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**Datasheet for the decision
of 12 April 2011**

Case Number: T 1387/08 - 3.3.09

Application Number: 00921862.9

Publication Number: 1168929

IPC: A23C 9/20

Language of the proceedings: EN

Title of invention:
POWDERED HUMAN MILK FORTIFIER

Patentee:
ABBOTT LABORATORIES

Opponent:
N.V. Nutricia

Headword:

-

Relevant legal provisions:
EPC Art. 100(b), 123(2), 84, 54, 56
RPBA Art. 12(1)(c)

Relevant legal provisions (EPC 1973):

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Keyword:

"Late submitted ground under Article 100(b) EPC - non-
admission confirmed"
"Amendments - added subject-matter (no)"
"Clarity (yes)"
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:

T 0381/02, T 0608/07, G 0010/91

Catchword:

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Case Number: T 1387/08 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 12 April 2011

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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
25 April 2008 concerning maintenance of
European patent No. 1168929 in amended form.

Composition of the Board:

Chairman: W. Sieber
Members: M. O. Müller
R. Menapace

Summary of Facts and Submissions

I. This decision is on the appeal by the opponent against the decision of the opposition division that European patent No. 1 168 929 as amended met the requirements of the EPC.

II. The opponent had requested revocation of the patent in its entirety on the grounds that the claimed subject-matter was neither novel nor inventive (Article 100(a) EPC). By letter of 11 January 2008 and during the oral proceedings before the opposition division, the opponent raised additional objections under Articles 100(b) and 123(2) EPC.

III. The documents cited during opposition proceedings included:

D2: WO 92/22219 A1;

D5: US 4,112,123 A;

D10: G. E. Moro et al, "Fortification of Human Milk: Evaluation of a Novel Fortification Scheme and of a New Fortifier", J. Pediatr. Gastroenterol. Nutr., volume 20, number 2, 1995, pages 162-171;

D11: R. G. Jensen et al, "Specialty Lipids for Infant Nutrition. I. Milks and Formulas", J. Pediatr. Gastroenterol. Nutr., volume 15, number 3, 1992, pages 232-245;

D12: M. Lavine et al, "The Effect of Short-Term Refrigeration of Milk and Addition of Breast Milk

Fortifier on the Delivery of Lipids During Tube Feeding", J. Pediatr. Gastroenterol. Nutr., volume 8, number 4, 1989, pages 496-499; and

D13: CRC Handbook of Chemistry and Physics, R. C. Weast et al (ed.), CRC Press, Inc. Boca Raton, Florida, 66th edition, 1985-1986, pages B-81 - B-84.

IV. The opposition division's decision was announced orally on 13 March 2008 and issued in writing on 25 April 2008. The decision was based on a main request filed on 11 January 2008, which contained 14 claims, independent claims 1 and 8 of which read as follows:

"1. A powdered human milk fortifier comprising:

(a) a protein component present in a quantity of from 24 wt/wt% to 55 wt/wt% of the powdered human milk fortifier,

(b) a fat component present in a quantity of from 1 wt/wt% to 30 wt/wt% of the powdered human milk fortifier wherein said fat component further comprises an emulsifier present in a quantity of from 1 wt/wt% to 10 wt/wt% of said fat component, and

(c) a carbohydrate component present in a quantity of from a [sic] 15 wt/wt% to 75 wt/wt% of the powdered human milk fortifier,

and further comprising at least one additional nutrient consisting of calcium, wherein said calcium source is insoluble."

"8. Use of a human milk fortifier powder for the manufacture of a formulation for providing supplemental nutrients to preterm infants by adding the human milk

fortifier to human milk and by administration of the fortified human milk to a premature infant, said human milk fortifier powder comprising:

- (a) a protein component present in a quantity of from 24 wt/wt% to 55 wt/wt% of the powdered human milk fortifier,
- (b) a fat component present in a quantity of from 1 wt/wt% to 30 wt/wt% of the powdered human milk fortifier, wherein said fat component further comprises an emulsifier present in a quantity of from 1 wt/wt% to 10 wt/wt% of said fat component, and
- (c) a carbohydrate component present in a quantity of from 15 wt/wt% to 75 wt/wt% of the powdered human milk fortifier."

Independent claims 4 and 7 referred to a unit dose of powdered human milk fortifier comprising a container and a fortifier as defined in claims 1 and 3, respectively. Independent claim 10 referred to the use of fortified human milk comprising human milk and the fortifier as defined in claim 8 for the manufacture of a formulation for promoting the growth of a premature infant by administration of the fortified human milk to a premature infant. Claims 13 and 14, though formally independent, comprised all the features of claims 8 and 10, respectively.

