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Title of invention:
HUMAN MILK FORTIFIER WITH HIGH PROTEIN AND LONG CHAIN POLY UNSATURATED FATTY ACIDS FOR IMPROVING BODY ADIPOSE TISSUE DISTRIBUTION

Patent Proprietor:
N.V. Nutricia

Opponent:
Société des Produits Nestlé S.A.

Relevant legal provisions:
EPC Art. 53(c), 54, 54(5), 56
RPBA 2020 Art. 12(4), 12(6), 13(2)

Keyword:
Novelty - novelty of use - second (or further) medical use
Inventive step

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Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 0884/23 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 30 July 2024

Appellant: (Opponent)	Société des Produits Nestlé S.A. Avenue Nestlé 55 1800 Vevey (CH)
Representative:	Rupp, Christian Mitscherlich PartmbB Patent- und Rechtsanwälte Karlstraße 7 80333 München (DE)
Respondent: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 2 March 2023 concerning maintenance of the European Patent No. 2432333 in amended form.**

Composition of the Board:

Chairman	M. O. Müller
Members:	P. O'Sullivan
	M. Blasi

Summary of Facts and Submissions

I. The appeal of the opponent (hereinafter appellant) lies from the decision of the opposition division according to which European patent 2 432 333 in amended form (main request) was found to meet the requirements of the EPC.

II. The following documents *inter alia* were submitted by the parties in opposition proceedings:

D2 : US 2008/0286416 A1
D5 : WO 2008/054192 A1
D10: WO 2007/039596 A1

III. A communication pursuant to Article 15(1) RPBA was sent in preparation for the oral proceedings. Therein the board *inter alia* expressed the preliminary view that claim 2 of the main request met the requirements of Article 123(2) EPC and that the invention defined in claims 1 and 2 of the main request was sufficiently disclosed.

IV. Requests relevant to the present decision

The appellant requested that the contested decision be set aside and that the patent be revoked in its entirety. The appellant also requested that *inter alia* auxiliary request 32 not be admitted into the proceedings.

The respondent requested dismissal of the appeal, implying maintenance of the patent as amended according to the main request found allowable by the opposition division, or alternatively, that the patent be

maintained in amended form on the basis of one of the sets of claims of auxiliary requests 1 to 55 submitted with the reply to the grounds of appeal.

The respondent also requested that the appellant's objection under Article 56 EPC against claim 1 of auxiliary request 32 starting from D2 in combination with D5 not be admitted into the proceedings.

V. For the text of the relevant claims, reference is made to the reasons for the decision, below.

VI. For the submissions of the parties relevant to the present decision, reference is made to the reasons for the decision set out below.

Reasons for the Decision

Main request

The main request was the version of the patent as found allowable by the opposition division.

1. Novelty - Article 54 EPC

1.1 Claim 1 of the main request reads as follows:

"A human milk fortifier comprising

a) at least 20 % protein is present based on total calories,
b) at least 5 % fat is present based on total calories wherein the fat comprises from 0.15 wt.% to 4 wt.% docosahexaenoic acid based on total fatty acids,

for use in prevention of visceral adiposity and/or decreasing the ratio visceral adipose tissue to subcutaneous adipose tissue in a preterm infant."

1.2 In the following, in line with the parties' submissions and the differing terminology used in the prior art, "adipose tissue" and "fat" are to be considered synonyms of each other.

1.3 Claim 1 is formulated as a medical use claim pursuant to Article 54(5) EPC. According to this provision, *inter alia*, the patentability of any composition comprised in the state of the art for any specific use in a method for treatment of the human or animal body by therapy set out in Article 53(c) EPC is not excluded under Article 54(2) or (3) EPC, provided that such use is not comprised in the state of the art.

1.4 The appellant argued that the second alternative use stipulated in the claim, namely "for use in decreasing the ratio visceral adipose tissue to subcutaneous adipose tissue in a preterm infant", was not to be considered as a medical use. Consequently, the functional feature related to said use was not limiting in the sense of Article 54(5) EPC, and any human milk fortifier (hereinafter HMF) comprising the structural features of claim 1, which was "suitable" for the claimed purpose of decreasing the ratio of visceral adipose tissue to subcutaneous adipose tissue in a preterm infant, would be prejudicial to novelty. D2 disclosed such a composition suitable for said purpose.

