human milk fortifier. Lastly, they can be regarded as a reaction to the opposition division's decision to deny novelty over example 4 of D1. In this respect it is to be noted that in its preliminary opinion the opposition division had only stated that certain aspects as regards novelty over D1 needed to be discussed but did not raise any specific novelty objection. Therefore, the board does not share

respondent 2's argument that it would have been the appellant's duty to file D17a, D36 and arguments related thereto already in reaction to the opposition division's preliminary opinion.

For these reasons, the board decided to admit D17a, D36 and the arguments related thereto into the proceedings.

- 1.1.2 The appellant had initially requested that the respondents' documents D36a, D36b, D37 and D38 not be admitted into the proceedings. After D17a and D36 had been admitted, the appellant acknowledged that also D36a, D36b, D37 and D38 should be admitted. In fact, these documents represent a timely reaction of respondents 1 and 2 to the appellant's filing of D17a and D36. The board therefore decided to admit D36a, D36b, D37 and D38 into the proceedings.
- 1.2 Novelty had been denied by the opposition division in view of example 4 of D1. This decision was contested by the appellant.
 - 1.2.1 Example 4 of D1 discloses a supplement for persons with volume restrictions (infants, persons suffering from illness, cancer or neurophatic diseases) having a caloric density of 150 kcal/100 ml and comprising 8.2 g protein. The composition has a solid content of 31.3 g (sum of the weight amounts given in the table of example 4). The amount of protein is thus 26.5 wt%, on a dry matter basis, which is within the range defined in claim 1. Also, the caloric density of 150 kcal/100 ml, i.e. 1.5 kcal/ml, is within the range defined in claim 1.
 - 1.2.2 The appellant argued in writing that there was no indication that the composition of example 4 of D1

should be added to human milk in a volume ratio as required by claim 1. Therefore, the feature of claim 1 "intended to be added to human milk in a volume-volume ratio of from 1:3 to 1:9" established novelty over example 4 of D1. However, as acknowledged by the appellant during the oral proceedings, claim 1 is a product claim and any intention expressed in this claim is therefore not limiting. This intention thus cannot establish novelty.

- 1.2.3 The appellant further argued that human milk fortifiers were only sold with an appropriate packaging and labelling and that no such packaging and labelling was disclosed in example 4 of D1.

This argument is not convincing. Claim 1 refers to "A liquid human milk fortifier composition" and does not restrict this composition in any way to a packaged composition, let alone one with a packaging and labelling as referred to by the appellant.

- 1.2.4 The appellant's main argument was that the supplement of example 4 of D1 was not suitable as a human milk fortifier, since its addition to human milk resulted in calcium and phosphorous amounts that were lower than those recommended in D17 and in manganese amounts that were higher than recommended in D17a for human milk fortifiers. The appellant in this respect referred to the recommendations in the last paragraph of page 1465S of D17 (123 to 185 mg/100 kcal calcium), the first full paragraph in the right-hand column of page 1467S of D17 (82 to 109 mg/100 kcal phosphorous) and the last full paragraph in the left-hand column of page 1498S of D17a (6.3 to 25 µg/100 kcal manganese).

The board does not find this argument convincing:

Looking at the description of the opposed patent, one finds in paragraph [0057] that the amounts of calcium, phosphorous and manganese in the human milk fortifier ("liquid embodiments of the present invention") are within the ranges of least 50 mg/100 kcal, at least 25 mg/100 kcal and at least 5 µg/100 kcal, respectively. In terms of the opposed patent, suitability as a human milk fortifier thus implies that it must contain calcium, phosphorous and manganese amounts within these ranges. This condition is met in example 4 of D1. More specifically, the amounts in this example are 230 mg/150 kcal calcium, 150 mg/150 kcal phosphorous and 2.0 mg/150 kcal manganese, which are all within these ranges. Hence, the supplement of example 4 of D1 must be suitable as a human milk fortifier.

In this respect, the appellant argued that the specific ranges given in the description of the opposed patent had to be ignored, since the skilled person would immediately see that they did not match with the amounts recommended in D17 and D17a. Those amounts had to be present for a composition to be suitable as a human milk fortifier.