The opposition division reasoned *inter alia* as follows:

The grounds under Article 100(b) EPC as well as under "Articles 100(c) and 123(2) EPC" were late-filed and not *prima facie* relevant. The opposition division

therefore did not admit these grounds into the proceedings.

The claimed subject-matter was novel over D2 and D5. In view of D2, to arrive at the claimed subject-matter a double selection was necessary, namely of the protein content and of the type of calcium source as required by the claims. Also with regard to D5, a double selection was necessary, namely of a food composition in a dried form and of a protein amount as required by the claims. Even further selections were necessary with regard to those claims which required an insoluble calcium source.

The claimed subject-matter was also inventive. Starting from D12 as the closest prior art, the skilled person would be faced with the problem of avoiding the dilution of human milk while ensuring the high stability thereof. None of the cited documents suggested the use of a powdered human milk fortifier including an emulsifier. As regards the opponent's argument that the problem was not solved over the whole scope of independent claim 8, which did not require the presence of an insoluble calcium source, the opposition division considered the choice of such a calcium source to be a secondary problem. The primary problem was the improvement of the bioavailability of lipids present in human milk supplemented with human milk fortifiers (paragraph [0013] of the patent specification), which was considered to be solved by the addition of the emulsifier as required by independent claim 8.

- V. On 2 July 2008, the appellant (opponent) filed a notice of appeal against the above decision and paid the

prescribed fee on the same day. A statement setting out the grounds of appeal was filed on 4 September 2008 together with

D18: K. Sankaran et al, "A randomized, controlled evaluation of two commercially available human breast milk fortifiers in healthy preterm neonates", JOURNAL OF THE AMERICAN DIETETIC ASSOCIATION, November 1996, volume 96, number 11, pages 1145-1149.

VI. By letter of 17 October 2008, the respondent (proprietor) filed its response and requested that the appeal be dismissed, ie that the patent be maintained on the basis of the main request found allowable by the opposition division.

VII. In the annex to the summons to oral proceedings issued on 11 October 2010, the board communicated its preliminary opinion to the parties and specifically raised the question of whether the amount of emulsifier in the fortifiers disclosed in D10 and D12 was as required by the claims of the main request. The annex contained

D19: S. H. Zeisel et al, "Choline, Phosphatidylcholine and Sphingomyelin in Human and Bovine Milk and Infant Formulas", J. Nutr. 116, 1986, pages 50-58.

VIII. In response thereto, the respondent submitted with its letter of 11 February 2011 four claim sets as first to fourth auxiliary requests.

IX. On 12 April 2011, oral proceedings were held before the board. No new requests were filed by the parties.

X. The appellant's arguments can be summarised as follows:

The claimed invention lacked sufficiency of disclosure as it was impossible to reproduce the invention if the highest level of carbohydrates was selected, namely 75 wt%. Then the total amount of nutrients present in the composition would unavoidably add up to more than 100%. Furthermore it was not sufficiently disclosed what insoluble calcium was. These objections were not filed late and were thus admissible as they had been triggered by the amendments filed by the proprietor in reply to the notice of opposition.

The feature of at least one additional nutrient consisting of calcium in claim 1 of the main request did not meet the requirements of Article 123(2) EPC as, contrary to claim 1 of the main request, original claim 3 did not refer to one or more nutrients consisting of calcium.

The claimed subject-matter lacked novelty with regard to D2, since no double selection was necessary as in view of the undefined nature of the insoluble calcium source, any selection of such a source was without meaning. Also with regard to D5, no true selection was necessary as the only possible calcium source disclosed in D5 was calcium hydroxide, which was an insoluble calcium source. Hence, the claimed subject-matter further lacked novelty in view of D5.

The claimed subject-matter furthermore lacked inventive step in view of D12 as the closest prior art. Though no solid proof was possible, the emulsifier amount appeared to be as required by the claims of the main request, as derivable from inter alia the phospholipid content of the milk in D11 and the fat content of the milk in D12. The claimed subject-matter differed from D12 only in that the human milk fortifier was in a powdered form, which solved the problem of minimum dilution of human milk. The solution to this problem was however already known from eg D18. The further problems addressed in the opposed patent could not contribute to inventive step. More particularly, high emulsion stability was already achieved by the fortifier of D12, as it already contained an emulsifier and the problem of enhancing the growth of preterm infants was not proven to be solved by fortifiers that contained a soluble instead of an insoluble calcium source.

Inventive step also had to be denied in view of D10 as the closest prior art. The claimed subject-matter differed from this document in terms of the protein and carbohydrate contents. D10 itself did however already disclose a fortifier with reduced protein content in the form of an "EBMF" fortifier and hence the claimed subject-matter was obvious.