1.5 The board agrees. The exception set out in Article 54(5) EPC applies solely to compositions used in methods excluded under Article 53(c) EPC. Hence, to determine whether claim 1 is limited by the feature

"for use in decreasing the ratio visceral adipose tissue to subcutaneous adipose tissue in a preterm infant" (hereinafter "ratio decreasing feature") in the sense of Article 54(5) EPC, it was relevant whether this feature constituted a method for treatment by therapy excluded from patentability under Article 53(c) EPC.

1.6 The respondent argued that the ratio decreasing feature led to the prevention of *inter alia* obesity later in life, and was thus an appropriate marker for the prevention of future disease, i.e. a prophylactic therapy.

1.7 It was not disputed by the respondent that prophylactic therapies as such may be considered as methods of treatment by therapy referred to in Article 53(c) EPC. As argued by the appellant however, there is no evidence that the ratio decreasing feature has any prophylactic effect.

1.8 Specifically, as submitted by the appellant, "decreasing the ratio visceral adipose tissue to subcutaneous adipose tissue in a preterm infant" is a relative expression which requires a decrease in said ratio relative to something else. The value relative to which this decrease is to be assessed is however not specified in claim 1.

1.9 The respondent argued at oral proceedings that said decrease was to be assessed relative to preterm infants receiving a "standard HMF". Such a decrease in the ratio was demonstrated in the examples of the patent in which a HMF according to the invention ("Trial HMF") was compared with a HMF of the prior art ("Standard HMF"; patent, page 7, table 1). In the tests performed,

preterm infants treated with trial HMF and standard HMF both had the same amount of visceral adipose tissue (final row, "Internal abdominal adipose tissue mass (kg))", while the infants treated with trial HMF had a greater mass of subcutaneous adipose tissue (table 2, penultimate row). Hence the ratio of visceral adipose tissue to subcutaneous adipose tissue decreased from 0.030 (0.019/0.616) in the infants treated with the standard HMF to 0.029 (0.019/0.650) in the infants treated with the trial HMF.

1.10 However, even accepting these data, it is not credible that the ratio decreasing feature has any prophylactic therapeutic effect. In particular, although a decrease in the ratio for the trial HMF compared to the standard HMF was recorded as set out above, as stated by the appellant, both ratios were below the ratio recorded for term-born infants (patent, table 2, right hand column, last two entries), namely 0.043 (0.028/0.650).

1.11 More specifically, as noted by the appellant, term-born infants are, according to the patent (paragraph [0038]), considered the "golden standard" i.e. term-born infants are best prepared against future health risks. Hence, the ratio of visceral adipose tissue to subcutaneous adipose tissue in term-born infants must be considered as the baseline, in terms of future health risks e.g. for future obesity. In the absence of further evidence, there is no credible reason why a further reduction in the ratio, i.e. to below the ratio obtained when administering standard HMF, would have any prophylactic therapeutic benefit. Consequently, there is no credible link between the ratio decreasing feature and a method of treatment by therapy pursuant to Article 53(c) EPC.

1.12 The respondent's further arguments to the contrary failed to convince the board. It was argued that claim 1 was directed to preterm infants, which were considered a vulnerable target group. Since the claim involved the treatment of this vulnerable group, it was necessarily of a therapeutic nature.

1.13 The board disagrees. The therapeutic nature of a medical use is defined by the functionally defined use feature underlying said claim. If there is no evidence that the use corresponds to a method of treatment by therapy, the ratio decreasing feature of claim 1 is non-therapeutic in nature by definition.

1.14 As evidence for a credible therapeutic effect linked to the ratio decreasing feature, the respondent referred to the background section of the patent, supported by documents D5, D7 and D8 as cited by the opposition division in point 7.2 of the contested decision. Therein, the need for catch up growth in preterm infants was identified, as was the risk associated with the acquisition of undesirable visceral fat. Avoidance of visceral fat was therefore desired.

