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Datasheet for the decision of 28 May 2025

Case Number: T 0594/23 - 3.3.07

Application Number: 14761640.3

Publication Number: 3079770

IPC: A61P3/04

Language of the proceedings: EN

Title of invention:
SYNTHETIC MILK COMPOSITIONS FOR INFANTS LESS THAN THREE MONTHS OLD AND FOR INFANTS AND CHILDREN MORE THAN THREE MONTHS FOR ENSURING OPTIMAL GROWTH AND PREVENTING OBESITY

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponents:
N.V. NUTRICIA
MJN U.S. Holdings LLC

Headword:
Snythetic milk compositions for infants / NESTLÉ

Relevant legal provisions:
RPBA 2020 Art. 13(1), 13(2)
EPC Art. 83, 56

Keyword:
Late filed evidence and arguments - suitability of the amendment to resolve the issues raised (no)
Late filed evidence and arguments - exceptional circumstances (no)
Sufficiency of disclosure - main request (yes)
Inventive step - main request (yes)

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Boards of Appeal

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Case Number: T 0594/23 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 28 May 2025

Appellant: (Opponent 1)	N.V. NUTRICIA Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Respondent: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Party as of right: (Opponent 2)	MJN U.S. Holdings LLC 2400 West Lloyd Expressway Evansville IN 47721 (US)
Representative:	Bovill, Sally Marina Reckitt Benckiser Corporate Services Limited Legal Department - Patents Group Dansom Lane Hull HU8 7DS (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 23 January 2023 concerning maintenance of the European Patent No. 3079770 in amended form.**

Composition of the Board:

Chair	A. Jimenez
Members:	J. Lécaillon
	M. Steendijk

Summary of Facts and Submissions

I. European patent 3 079 770 (hereinafter "the patent") was granted on the basis of 8 claims and related to synthetic nutritional compositions for infants.

II. Two oppositions were filed against the patent on the grounds that its subject-matter lacked inventive step and it was not sufficiently disclosed.

III. The opposition division took the interlocutory decision that, on the basis of the main request filed on 15 July 2022, the patent met the requirements of the EPC.

IV. The decision of the opposition division, posted on 23 January 2023, cited *inter alia* the following documents:

D2: WO 2013/153071 A2
D3: Thakkar S. *et al.*, American Journal of Human Biology, 25: 770-779 (2013)
D9: WO 2010/003878 A1
D10: Codex Alimentarius - Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)

V. The opposition division decided in particular as follows:

(a) The subject-matter of the main request was sufficiently disclosed. In particular, the therapeutic application claimed in claims 4 to 8 was considered to be credibly achieved by the claimed compositions.

(b) The main request fulfilled the requirement of Article 56 EPC. Starting from the closest prior art D2, the objective technical problem resided in the provision of an alternative nutritional product providing the same nutritional benefits as breast milk (including balanced or optimal growth thereby reducing risk of obesity in infants and young children). None of the prior art documents D2, D3 or D9, alone or in combination, rendered the claimed solution obvious.

VI. Opponent 1 (appellant) lodged an appeal against the above decision of the opposition division.

VII. With its reply to the appellant's statement setting out the grounds of appeal the patent proprietor (respondent) defended its case on the basis of the main request filed on 15 July 2022 and maintained by the opposition division, and on the basis of one of the auxiliary requests 1 to 3 submitted therewith and corresponding to auxiliary request 3 filed on 14 July 2021 and auxiliary requests 7 and 8 filed on 15 July 2022.

VIII. The independent product claims of the main request upon which the present decision is based read as follows:

"1. A set of synthetic nutritional compositions for infants or young children wherein the first composition comprises:

a. 1.0-1.2 g/100ml protein, and

b. 3.8-4.6 g/100ml lipid,

and the second composition comprises:

a. 0.7-0.9 g/100ml protein, and

b. 4.2-5.2 g/100ml lipid,

wherein the first composition is especially adapted to the nutritional needs of an infant of less than three months old and the second composition is especially adapted to the nutritional needs of infants or young children more than three months old, and wherein the quantities of all the nutrients expressed as mg/100ml or g/100ml reflect the amounts of nutrients present in the final liquid product, to be consumed by the infant or young child,
wherein the first and second compositions are an infant formula in the form of a liquid,
wherein the first composition comprises, in addition, any one or a mixture of phospholipids c.-e.:

c. 5.4-6.6 mg/100ml of phosphatidylcholine,
d. 6.0-7.5 mg/100ml of phosphatidylethanolamine, and
e. 1.0-1.2 mg/100ml of phosphatidylinositol,

and the second composition comprises, in addition, any one or a mixture of phospholipids c.-e.:

c. 4.4-5.4 mg/100ml of phosphatidylcholine,
d. 7.3-8.9 mg/100ml of phosphatidylethanolamine, and
e. 1.5-1.9 mg/100ml of phosphatidylinositol."