Finally, the subject-matter of claim 8 was not inventive as it covered fortifiers containing a soluble calcium source and hence did not solve the problem of protein precipitation.

XI. The respondent's position can be summarised as follows:

The objections raised under Article 100(b) EPC should be rejected as not admissible, because they related to subject-matter already present in granted claims, and had not been duly raised as a ground in the notice of opposition. Moreover, the objection that the sum of the percentages in claim 1 exceeded 100% in fact related to clarity only and did not constitute any difficulty for the skilled person in putting the claimed invention into practice. Also, the respondent's objection based on the insoluble calcium source was without merit as firstly, it constituted a clarity objection only and as secondly, the opposed patent and the CRC Handbook D13 cited therein provided sufficient guidance as to how to differentiate between insoluble and soluble calcium sources.

The objection under Article 123(2) EPC should not be admitted as it was filed late. Moreover, the requirements of Article 123(2) EPC were met. The inclusion in claim 1 of at least one additional nutrient consisting of calcium wherein said calcium source was insoluble was based on claims 3 and 4 as filed in conjunction with page 16, lines 19-20 and table 2. In this context, it was clear to the skilled person that the term "calcium" in claim 1 in fact referred to a calcium source.

Novelty in view of D2 and D5 had to be acknowledged. D2 did not disclose any use for preterm infants or any insoluble calcium source and further differed from the claimed subject-matter in terms of the protein and emulsifier content. D5 did not disclose any use for

preterm infants and furthermore, a multiple selection was necessary, namely of a powder composition and of a protein and emulsifier content as required by the claims. With regard to the claims requiring an insoluble calcium source, even further selections were necessary.

Inventive step in view of D12 as the closest prior art had to be acknowledged. The claimed product differed from the product Similac Natural Care disclosed in D12 not only in that it was a powdered composition but also in terms of the emulsifier and protein content. The opposed patent proved that by way of this difference, human milk was stabilised and the preterm infants' growth was improved, while none of the prior art documents provided any indication to this effect.

The claimed subject-matter was also inventive in view of D10 as the closest prior art. The two fortifiers disclosed in this document differed from the claimed fortifiers in terms of protein content. Furthermore, no emulsifier was present in the fortifiers of D10 as these had been prepared by defatting human milk. Neither D10 nor any of the further prior art documents provided any motivation to add an emulsifier or to choose a protein content as required by the claims of the main request.

Finally, the fact that claim 8 did not solve the further problem of protein precipitation did not affect its validity in terms of inventive step.

- XII. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked in its entirety.
- XIII. The respondent (patent proprietor) requested that the appeal be dismissed (main request) or that the decision under appeal be set aside and the patent be maintained on the basis of one of the first to fourth auxiliary requests filed with letter of 11 February 2011.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. *Sufficiency of disclosure - Article 100(b) EPC*
- 2.1 During the first instance opposition proceedings and after filing the notice of opposition, the appellant argued that the invention as defined in claim 1 was not sufficiently disclosed. The objections raised in this context were not admitted into the proceedings by the opposition division as they constituted a new ground of opposition under Article 100(b) EPC that was late-filed and not *prima facie* relevant. This aspect of the decision was challenged by the appellant.
- 2.2 The contested part of claim 1 of the main request refers to a powdered human milk fortifier comprising
- a protein component in a quantity of 24 wt/wt% to 55 wt/wt% of the powdered human milk fortifier,

- a fat component in a quantity of 1 wt/wt% to 30 wt/wt% of the powdered human milk fortifier,
- a carbohydrate component in a quantity of 15 wt/wt% to 75 wt/wt% of the powdered human milk fortifier,
- and "further comprising at least one additional nutrient consisting of calcium, wherein said calcium source is insoluble".

2.3 The appellant's first argument with regard to insufficiency of disclosure was that a fortifier of claim 1 containing 75 wt% carbohydrates could not be reproduced, as such a fortifier would comprise more than 100 wt% of ingredients (75 wt% carbohydrates + the minimum level of 24 wt% protein + the minimum level of 1 wt% fat + insoluble calcium source).

2.3.1 This alleged deficiency was already present in granted claim 2, which depends on claim 1 and relates to the presence of additional nutrients such as calcium. Hence, the appellant's objection could have been raised in the notice of opposition. Therefore, as stated in the opposition division's decision, this objection was indeed late-filed.