1.15 The board does not agree that this evidence supports a therapeutic effect for the ratio decreasing feature. While it is undeniable that the accumulation of visceral adipose tissue in absolute terms is undesirable in terms of future health risks, the ratio of visceral to subcutaneous adipose tissue gives no indication of the absolute amounts of visceral adipose tissue present. For example, in the data provided in table 2 of the patent and addressed above, the absolute amount of visceral adipose tissue of 0.019 kg remains the same both for preterm infants fed with standard HMF and those fed with trial HMF, despite a decrease in the

ratio (patent, table 2, final row). Hence, an absolute decrease in the amount of visceral adipose tissue is not synonymous with the ratio decreasing feature.

1.16 Furthermore, none of the cited documents demonstrate a link between the ratio decreasing feature, i.e. a further decrease in the ratio, compared to standard HMF, to a level below that found in term-born infants, and a prophylactic therapeutic effect. D7, for example, although referring to relative visceral adiposity, does not indicate the specific ratios to be attained, let alone indicate a therapeutic effect associated with a ratio lower than that found in term-born infants (D7, abstract, and page 911, right hand column, first full paragraph).

1.17 Consequently, decreasing the ratio of visceral adipose tissue to subcutaneous adipose tissue in a preterm infant is not a method of treatment by therapy pursuant to Article 53(c) EPC. Consequently, it cannot establish novelty over prior art disclosing a composition as defined in claim 1 suitable for the same purpose.

1.18 Novelty over D2

1.18.1 Patent document D2 relates to liquid human milk supplements for infants (paragraph [0001]), including pre-term infants or low birth weight infants (paragraph [0061]). Such supplements are said to provide appropriate pre-term nutrition while maintaining microbiological quality throughout the shelf-life of the product (paragraph [0009]).

1.18.2 It is undisputed that a HMF falling within the scope of the composition defined by ingredients a) and b) in claim 1 of the main request is disclosed in table 1 of

D2 (paragraph [0069]). Specifically, this composition comprises approximately 30% protein based on total calories, and at least 5% fat based on total calories, wherein the fat comprises DHA in an amount within the claimed range.

1.18.3 It was also undisputed that this composition is suitable for "decreasing the ratio visceral adipose tissue to subcutaneous adipose tissue in a preterm infant" as required by claim 1.

1.19 Hence, the subject-matter of claim 1 of the main request lacks novelty over D2.

Auxiliary requests 1 to 5

2. The respective claim 1 of auxiliary requests 1 to 4 is identical to claim 1 of the main request.

2.1 Claim 1 of auxiliary request 5 differs from claim 1 of the main request by the addition of the following text:

"wherein the human milk fortifier is to be administered in a quantity of 0.1 to 20 g dry weight per day".

This amendment was submitted by the respondent to overcome an objection of sufficiency of disclosure.

2.2 During oral proceedings, after the conclusion of lack of novelty of claim 1 of the main request was announced, the board stated that the same conclusion appeared to apply in relation to claim 1 of auxiliary requests 1 to 5.

2.3 The respondent stated that it did not wish to comment further on auxiliary requests 1 to 5. Since no reasons

were provided in the appeal proceedings as to why the respective claim 1 of these requests overcame the objection against claim 1 of the main request, the board concludes that auxiliary requests 1 to 5 are not allowable.

Auxiliary request 6 - Inventive step - Article 56 EPC

3. Claim 2 of auxiliary request 6 reads as follows:

"A human milk fortifier comprising

a) at least 20 % protein is present based on total calories,
b) at least 5 % fat is present based on total calories wherein the fat comprises from 0.15 wt.% to 4 wt.% docosahexaenoic acid based on total fatty acids, and
c) comprising at least 20% digestible carbohydrates based on total calories,

for use in promoting catch up growth in an infant selected from the group consisting of preterm infants and infants small for gestational age, wherein the growth does not result in excess visceral tissue."

3.1 The appellant argued that the subject-matter of claim 2 lacked inventive step starting from D2 in combination with D5.