The board does not agree. First of all, these amounts are recommended for preterm infants. Hence, if at all, D17 and D17a define what is suitable to be a human milk fortifier for preterm infants. This is not relevant to claim 1, which covers human milk fortifiers for term infants. Secondly, the fact that there is a specific recommendation of an expert panel on certain calcium, phosphorous and manganese amounts in D17 and D17a does not mean that a generally-accepted definition exists

that inherently limits the compositions that are suitable as human milk fortifiers to those with specific amounts of calcium, phosphorous and manganese.

In a similar line of argument, the appellant argued that a composition was only suitable as a human milk fortifier composition if it did not contain betaine. The appellant referred in this respect to European Commission decision D36 where it was decided that betaine could not be placed on the community market as food or as a food ingredient. Since the supplement of example 4 of D1 contained betaine, it was not suitable as a human milk fortifier.

The board cannot accept this argument. Neither claim 1 on its own nor the description of the opposed patent contains any indication that betaine must be absent. The decision D36 only applies to food or food ingredients, but not necessarily to compositions suitable as human milk fortifiers, which are frequently applied in a clinical environment under the supervision of a medical doctor. Furthermore, it follows from point (3) of D36, that in their initial assessment, i.e. before forwarding it to the other member states, the Finish authorities came to the conclusion that betaine could be placed on the market. As evidenced by D38, the FDA in the US also considered betaine to be safe in selected applications before the priority date of the opposed patent. Hence, there was no common agreement at this date as to whether betaine was an accepted food ingredient, let alone a generally accepted understanding that a composition had to be devoid of betaine to be suitable as a human milk fortifier.

Therefore, the supplement of D1 is to be considered to be suitable as a human milk fortifier. It thus anticipates the feature "human milk fortifier" of claim 1.

- 1.2.5 A further argument of the appellant was that example 4 of D1 did not directly and unambiguously disclose that the supplement was in a liquid form as required by claim 1.

Example 4 of D1 refers to the amount of components contained in the supplement "per 100 ml" and states that the supplement is "packed in 1 liter cartons". A reference to a volume implies that the composition is in liquid form. This is supported by paragraphs [0034] and [0035] of D1, where in the context of liquid compositions, reference is made to milliliters ("The complete food can be liquid, wherein the daily dosage is contained in e.g. 2000 ml;") while in the context of solid compositions, reference is made to gram ("... in dry form, e.g. in sachets of 10 g.").

The appellant argued that the one-liter carton in which the supplement of example 4 of D1 was packed was not a viable container for a liquid human milk fortifier, since it would contain about 200 doses and would thus have to be used for such a long time that the supplement could not be kept sterile. This argument is not convincing since one liter cartons may be used in neonatal intensive care for several infants and thus the one liter amount would be quickly consumed.

- 1.2.6 In view of the above, the feature of claim 1 that the human milk fortifier composition is liquid is also anticipated by example 4 of D1. The subject-matter of claim 1 therefore lacks novelty over this document.

2. Respondents 1 and 2 had also raised objections of added matter and insufficiency of disclosure. During the oral proceedings, the board came to the conclusion that the main request did not contain any added matter and the invention defined therein was sufficiently disclosed. Since the subject-matter of claim 1 of the main request lacks novelty, there is however no need to give a detailed reasoning on these issues.

First auxiliary request

3. Admittance

- 3.1 The respondents requested that the first auxiliary request not be admitted into the proceedings. After the discussion of this issue during the oral proceedings, the board decided to admit the request into the proceedings. In view of the fact that this request is not allowable under Article 123(3) EPC (see point 4 below), the board sees no need to provide a detailed reasoning for this decision.

4. Amendments - Article 123(3) EPC

- 4.1 Claim 1 of the first auxiliary request differs from claim 1 of the main request in that the claim has been reworded as a use claim, namely as a use "as a human milk fortifier for providing nutrition to preterm infants, wherein in use the liquid composition is added to human milk in a volume-volume ratio of from 1:3 to 1:9".

4.2 As set out in T 401/95 (point 4.3.2 of the reasons), there are two different categories of use claims, namely

(a) the use of a physical entity to achieve an effect,
and

(b) the use of a physical entity to produce a product.