2.3.2 This late-filed objection in fact relates to the question of where the boundaries of claim 1 lie with regard to the upper limit of the carbohydrate content. More particularly, to avoid the components of claim 1 adding up to more than 100 wt%, the skilled person has two possibilities to interpret the claim: (i) the upper limit for the carbohydrate amount is in fact below 75 wt%, based on all the components of the fortifier, or, (ii) the upper limit for the amount of carbohydrate

is not based on all the components of the fortifier but only on the macronutrients (carbohydrates, proteins and fats) contained therein. The upper limit of the carbohydrate amount is thus ambiguous.

Although the board accepts that, depending on the circumstances, an ambiguity (or lack of clarity) may lead to an insufficiency objection, it should be borne in mind that, as pointed out in T 608/07 of 27 April 2009 (point 2.5.2 of the reasons; not published in OJ EPO), for an insufficiency objection, it is not enough to show that an ambiguity exists. It would normally be necessary to prove that the ambiguity deprives the skilled person of the promise of the invention by not enabling him to obtain the desired effects.

In the present case, however, the ambiguity exists only at the very edge of the scope of claim 1 (the upper limit of the carbohydrate amount), and does not permeate the whole claim. Therefore, the appellant's objection in effect merely relates to the determination of the exact scope of the claim, which is a matter of Article 84 EPC rather than Article 83 EPC. Consequently, in line with the opposition division's decision, the appellant's first objection cannot form a *prima facie* relevant ground of opposition.

- 2.4 The appellant's second argument with regard to insufficiency of disclosure was that it is not clear what is meant by "insoluble calcium" in claim 1.
- 2.4.1 Again, this deficiency was already present in granted claim 3. Hence, this objection could have been raised in the notice of opposition. Therefore, as set out in

the opposition division's decision, this objection was late-filed as well.

2.4.2 Moreover, in the same way as with regard to the upper limit of the carbohydrate amount, this objection relates to the question of where the boundaries of claim 1 lie, this time with regard to the solubility of the calcium source. No evidence has been provided that this alleged ambiguity prevents the skilled person from obtaining the effects aimed at by the claimed invention. Thus, again, the appellant's objection relates to clarity rather than sufficiency of disclosure and for this reason alone the appellant's second objection cannot form a *prima facie* relevant ground under Article 100(b) EPC.

2.4.3 Moreover, with regard to the insoluble calcium source, the opposed patent defines the term "insoluble calcium" in paragraph [0025] as follows:

"The term "insoluble calcium" refers to food grade calcium sources listed in the CRC Handbook of Chemistry and Physics as sparingly soluble in water."

From this CRC Handbook (D13), it can be deduced that the solubility of those calcium salts that are described in paragraph [0056] of the opposed patent as insoluble (calcium carbonate, calcium citrate, calcium phosphate dibasic and calcium phosphate tribasic) differs from the solubility of typical soluble calcium salts by several orders of magnitude. In particular, the solubility (expressed in grams per 100 cc) of calcium carbonate is between 0.0014 and 0.0019 (cold and hot water), that of calcium citrate between 0.085

and 0.096, that of calcium dibasic phosphate between 0.0316 and 0.075 and that of calcium tribasic phosphate is 0.002, while eg soluble calcium acetate has a solubility between 29.7 and 34.7. The opposed patent thus provides sufficient guidance to make it possible to differentiate between insoluble and soluble calcium sources. Also for this reason, the appellant's objection with regard to the insoluble calcium source does not constitute a *prima facie* relevant ground of opposition under Article 100(b) EPC.

2.5 As regards the exact scope of claim 1 with respect to "75% wt/wt carbohydrate", this feature would have to be interpreted broadly if it became decisive to be able to distinguish the claimed subject-matter from the relevant prior art. Since, however, this is not an issue in the present case, there is no need to elaborate further on the interpretation of this feature in claim 1.

2.6 In summary, the board therefore does not see any reason to overturn the opposition division's decision not to admit the new ground under Article 100(b) EPC.

3. *Amendments - Article 123(2) EPC*

3.1 Claim 1 of the main request corresponds to claim 1 as granted where the wording "and further comprising at least one additional nutrient consisting of calcium, wherein said calcium source is insoluble" has been introduced. The appellant argued that this amendment to claim 1 of the main request does not meet the requirements of Article 123(2) EPC.

3.2 Before this issue is decided, the meaning of the wording "and further comprising at least one additional nutrient consisting of calcium, wherein said calcium source is insoluble" in claim 1 must be determined.