3.2 The respondent did not dispute that D2 could represent the closest prior art.

3.3 Distinguishing features

3.3.1 As set out for claim 1 of the main request, the composition of the human milk supplement in table 1 of

D2 meets the requirements for components a) and b). These requirements are identical in claim 2 of the present request.

3.3.2 It was common ground among the parties that the composition of claim 2 of the present request was distinguished from the HMF of D2 by the amount of digestible carbohydrate, namely, at least 20% based on total calories as required by component c).

3.3.3 To the respondent's advantage, it is assumed in the following that the therapeutic use feature of claim 2, namely "for use in promoting catch up growth in an infant selected from the group consisting of preterm infants and infants small for gestational age, wherein the growth does not result in excess visceral tissue", is a method for treatment by therapy pursuant to Article 53(c) EPC and therefore limits claim 2. It is undisputed that this therapeutic use is not disclosed in D2. Hence, it represents a further distinguishing feature of claim 2 over D2.

3.4 Objective technical problem

3.4.1 The respondent argued that the effects of the distinguishing features were that an alternative HMF having a low osmolality for a different therapeutic use to the composition of D2 was provided.

3.4.2 The appellant disputed that "low osmolality" could be seen as a technical effect of the distinguishing feature, since any alleged effects in relation to osmolality had not been demonstrated.

3.4.3 The board agrees. Any alleged technical effect must be related to the distinguishing feature of the HMF

composition of claim 2, and therefore to the presence of component c), namely at least 20% digestible carbohydrates based on total calories. Since no such effect had been demonstrated in the patent nor elsewhere as originating in the distinguishing feature, a technical effect related to osmolality cannot be taken into account in the formulation of the objective technical problem.

3.4.4 Hence the objective technical problem underlying claim 2 is merely the provision of an alternative HMF for a different therapeutic use to the composition of D2.

3.5 Obviousness

3.5.1 In assessing whether the claimed solution to the above problem was obvious to the skilled person, the board considered that at least one of two distinct but sequential questions needs to be answered. The first question is whether it was obvious to the skilled person to use the HMF of D2 for the claimed therapeutic use. If the answer to this question is negative, then the claimed subject-matter involves an inventive step, because it was *a fortiori* not obvious to use an alternative HMF to that of D2. However, if the answer is positive, then a second question is to be posed, namely whether it was obvious to the skilled person to employ, for the claimed therapeutic use, the claimed HMF as an alternative to the HMF disclosed in D2. If both questions are answered in the positive, then the claimed subject-matter lacks inventive step.

3.5.2 In relation to the first question, as stated by the appellant, D2 at least suggests that the HMF disclosed therein can be used for catch up growth in preterm and low birth weight infants. Thus, in paragraph [0004],

growth rates, and in particular catch up growth for preterm infants is addressed. It is stated in paragraph [0006] that human milk is typically too low in protein and certain minerals to meet the demands for rapid growth required by many preterm infants. The summary of the invention in paragraphs [0009] and [0010] then refers to the human milk supplement of the invention for administration to infants. In paragraph [0061] it is stated that the HMF of the invention is useful in the feeding of preterm infants or low birth weight infants, and in enhancing the growth of an infant. Hence D2 indicates that the HMF disclosed therein may be used for administration to preterm infants in the context of catch up growth.

3.5.3 D2 however does not mention visceral adipose tissue at all, let alone whether the catch up growth addressed therein results in excess visceral adipose tissue.

3.5.4 The appellant argued that the use of the composition of D2 for the medical use stipulated in claim 2, namely for catch up growth, wherein the growth does not result in excess visceral adipose tissue, was obvious in view of D5.

3.5.5 The board agrees. Patent document D5 relates to nutritional compositions for infants (page 1, lines 4-5). In the summary of the invention, it is stated that the adipose tissue mass (i.e. total fat mass) of infants is not a good predictor to determine the risk of disease later in life. It is recognised that body fat can be distributed and stored in fat tissue in different places within the body, and that different fat tissues have different metabolic effects, particularly in infants. In particular, visceral fat mass developed early in infancy was seen as a main

contributor in the development of certain disorders later in life, including obesity (D5, page 2, lines 12-27). An aim of the invention of D5 was therefore to provide a nutritional composition which reduced visceral adiposity and other disorders later in life (page 2, lines 27-29 and page 3, lines 16-20).