A use claim of the latter category (b) is to be considered as a process claim comprising physical steps for producing the product using the physical entity. Pursuant to Article 64(2) EPC, the product insofar as it is directly obtained by that process, is also protected. Hence, the product, when obtained by that process for producing the product, is within the scope of protection conferred by that type of use claim (see decisions G 2/88, point 5.1 of the reasons and T 282/09, point 2.3 of the reasons).

4.3 In the present case, the wording in claim 1 "wherein in use the liquid composition is added to human milk in a volume-volume ratio of from 1:3 to 1:9." represents a process step of adding the liquid human milk fortifier composition to human milk. There can therefore be no doubt that claim 1 of the first auxiliary request belongs to the latter type of use claims (b). It thus, by way of Article 64(2) EPC, covers the fortified human milk directly obtained by the claimed use.

4.3.1 The appellant argued that in view of claim 1 as granted the scope of protection had not been extended. More specifically, claim 1 as granted was a product claim referring to a liquid human milk fortifier composition. Since a product claim also covered any use of the

claimed product, claim 1 as granted also covered the use of the human milk fortifier composition and the product resulting from this use.

The board acknowledges that claim 1 as granted covers a liquid human milk fortifier composition and its use. However, its scope by no means extends to the product obtained by this use, since, even though covering a use, claim 1 itself is not a use claim.

4.3.2 There was also the argument that there was no extension of the scope of protection in view of claim 18 as granted. This claim reads as follows:

"18. Use of from 15% to 45% by weight of protein, on a dry weight basis, and having a caloric density of from 1.25 kcal/ml to 6.0 kcal/ml for the manufacture of a liquid human milk fortifier composition for providing nutrition to preterm infants by addition of said composition to human milk in a volume-volume ratio of from 1:3 to 1:9 and by administration of the fortified human milk to the preterm infant." (emphasis added by the board)

This granted use claim is in the Swiss-type form for a second medical use and requires two steps, namely firstly that the human milk fortifier composition is added to human milk and secondly that the resulting product is administered to a preterm infant. Unlike this granted claim, claim 1 of the first auxiliary request does not require this second step. It thus covers uses wherein this second step does not occur. Its scope is therefore different from that of granted claim 18.

4.3.3 In view of the above, claim 1 of the first auxiliary request does not meet the requirements of Article 123(3) EPC. The first auxiliary request is thus not allowable.

4.4 The respondents also raised an objection of added matter and an objection under Article 53(c) EPC. In view of the fact that the first auxiliary request is not allowable under Article 123(3) EPC, the board did not need to give a decision on these issues.

Second and third auxiliary requests

5. Admittance

5.1 During the oral proceedings, the respondents had requested that the second and third auxiliary requests not be admitted into the proceedings. After the discussion of this issue, the board decided to admit the requests into the proceedings. In view of the fact that these requests contain added matter (see point 6 below), the board sees no need to provide a detailed reasoning for the decision of admitting the requests.

6. Amendments - Added matter

6.1 Claim 1 of the second and third auxiliary requests differs from claim 1 of the main request in that the human milk fortifier composition comprises a water-insoluble calcium component, which represents 50% to 100% of the total calcium in the composition.

6.2 The appellant relied on the paragraph bridging pages 7 and 8 of the application as filed as a basis for the amendment. This paragraph reads as follows:

"The liquid concentrates of the present invention include calcium-fortified embodiments wherein at least 50% by weight of the calcium is water-insoluble or otherwise insoluble within the selected concentrate formula. The insoluble calcium component preferably represents from 50% to 100%, including from 80% to 100%, and also including from 90% to 99%, by weight of the total calcium in the selected concentrate." (emphasis added by the board)

6.3 This passage of the application as filed discloses the calcium amounts as weight percentages, while claim 1 refers to percentages as such, without any specification as to whether they are e.g. molar or weight percentages.

6.4 The appellant argued that the percentage in claim 1 referred to a ratio between insoluble and total calcium, rendering the indication as to whether the percentage was a molar or weight percentage superfluous. Omitting the specification of the percentage as weight percent thus did not add matter.

The board agrees with the appellant that if claim 1 referred to a ratio between insoluble and total calcium, the indication as a weight or molar percentage would indeed be superfluous, because the molar ratio of two calcium atoms is the same as their weight ratio. However, claim 1 does not refer to a percentage formed by the ratio between insoluble and total calcium but a percentage formed by the ratio between an insoluble calcium component to the total calcium in the composition. Since the molar ratio between a calcium component and calcium is not the same as their weight

ratio, it matters whether this ratio and thus percentage is by moles or weight.