Because this wording refers to "calcium" followed by a reference to "said calcium source" without proper antecedent, it is at first sight not clear whether the additional nutrient consists of calcium or a calcium source. However, the board accepts that, as set out by the respondent, it is evident to the skilled reader that a nutrient must be a biologically available calcium source and cannot be "calcium", ie calcium metal, as calcium metal is toxic and thus cannot be used in a nutrient, let alone one for preterm infants. This is supported by the description of the opposed patent (see eg paragraphs [0025] and [0111]), where the terms "calcium" and "calcium source" are used synonymously. So, in fact, the above wording in claim 1 has to be read as "at least one additional nutrient consisting of a calcium source, wherein said calcium source is insoluble".

3.3 The added wording is derived from claims 3 and 4 as filed, which read as follows:

"3. The powdered human milk fortifier according to claim 1 further **comprises at least one additional nutrient selected from the group consisting of** Vitamin A, Vitamin B₁ Vitamin B₂, Vitamin B₆, Vitamin B₁₂, Vitamin C, Vitamin D, Vitamin E, Vitamin K, Biotin, Folic Acid, Pantothenic Acid, Niacin, m- inositol, **calcium**, phosphorus, magnesium, zinc,

manganese, copper, sodium, potassium, chloride, iron, selenium, chromium, molybdenum, carnitine and taurine" (emphasis added by the board).

"4. The powdered human milk fortifier according to claim 3 **wherein said calcium source is insoluble**" (emphasis added by the board).

3.3.1 The appellant argued that claim 3 as filed refers to one or more different types of nutrients, such as calcium and a second nutrient different from calcium. This, in the appellant's view, is different from amended claim 1 of the main request, which refers to one or more nutrients consisting of calcium, eg including two different calcium sources.

On the basis of original claim 3 alone, there is indeed an ambiguity as to whether the additional nutrients have to be one or more nutrients of a different type and/or of the same type, ie one or more calcium sources. However, the second option is explicitly disclosed twice in the application as filed, namely on page 16, lines 19-20, and in table 2, where the combination calcium phosphate tribasic / calcium citrate and calcium carbonate / tricalcium phosphate is described. Hence, original claim 3 in conjunction with the description of the application as filed clearly and unambiguously discloses this second option, ie that the additional nutrients are one or more calcium sources. This feature in claim 1 of the main request thus meets the requirements of Article 123(2) EPC.

3.4 The appellant did not raise any further objections and the board is satisfied that the remaining claims of the main request are based on the application as filed and thus that the requirements of Article 123(2) EPC are met.

3.5 The respondent contended during oral proceedings before the board that the objection under Article 123(2) EPC to this amendment should not be admitted as it had been raised late by the appellant, namely during the oral proceedings before the opposition division. In the board's view, this is not correct. In case of amendments to the claims of a patent in the course of opposition or appeal proceedings, such amendments are to be fully examined ex officio as to their compliance with the requirements of the EPC, eg with regard to the provisions of Article 123(2) EPC (G 10/91, point 19 of the reasons). Furthermore a corresponding objection was already made in the annex to the summons issued by the board more than half a year prior to oral proceedings (Article 12(1)(c) RPBA). The respondent's argument concerning the admissibility of the objection under Article 123(2) EPC thus cannot succeed.

4. *Amendments - Article 84 EPC*

The potential deficiencies in claim 1 of the main request, namely that the amounts of ingredients could exceed 100 wt%, that the term "said calcium source" has no proper antecedent and that the term "insoluble calcium source" is ambiguous, were already present in granted claims 1-3. Any lack of clarity arising from a mere combination of granted claims generally cannot be attacked under Article 84 EPC in opposition proceedings

(eg T 381/02 of 26 August 2004, point 2 of the reasons; not published in OJ EPO). No further objections under Article 84 EPC were raised by the appellant and the board is satisfied that no lack of clarity arises out of the amendments.

5. *Novelty*

The appellant has attacked the novelty of the claimed subject-matter on the basis of D2 and D5.

5.1 Novelty in view of D2

5.1.1 D2 refers to nutritionally balanced water-soluble powdered food compositions for ingestion along the digestive tract of a patient (page 1, lines 10-14). The composition comprises 6-28 wt% of water-soluble protein alpha-amino acids, 4-22 wt% of triglycerides, ie a fat component, 45-78 wt% of carbohydrates and 0.1-10 wt% of an emulsifier (page 3, lines 8-18 and claim 1).

5.1.2 The broadest range of protein amount covered by the independent claims of the main request is 24-55 wt% of the human milk fortifier and the broadest range for the emulsifier amount is 1-10 wt% of the fat component. To arrive at the subject-matter of the independent claims of the main request, the following selections have to be made from the disclosure of D2:

- (1) a protein content as required by the claims of the main request out of the range disclosed in D2, ie 6-28 wt%, and

(2) an emulsifier amount as cited in the claims of the main request.