3.5.6 To achieve this aim, D5 teaches that long chain polyunsaturated fatty acids, including *inter alia* docosahexaenoic acid (DHA), reduce the visceral fat mass accumulation while maintaining normal growth and development, and were therefore advantageously incorporated in compositions for reducing visceral adiposity (D5, page 4, lines 4-9).

3.5.7 Since DHA is also a component of the HMF of D2, table 1, the skilled person, in view of the teaching of D5, would have used the HMF of D2 for the use set out in claim 2, namely for promoting catch up growth in an infant selected from the group consisting of preterm infants and infants small for gestational age, wherein the growth does not result in excess visceral tissue.

3.5.8 The respondent's further arguments to the contrary failed to convince the board. It was argued that the skilled person would not have turned to D5 for the solution to the above problem, as D5 did not concern a HMF, taught a maximum of 15% calories from protein, and did not concern preterm infants.

3.5.9 The board disagrees for the reasons provided by the appellant. As addressed above, D5 refers to infant formulae and the effects of ingredients therein on health later in life. Even though infant formula replaces, rather than supplements human milk as is the case for the HMF of D2, both infant formula and HMF are

compositions for administration to infants in the context of feeding. Hence, the subject-matter of D5 is closely related to that of D2. Therefore, the skilled person starting from D2 and seeking a different therapeutic use for the composition thereof, would have turned to D5 for the solution.

3.5.10 Furthermore, even if the protein content of the infant formula of D5 is different from that of D2, it would not prevent the skilled person from taking D5 into account. Specifically, as set out above, D5 teaches that *inter alia* DHA itself reduces visceral fat mass accumulation, and there is no indication that other components of the composition, such as proteins, are required in specific amounts for this effect to take place.

3.5.11 Consequently, the first question is to be answered in the positive.

3.5.12 In relation to the second question, the appellant argued that although the claimed HMF was distinguished from that of D2 in that it comprised at least 20% digestible carbohydrates based on total calories, the choice of the amount provided in claim 2 represented an arbitrary selection from the amounts disclosed in D2.

3.5.13 The board agrees. As stated by the appellant, D2 (paragraph [0032]) teaches that the HMF disclosed therein, on a dry weight basis, could comprise up to 65% of a carbohydrate component.

3.5.14 The respondent did not dispute that this amount of carbohydrate by weight would at least meet the requirement in claim 2, component c) that the

composition comprise at least 20% digestible carbohydrates based on total calories.

3.5.15 The respondent submitted however that D2 taught the skilled person against using an amount of carbohydrate within the claim range. Specifically, D2 disclosed in paragraph [0011] that the carbohydrate component of the HMF comprised less than about 10% of the caloric content thereof. In paragraph [0025], an embodiment was described in which the fat component comprised greater than 30% of the calories and the carbohydrate less than 10% of the calories, and it was explained that these levels of fat and carbohydrate provide increased caloric content for preterm infants, but minimised unnecessary increase in the osmolality of the human milk.

3.5.16 The board disagrees. Although the embodiment identified by the respondent in D2 proposes a carbohydrate content of less than 10%, the overall teaching of D2 includes other embodiments in which the carbohydrate is present in an amount of up to 65% on a dry weight basis, as set out in paragraph [0032]. Hence, D2 does not teach away from using a carbohydrate component in an amount falling within the claimed range.

3.5.17 Therefore, it would have been a routine matter for the skilled person wishing to provide an alternative to the HMF disclosed in table 1 of D2 to adjust the amount of carbohydrate and thereby arrive at a composition according to claim 2.

3.5.18 Consequently, also the second question is to be answered in the positive. It follows therefore that the subject-matter of claim 2 of auxiliary request 6 lacks inventive step pursuant to Article 56 EPC.

Auxiliary requests 7 to 31

4. The board notes that neither in written appeal proceedings nor during oral proceedings before the board did the respondent submit any arguments as to why the amendments implemented in auxiliary requests 7 to 31 overcame the objections raised against the higher ranking requests.