- 6.5 Omitting the specification as weight percent therefore adds matter such that the second and third auxiliary requests are not allowable.
- 7. The respondents also raised objections under Article 84 EPC against the second auxiliary request. In view of the fact that this request contains added matter, the board did not need to take a decision as regards the objection under Article 84 EPC.

Fourth auxiliary request

- 8. Admittance
 - 8.1 The respondents requested that the fourth auxiliary request not be admitted into the proceedings.
 - 8.2 This request has been filed at the earliest possible time during the appeal proceedings, namely with the statement of grounds of appeal.

The fourth auxiliary request contains only one independent claim, namely product claim 1. This claim differs from claim 1 of the main request in that the liquid human milk fortifier composition is aseptically packaged. This amendment has been made to render the claimed subject-matter novel over example 4 of D1 and thus to meet the novelty objection made in the opposition division's decision. As set out in point 1.1 above, in its preliminary opinion, the opposition division had only stated that certain aspects as regards novelty over D1 needed to be discussed but did not raise any specific novelty objections. Therefore,

the board does not share the respondents' argument that it would have been the appellant's duty to file the fourth auxiliary request already in reaction to the opposition division's preliminary opinion.

Lastly, the amendment in the fourth auxiliary request can be regarded as a follow-up of what the appellant had argued throughout the opposition proceedings, namely that the supplement of example 4 of D1 was not a human milk fortifier. One aspect of a human milk fortifier is its packaging and labelling, and this is what is now reflected in claim 1 of the fourth auxiliary request.

The board therefore decided to admit the fourth auxiliary request into the proceedings.

9. Amendments - Article 123(2) EPC

9.1 As set out above, claim 1 of the fourth auxiliary request differs from that of the main request in that the composition has been defined to be aseptically packaged.

9.2 Respondent 2 objected to this amendment under Article 123(2) EPC. The respondent argued that aseptic packaging was disclosed in the third full paragraph from the bottom of page 2 of the application as filed only in combination with specific amounts of fat and carbohydrate. Since these specific amounts were missing in claim 1 of the fourth auxiliary request, this passage of the application as filed could not provide a basis.

The board agrees that this passage does not provide a basis for the amendment in claim 1 of the fourth

auxiliary request. In fact, this passage refers to retort packaging rather than aseptic packaging. However, aseptic packaging as required by claim 1 of the fourth auxiliary request is disclosed under item VI on pages 10 and 11 of the application as filed. The aseptic packaging in this passage is not linked to any particular amounts of fats or carbohydrates. Therefore, this passage provides a basis for the feature of aseptic packaging in claim 1 of the fourth auxiliary request. This claim hence meets the requirements of Article 123(2) EPC.

10. Amendments - Articles 100(c), 84 and 123(3) EPC and Rule 80 EPC

10.1 Respondent 1 had argued in writing that claim 1 contravened Article 123(3) EPC. The feature of aseptic packaging was contained in claim 7 as granted, which referred back to claim 2 as granted and thereby required certain amounts of fat and carbohydrate to be present. Since claim 1 of the fourth auxiliary request did not contain these limitations, it violated Article 123(3)EPC.

This argument is not convincing. The broadest claim in the set of granted claims is claim 1 and this does not limit the amounts of fats and carbohydrates. The scope of protection of claim 1 of the fourth auxiliary request is thus not broader than that of claim 1 as granted.

10.2 The respondents did not have any objections under Articles 100(c) and 84 EPC and Rule 80 EPC. The board does not see any reason why the requirements of these Articles and Rule should not be fulfilled.

11. Sufficiency of disclosure

11.1 Respondent 2 argued that the invention defined in claim 1 of the main request was insufficiently disclosed. This argument applies by way of analogy to the fourth auxiliary request. According to the respondent, it was well-known that 1 g protein resulted in a caloric content of 4 kcal/ml. This implied that the 15 to 45 wt% of protein that had to be comprised in the liquid human milk fortifier composition of claim 1 correlated to a caloric density of only 0.6 to 1.8 kcal/ml. Without adding another additional energy-contributing component it was thus not possible to prepare a composition with a caloric density as high as e.g. 6 kcal/ml (the upper limit of the range defined in claim 1 for the caloric density). Nevertheless, claim 1 did not require any such additional energy-contributing components to be present.