With regard to the second point, it is noted that the emulsifier amount in the claims of the main request is based on the fat amount, while the values for the emulsifier amount in D2 are based on the food composition. If the emulsifier amount in D2 is recalculated relative to the fat content, it ranges from 0.025-45 wt% of the fat component, compared to 1-10 wt% in the claims of the main request. Hence, the emulsifier amount required by the claims of the main request represents a selection out of the range derivable from D2.

No pointer to the above two-fold selection is present in D2. In particular, the protein content in all the examples is below the lower limit of the range required by the claims of the main request. For this reason alone, the claimed subject-matter is novel over D2.

5.1.3 Moreover, the independent product claims (claims 1, 4 and 7) of the main request require the presence of an additional nutrient consisting of an insoluble calcium source.

D2 does not disclose the presence of an insoluble calcium source. Calcium panthothenate, used in example 1 of D2, and calcium lactate (example 3) are both soluble calcium sources. Calcium phosphate, also used in example 1, does not constitute an unambiguous disclosure of an insoluble calcium source as this term equally covers a soluble calcium source, namely calcium phosphate monobasic.

5.1.4 The remaining independent claims of the main request, which are all in the form of second medical use claims (claims 8, 10, 13 and 14) require a specific therapeutic use.

The food composition of D2 is, however, intended to be reconstituted as a drink (page 2, lines 21-23), and no use for preterm infants is disclosed, let alone a use in which the specific therapeutic effects required by claims 8, 10, 13 and 14 are achieved.

5.1.5 In view of the above, the subject-matter of all the claims has to be acknowledged as novel in view of D2.

5.2 Novelty in view of D5

5.2.1 D5 discloses a nutritionally balanced powdered or liquid food composition for oral ingestion by patients having an abnormal catabolic state, such as burn patients (column 1, lines 5-8 and 26-28, column 7, lines 43-44 and lines 52-54). The composition comprises a protein, medium chain triglycerides, ie a fat component, carbohydrates and an emulsifier (column 3, lines 45-53 and claim 1).

D5 discloses various ranges for the protein amounts. However, only the broadest ranges disclosed in D5, namely 3.5-27 wt% (column 3, line 48 of D5) and 8-27 wt% (claim 1 of D5) overlap slightly with the broadest range required by the claims of the main request (24-55 wt%).

The amount of emulsifier is 0.1-5 wt% of the food composition (column 7, lines 5-9 and claim 1 of D5). With an amount of fat component of 5-20 wt% (column 6, lines 50-52 and claim 1 of D5), this implies that the emulsifier amount in D5 can theoretically range from 0.5-100 wt% of the fat component, compared to 1-10 wt% according to the claims of the main request.

Consequently, to arrive at a composition as required by the independent claims of the main request, at least a triple selection is necessary, namely the use of a powdered composition, a protein amount and an emulsifier amount as required by the claims of the main request. For this reason alone, the claimed subject-matter is novel in view of D5.

5.2.2 With regard to the subject-matter of independent product claims 1, 4 and 7 of the main request, even a further selection is necessary. In particular, calcium hydroxide must be selected out of the edible bases which may be present in the compositions of D5 (column 7, line 68 through column 8, line 2). This additional selection even further delimits the subject-matter of independent claims 1, 4 and 7 from the disclosure of D5.

5.2.3 With regard to the subject-matter of the remaining independent claims (second medical use claims 8, 10, 13 and 14), a further distinguishing feature is the specific therapeutic effect required by these claims, which is not disclosed in D5. More particularly, as has been set out above, D5 discloses the feeding of patients having an abnormal catabolic state, such as burn patients, but does not disclose any use in preterm

infants, let alone any specific therapeutic effects on these infants by means of this use.

5.2.4 Novelty in view of D5 must thus be acknowledged.

6. *Inventive step*

6.1 The opposed patent relates to a powdered human milk fortifier which is used to provide nutrition to preterm infants by adding the fortifier to human milk and administering the fortified human milk to a premature infant (paragraph [0001]).

6.2 The closest prior art for assessing inventive step is normally the prior art document disclosing subject-matter conceived for the same purpose and aiming at the same objective as the claimed invention.

6.2.1 As set out above, D2 is directed to food compositions that can be reconstituted to drinks for patients, and D5 is concerned with food compositions for oral ingestion by patients having an abnormal catabolic state, such as burn patients. Neither of these documents addresses the fortification of human milk or the feeding of preterm infants. Hence, these documents do not qualify as the closest prior art.