4.1 In fact, during oral proceedings, the board expressed the preliminary view that auxiliary requests 7 to 27 were combinations of auxiliary requests earlier considered such that the same conclusions in relation to those earlier requests appeared to apply. The board notes that in its written submissions the respondent also referred to said requests as combinations of earlier requests. Furthermore, the board expressed the preliminary view that, in relation to the respective claim 2 of auxiliary requests 28 to 31, the same considerations of lack of inventive step as for auxiliary request 6 seemed to apply. When asked how it wished to proceed, and thus being given the opportunity to present its views on any or all of auxiliary requests 7 to 31, the respondent stated that it wished to continue with the discussion of auxiliary request 32, and accordingly made no oral submissions as regards auxiliary requests 7 to 31.

4.2 In view of the fact that the respondent did not provide any reasons substantiating how auxiliary requests 7 to 31 overcome the objections raised for the higher ranking requests, and since the respondent did not contest the board's preliminary view that the same conclusions in relation to the higher-ranking requests

applied, the board concludes that the sets of claims of auxiliary requests 7 to 31 are not allowable.

Auxiliary request 32

5. The set of claims of auxiliary request 32 is identical to that of auxiliary request 4 with the exception that in claim 1, the second alternative medical use, namely "for ... decreasing the ratio visceral adipose tissue to subcutaneous adipose tissue in a preterm infant" is deleted.

6. Admittance

6.1 Auxiliary request 32 was submitted by the respondent with the reply to the statement of grounds of appeal.

6.2 The appellant requested that it not be admitted into appeal proceedings on the ground that it represented an amendment to the respondent's case which should have been submitted before the opposition division.

6.3 Admittance was decided in light of Articles 12(4) and (6) RPBA. According to Article 12(4) RPBA, any amendment to a party's case may be admitted only at the discretion of the board. The party shall clearly identify each amendment and provide reasons for submitting it in the appeal proceedings, indicate the basis for the amendment in the application as filed, and provide reasons why the amendment overcomes the objections raised. The board shall exercise its discretion in view of, inter alia, the complexity of the amendment, the suitability of the amendment to address the issues which led to the decision under appeal, and the need for procedural economy.

6.4 According to Article 12(6) RPBA, the board shall not admit *inter alia* requests which should have been submitted in the proceedings leading to the decision under appeal, unless the circumstances of the appeal case justify their admittance.

6.5 As stated by the respondent and not disputed by the appellant, the objection that the use "in decreasing the ratio visceral adipose tissue to subcutaneous adipose tissue" in claim 1 was not a medical use was first raised by the appellant in opposition proceedings with the letter dated 16 November 2022 (point 2.1), approximately two months in advance of oral proceedings before the opposition division, which took place on 23 January 2023. As stated above, this use has been deleted in claim 1 of auxiliary request 32. The submission of auxiliary request 32 can thus be considered as a reaction to the appellant's objection raised approximately two months in advance of oral proceedings before the opposition division.

6.6 As stated by the respondent, since this objection was raised only two months in advance of oral proceedings before the opposition division, it was submitted late in opposition proceedings. During oral proceedings the opposition division found the main request to be allowable. Hence, the filing of new claim requests during oral proceedings was not necessary. The submission of auxiliary request 32 with the reply to the statement of grounds of appeal can therefore be considered a timely reaction to the new objection.

6.7 Furthermore, the reason why the amendment overcame the objection raised is immediately apparent, namely by overcoming the novelty objection based on D2, and is set out by the respondent in the reply (page 16, first

paragraph). The amendment concerns a mere deletion and is not complex in nature. Hence, it does not negatively affect procedural economy.

Consequently, the board decided to admit auxiliary request 32 into the proceedings pursuant to Article 12(4) and (6) RPBA.

7. Inventive step - Article 56 EPC

7.1 Admittance of the objection under Article 56 EPC starting from D2 in combination with D5 against claim 1 of auxiliary request 32

7.1.1 During oral proceedings before the board, the appellant raised a new objection against claim 1 of this request starting from D2 in combination with D5.

7.1.2 The appellant conceded that this objection had not been raised in written appeal proceedings for claim 1 of this request, let alone for claim 1 of any other request, in advance of the oral proceedings.