This argument is not convincing. If the skilled person adds a certain amount of protein within the range required by claim 1 and obtains a composition with a caloric density that is too low, it is well within its common general knowledge to add a further energy-contributing component, such as a carbohydrate or fat to achieve the required caloric density. It is to be noted in this respect that claim 1 uses "comprising-language" and thus allows for such further components to be present. Therefore, the skilled reader would understand claim 1 such that for protein amounts too low to achieve the required caloric density, the claim implicitly requires the presence of additional energy-contributing components, such as fats or carbohydrates.

11.2 In the written proceedings, respondent 2 had raised an additional objection against claim 8 as granted. Since

this claim is no longer present in the fourth auxiliary request, this objection is rendered moot.

11.3 Equally in the written proceedings, respondent 2 had argued that the invention as defined in claim 12 of the main request was insufficiently disclosed. Claim 12 of the main request is now claim 9 of the fourth auxiliary request. This claim refers to a monosaccharide which is sucrose. Respondent 2 correctly argued that sucrose is not a monosaccharide but a disaccharide. However, this is not an issue of sufficiency of disclosure but, if at all, clarity.

11.4 Consequently, the ground under Article 100(b) EPC does not prejudice the maintenance of the patent in the form of the fourth auxiliary request.

12. Novelty

12.1 Respondent 2 argued that the supplement of example 4 of D1 was a food composition as defined in claim 1 of this document, which was a complete enteral food for a clinical or dietary use. Furthermore, according to paragraph [0001] of D1, the invention disclosed in this document related to universal medicinal food. Such a food was inherently aseptically packaged. Claim 1 of the fourth auxiliary request therefore lacked novelty over example 4 of D1.

The board does not share the respondent's argument. As set out by the appellant during the oral proceedings, there are various ways of packaging food for clinical or dietary use. This was in fact confirmed by respondent 2 during the oral proceedings. Thus even if the supplement of example 4 of D1 is assumed to be packaged, the packaging must not necessarily be an

aseptic one. In this respect, respondent 2 argued that the only place where a packaging was disclosed in D1 was example 3. Since this packaging was an aseptic one, this type of packaging also had to be present in example 4 of D1. However, in view of the fact that example 4 does not disclose any packaging at all and refers to a different supplement than that of example 3, the board does not see any reason why the type of packaging disclosed in example 3 should also be present in example 4.

The subject-matter of claim 1 of the fourth auxiliary request is thus novel over example 4 of D1.

Request for remittal

13. Respondent 1 requested that the board decide on inventive step rather than remitting the case to the opposition division to deal with this issue. It argued that the fourth auxiliary request should have been filed already before the opposition division in order to address the opposition division's novelty objection. The discussion on remittal was now only necessary because the appellant had not filed this request before the opposition division and had thereby prevented it from deciding on inventive step.

The board does not share respondent 1's argument. As set out above in point 1.1, the appellant had only been informed by the opposition division that certain aspects of novelty with regard to D1 would be discussed at the oral proceedings themselves. The appellant was therefore not under a duty to file the present fourth auxiliary request already before the opposition division. The appellant can therefore not be said to have intentionally caused the procedural delay that

arises if the case is remitted to the opposition division.

Furthermore, as set out by the appellant during the oral proceedings, and as follows from its written submission dated 10 October 2017, a decision on inventive step is not just a little step further to be taken after novelty over D1 has been acknowledged. On the contrary, the parties cited numerous documents in this context and it was a matter of dispute which document represented the closest prior art.

Furthermore, any discussion of inventive step would require a discussion of the respondents' request that certain documents that had not been admitted by the opposition division be admitted into the proceedings.

In view of this, and taking into account the appellant's and respondent 2's request that the case be remitted to the opposition division, the board refrained from discussing inventive step of the fourth auxiliary request and decided that the case was to be remitted to the opposition division for further prosecution.

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 for further prosecution on the basis of the fourth auxiliary request as filed by way of letter dated 10 October 2017.

The Registrar:

The Chairman:



M. Cañueto Carbajo

W. Sieber

Decision electronically authenticated