6.2.2 Contrary to D2 and D5, D10 and D12 are directed to fortified human milk to be fed to very-low-birth-weight infants (abstracts of D10 and D12). Each of D10 and D12 can thus be considered to represent the closest prior art. This was acknowledged by both parties.

6.3 D12 as closest prior art

- 6.3.1 D12 investigates the effect of the addition of a human milk fortifier on the delivery of lipids during tube feeding (title). The commercial product "Similac Natural Care" is used as a human milk fortifier (first full paragraph of the left-hand column of page 497).

As is apparent from table 4 on page 1148 of D18 and table 1 of the opposed patent, Similac Natural Care is a liquid composition that contains 14 wt% protein, 57 wt% carbohydrate and 29 wt% fat. The protein amount in D12 is thus below the lower limit of the range required by the claims of the main request.

Furthermore, the emulsifier amount is not disclosed in D12. In this context, the appellant referred to the second full paragraph of the right-hand column of page 497 of D12, where it is reported that freshly collected milk contains 1.03 mg/100 ml lipid phosphorus while freshly collected milk fortified with Similac Natural Care contains 1.11 mg/100 ml lipid phosphorus. The board agrees with the appellant that this implies that Similac Natural Care contains lipid phosphorus, which is present in phospholipids, which in turn represent emulsifiers. However, as acknowledged by the appellant during the oral proceedings, no solid proof can be derived from these lipid phosphorous values that the emulsifier amount is as required by the claims of the main request. In fact, the calculation presented by the appellant in this context in the statement of grounds of appeal does not constitute any such proof. The calculation contains, as a starting point, the correlation of the phospholipid content of the milk

disclosed in D11 with the fat content of the milk disclosed in D12. This correlation is based on the assumption that the phospholipid content of the milk disclosed in D11 and D12 respectively is the same. However, this assumption appears to be incorrect. More particularly, no indication is present in D11 and D12 that the respective milk of each document has been collected after the same lactation time. In fact, milk collected after different lactation times does not necessarily have the same phospholipid content. In this context, reference can be made to D19, which clearly shows that the amount of the phospholipids phosphatidylcholine and sphingomyelin changes by more than 100% within a few hours of lactation time (left-hand column of page 55, tables 3 and 4 of D19). Thus there is no proof that the emulsifier amount in D12 is as required by the claims of the main request and this implies that this amount constitutes a further distinguishing feature.

6.3.2 The problem addressed by the opposed patent is the provision of human milk fortifiers that improve the growth of preterm infants (paragraph [0016]).

As a solution to this problem, the opposed patent proposes a human milk fortifier and its use according to the claims of the main request which is characterised in that it contains specific amounts of protein and emulsifier. As has been set out above, none of these features is disclosed in D12.

In experiment I of the opposed patent a study is described which compares the emulsion stability of human milk with human milk containing a fortifier

according to the claims. It was found that due to the presence of the small amount of emulsifier in the fortifier, half as much fat was lost as in the non-fortified human milk. This resulted in more fat being delivered to the preterm infant, thereby improving its growth (table 3 and paragraphs [0081] and [0082]).

The same effect with respect to the growth of preterm infants is reported in experiment III of the opposed patent for the protein content. In the study described in this experiment, one group of preterm infants received milk supplemented with a commercially available powdered human milk fortifier (Enfamil[®] human milk fortifier, denoted "control"), and a second group of preterm infants received milk fortified with the fortifier according to the claims of the main request (denoted "experimental"). While the mean total energy intakes during the study were not different between the two groups, there was a difference in the protein amounts. More particularly, infants fed with the control received 3.1 ± 0.1 g protein/kg/day while infants fed with the experimental fortifier according to the claims of the main request received a higher protein amount of 3.5 ± 0.1 g protein/kg/day (paragraph [0106]). It was found that there were consistent differences among infants in the two fortifier groups with respect to growth, with the control group always growing more slowly (paragraph [0107]).

The appellant argued that the above-discussed effect of the protein amount was not proven to be present for fortifiers that contained soluble calcium sources and that therefore suffered from protein precipitation. However, for a given fortifier containing a soluble

calcium source, the higher the amount of protein initially contained in the fortifier, the higher the amount of protein that will remain in the fortifier after precipitation, and the higher the preterm infant's growth. There is thus no reason to believe and in particular no evidence to prove that the problem of improving growth is not solved by fortifiers that contain a soluble calcium source.

In view of the above, the problem addressed in the opposed patent of improving the growth of preterm infants indeed constitutes the objective technical problem, which is credibly solved.