7.1.3 The same objection starting from D2 in combination with D5 was however raised by the appellant against claim 2 of the main request (statement of grounds of appeal, point 2.5.1), and by analogy, claim 2 of auxiliary request 6. In relation to the latter objection, the board concluded that the subject-matter of claim 2 of auxiliary request 6 lacked inventive step (supra).

7.1.4 Claim 1 of auxiliary request 32 and claim 2 of auxiliary request 6, and indeed the respective claims 1 and 2 of all requests, differ *inter alia* in the medical use, the former concerning a "use in prevention of visceral adiposity in a preterm infant", and the latter

concerning a "use in promoting catch up growth ... wherein the growth does not result in excess visceral adipose tissue".

7.1.5 The admittance of this objection into appeal proceedings had to be assessed under Article 13(2) RPBA. According to this provision, any amendment to a party's appeal case made after notification of a communication under Article 15(1) RPBA shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

7.1.6 The appellant submitted that the objection against claim 1 (of the then relevant request) starting from D2 in combination with D5 was raised from the start of written opposition proceedings. Hence, it was not entirely new, and should be admitted in particular in view of the surprising decision of the board at oral proceedings to admit auxiliary request 32 into the proceedings. More specifically, with this claim request, the appellant's novelty objection against claim 1 vis à vis D2 had been overcome, and inventive step had become an issue. Furthermore, in view of the discussions during oral proceedings before the board related to the relevance of D2 for the assessment of inventive step in relation to claim 2 of auxiliary request 6, it had become clear that this objection was also highly relevant for claim 1 for the same reasons.

7.1.7 The board found the appellant's arguments unconvincing. According to Article 12(3) RPBA, an appellant must provide its complete appeal case with its statement of grounds of appeal. This means that in the present case, the appellant would have had to raise an objection of

lack of inventive step against claim 1 of the requests which had been submitted by the respondent during opposition proceedings in its statement of grounds of appeal. If not raised in the statement of grounds of appeal, as stated by the respondent, it should have been raised at the latest in reply to the respondent's reply to the statement of grounds of appeal with which *inter alia* auxiliary request 32 was submitted. Specifically, at least with the submission of the set of claims of auxiliary request 32, it should have become apparent to the appellant that if that request was admitted, the novelty objection against claim 1 vis à vis D2 was no longer relevant.

7.1.8 Furthermore, even if the board's decision to admit auxiliary request 32 into the proceedings was considered surprising, it is for the appellant to submit, in a timely manner, objections to claim requests submitted by the respondent. More specifically, for any contentious issue, such as the admittance of auxiliary request 32 in the present case, any party must expect a board to take a decision adverse to it. Therefore, the appellant could not and should not have relied on an expectation that auxiliary request 32 would not be admitted into the proceedings as a reason for not submitting, in a timely manner, relevant objections against that request.

7.2 Additionally, the board does not share the appellant's view that D2 only emerged as highly relevant to claim 2 of auxiliary request 6 during developments in oral proceedings before the board, such that a similar objection in relation to claim 1 of auxiliary request 32 would only have become apparent at this stage of the proceedings. Rather, the objection against claim 2 of the patent as granted starting from D2 was already

submitted in opposition proceedings. More importantly, as stated above, the objection against claim 2 of the main request was also submitted with the appellant's statement of grounds of appeal, as the first document addressed as closest prior art in relation to inventive step of claim 2 of the main request. Hence, any alleged high relevance of D2 for inventive step in relation to claim 2 of the main request, and thus also claim 2 of auxiliary request 6 by analogy, was already part of the appeal proceedings from the beginning, and did not emerge from discussions during oral proceedings before the board.

7.2.1 Therefore, the board's finding as regards the subject-matter of claim 2 of auxiliary request 6 in view of D2 cannot serve as an exceptional circumstance justifying the admittance of a corresponding objection against claim 1 of auxiliary request 32 at the latest possible stage of appeal proceedings, namely during oral proceedings before the board.

7.2.2 In view of the above, the board concludes that the appellant could not establish any exceptional circumstances in the sense of Article 13(2) RPBA justifying admittance of its objection.

7.2.3 Consequently, the board decided pursuant to Article 13(2) RPBA not to admit the objection against claim 1 of auxiliary request 32 under Article 56 EPC starting from D2 in combination with D5 into the proceedings.

8. Starting from D10 as closest prior art

During oral proceedings, the appellant submitted that the subject-matter of claim 1 lacked inventive step in

view of D10 alone, or in view of D10 in combination with D2.

Patent document D10 concerns nutritional formulations for promoting catch up growth in young mammals whose growth has been retarded due to physical or mental stress (page 1, first paragraph; claim 1).

8.1 Distinguishing features

The appellant argued that the composition of "Supplemented Diet 1" in table 1 of the D10 (page 10-11) fulfilled the requirements for the amounts of fat and DHA stipulated in claim 1 of auxiliary request 32. The composition of the HMF of claim 1 was distinguished from this composition of D10 by the protein content, which in the latter lay below the claimed range. Furthermore, D10 failed to disclose the claimed medical use, both in terms of the patient group, namely preterm infants, and the prevention of visceral adiposity.

The distinguishing features of claim 1 as set out by the appellant were not disputed by the respondent.

8.2 Objective technical problem

According to the appellant, the objective technical problem underlying the subject-matter of claim 1 was the provision of a further HMF for a further medical use.

The board agrees with the appellant's formulation of the objective technical problem.

8.3 Obviousness of the solution

8.3.1 In the same manner as set out for claim 2 of auxiliary request 6, above, obviousness may be assessed sequentially by first asking whether the claimed use was obvious to the skilled person starting from D10. Only if this question is answered in the positive is it necessary to ask a second question, namely whether, for the claimed further medical use, the claimed further HMF was obvious to the skilled person.

8.3.2 In relation to the first question, the appellant submitted that the nutritional compositions of D10 were intended for promoting catch up growth in young mammals, including humans from infancy (D10, page 1, third paragraph and claim 1). The composition may be a paediatric composition (claim 11). It was also taught that catch up growth should not be excessive, as periods of rapid catch up may be linked to a risk of future obesity (page 1, third paragraph). Furthermore, D10 disclosed that the nutritional composition thereof allowed to promote catch up growth without increasing the caloric intake, with equilibrated lean and fat body mass and without promoting obesity (page 5, fifth paragraph). The invention of D10 thus provided the possibility to promote catch up growth, without promoting obesity (page 2, penultimate paragraph).

8.3.3 The appellant therefore submitted *inter alia* in view of the teaching in D10 that the compositions thereof could prevent future obesity, that the claimed use in the prevention of visceral adiposity was obvious to the skilled person.

8.3.4 The board disagrees. As stated by the respondent, D10 fails to teach that the growth would prevent visceral

adiposity. References in D10 to obesity or fat body mass cannot be interpreted either implicitly or explicitly as referring to visceral fat specifically, which is distinct from subcutaneous fat. D10 rather refers more generally to body mass index, or total body fat mass (e.g. paragraph bridging pages 11 and 12). Hence, D10 contains no motivation nor incentive for the skilled person to employ the composition disclosed therein specifically for the claimed use in the prevention of visceral adiposity.

8.3.5 Hence, at least for this reason, the subject-matter of claim 1 involves an inventive step over D10 alone.

8.3.6 The claimed use was also not obvious to the skilled person starting from D10 in combination with D2. As stated by the respondent, D2 teaches that the HMF disclosed therein may be used for administration to preterm infants in the context of catch up growth. However, D2 fails to mention visceral adipose tissue at all, let alone the prevention of visceral adiposity using the compositions thereof. Consequently, the subject-matter of claim 1 involves an inventive step pursuant to Article 56 EPC over D10 in combination with D2.

9. Since there were no further objections, the set of claims of auxiliary request 32 is allowable.

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 in amended form with the claims of auxiliary request 32 filed with the reply to the statement of grounds of appeal, and a description to be adapted thereto, where applicable.

The Registrar: The Chairman:

T. Buschek M. O. Müller

Decision electronically authenticated