6.3.3 D12 does not disclose any amounts of proteins or emulsifiers (phospholipids). In particular, no indication is contained in D12 that a specific amount of protein and/or the presence of a specific amount of emulsifier would improve the growth of preterm infants. Such an indication is not present either in any of the additional prior art documents. This is not disputed by the appellant. On the contrary, D10 (first paragraph of the left-hand column of page 163) even teaches the skilled person that fortifiers with enhanced protein contents will not always match the needs of preterm infants. In fact, D10 (paragraph bridging pages 166 and 167) even finds improved growth for an experimental bovine milk fortifier ("EBMF") which has a protein content below the lower limit of the range required by the claims of the main request (protein content of 22.6 wt%, table 2 of D10), compared to the human milk protein concentrate ("HMP") of D10, which has a protein content above the upper limit of the range required by the claims of the main request (protein content of

60 wt%, table 2 of D10). So, if anything, the skilled person trying to improve the growth of preterm infants would be taught by D10 to reduce the protein content below the lower limit of the range required by the claims of the main request.

The claimed subject-matter must therefore be acknowledged as inventive in view of D12, taken alone or in combination with the further prior art documents.

6.4 No other conclusion with regard to inventive step can be reached when starting from D10 as the closest prior art.

6.4.1 D10 is concerned with the fortification of human milk to be administered to preterm infants ("very-low-birth-weight infants" or "VLBW infants") and evaluates the effect of a novel fortification scheme and a new fortifier. In particular, a new fortification regimen is tested in which the amount of fortifier is adjusted on the basis of the serum urea nitrogen level of the preterm infants. In one experiment, a human milk protein concentrate is used as a fortifier in fixed amounts (experiment "HMP"). In two further experiments, an experimental bovine milk fortifier ("EBMF") is applied once in fixed amounts (experiment "FIX") and once in amounts that are adjusted depending on the serum urea nitrogen level of the preterm infant (experiment "ADJ").

The human milk protein concentrate HMP has a protein content of 60 wt% or even 65-70 wt%, a lactose, ie carbohydrate, content of 11 or 12 wt% and a fat content of 9 wt% (table 2 and preceding paragraph on page 164).

The experimental bovine milk fortifier EBMF" contains 23 wt% protein, 49 wt% carbohydrate and 10 wt% fat (table 2).

The protein levels of the two fortifiers in D10 are thus outside the range required by the claims of the main request, namely above the upper limit of the HMP and below the lower limit of the EBMF.

Moreover, the presence of an emulsifier or its amount in the HMP or the EBMF is not disclosed in D10. The appellant argued in this context that it could be derived from table 4 of D1 that human milk contained 1.3 wt% phospholipids as an emulsifier and that hence, the HMP of D10 inherently contained an emulsifier in an amount as required by the claims of the main request. However, the HMP in D10 is obtained after defatting human milk (line 19 of the right-hand column on page 164). Such a defatting process can be assumed also to remove phospholipids from the human milk. This was not disputed by the appellant. It is thus not clear whether the HMP of D10 contains an emulsifier, and if so, in what amount.

Hence, the claimed subject-matter differs from the disclosure of D10 at least in terms of the amount of protein and in that a specific amount of emulsifier is additionally present.

6.4.2 As already set out above (point 6.3.2), the objective technical problem solved by the combination of a specific protein amount and the additional presence of a specific amount of emulsifier as required by the

claims of the main request is the improvement of growth of preterm infants.

- 6.4.3 As has equally already been set out above (point 6.3.3), D10 teaches the skilled person aiming at improving the growth of preterm infants to reduce the protein content below the lower limit of the range required by the claims of the main request. Moreover, no indication is contained in D10 to add an emulsifier to the fortifier in order to improve growth. Finally, none of the further prior documents contains any teaching that improved growth could be achieved by protein amounts in combination with an emulsifier as required by the claims of the main request.

The claimed subject-matter must thus be acknowledged as inventive as well in view of D10, taken alone or in combination with the further prior art documents.

- 6.5 In summary, the claimed subject-matter is based on an inventive step.
- 6.6 The appellant additionally argued that the opposed patent addressed the problem of avoiding protein precipitation and that this problem was not solved by the subject-matter of eg claim 8, because this claim covered fortifiers containing a soluble calcium source. In the appellant's view this implied that the claimed subject-matter lacked an inventive step.

The problem of avoiding protein precipitation is however not the objective technical problem (see point 6.3.2 above). Within the framework of the problem and solution approach, any objection that a problem

other than the objective technical problem is not solved has no bearing on inventive step. Consequently, the appellant's allegation has no relevance for the present decision.

Auxiliary requests

7. In view of the above, the auxiliary requests need not be discussed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

G. Röhn

W. Sieber