"2. A synthetic nutritional composition for infants comprising:

a. 1.0-1.2 g/100ml protein, and
b. 3.8-4.6 g/100ml lipid,

and any one or a mixture of the following phospholipids c.-e.:

c. 5.4-6.6 mg/100ml of phosphatidylcholine,
d. 6-7.5 mg/100ml of phosphatidylethanolamine, and
e. 1.0-1.2 mg/100ml of phosphatidylinositol,

wherein the composition is especially adapted to the nutritional needs of infants of less than three months old, and

wherein the quantities of all the nutrients expressed as mg/100ml or g/100ml reflect the amounts of nutrients present in the final liquid product, to be consumed by the infant or young child,
wherein the composition is an infant formula in the form of a liquid."

"3. A synthetic nutritional composition for infants or young children comprising:
a. 0.7-0.9 g/100ml protein, and
b. 4.2-5.2 g/100 ml lipid,
and any one or a mixture of the following phospholipids c.-e.:
c. 4.4-5.4 mg/100ml of phosphatidylcholine,
d. 7.3-8.9 mg/100ml of phosphatidylethanolamine, and
e. 1.5-1.9 mg/100ml of phosphatidylinositol,
wherein the composition is especially adapted to the nutritional needs of infants or young children of more than three months old, and
wherein the quantities of all the nutrients expressed as mg/100ml or g/100ml reflect the amounts of nutrients present in the final liquid product, to be consumed by the infant or young child,
wherein the composition is an infant formula in the form of a liquid."

IX. The following item of evidence was filed by the appellant during the appeal proceedings on 14 February 2025:

D20: Giuffrida *et al.*, 2019, Journal of Perinatology, 39:497-503

X. Oral proceedings were held before the Board on 28 May 2025.

XI. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

XII. The respondent requested that the appeal be dismissed, *i.e.* that the patent be maintained as amended during the opposition proceedings (main request), or that the patent be maintained on the basis of one of the auxiliary requests 1 to 3 submitted with the reply to the statement setting out the grounds of appeal.

The respondent also requested that the following submissions of the appellant not be admitted:

- a new line of argument in respect of sufficiency of disclosure based on a similarity with the lack of enabling disclosure of D3 brought forward by the respondent during the oppositions proceedings,
- document D20 filed with the submission of 14 February 2025,
- the new argument in respect of sufficiency of disclosure provided with the submission of 14 February 2025 based on the assertion that the measurements in the contested patent are wrong, and
- the objections of lack of inventive step provided with the submission of 14 February 2025 based either on D3 in combination with D10 or on D2.

XIII. The party as of right - opponent 2 did not make any submission in the appeal proceedings.

XIV. The arguments of the appellant, as far as relevant for the present decision, can be summarised as follows:

(a) D20 and the arguments based thereupon were to be admitted into the appeal proceedings because they were filed in response to the communication

pursuant to Article 15(1) RPBA and were highly relevant for the issue of patentability of the claimed subject-matter.

(b) The same approach regarding enabling disclosure should be applied to the patent and D3 since the data provided in both documents originated from the same clinical study. It followed that, if D3 would not be considered to provide an enabling disclosure, the patent would also not sufficiently disclose the claimed invention.

(c) The main request did not meet the requirements of Article 56 EPC.

Contrary to the findings of the impugned decision, D3 represented the closest prior art instead of D2. D3 provided the composition of human milk being the gold standard in terms of infant nutrition and was therefore closer to the invention than D2. In particular, the purpose of D2 was not to be as close as possible in composition to breast milk but as close as possible in outcome for infants and D2 did not envisage changes over time.

The claimed subject-matter differed from D3 in that it related to synthetic compositions and a set thereof. Starting from D3, the objective technical problem resided in the provision of synthetic nutritional compositions for infants or young children. The claimed compositions represented the mere implementation of the teaching of D3. D3 indeed provided the human breast milk composition in terms of lipids, phospholipids and lactose over time. Furthermore the protein concentration, while not explicitly provided in D3, could be determined

from these values and the energy value of the samples. Since it was commonly known that human breast milk was the gold standard for infant formulations (as also shown by D10 which represented evidence of common general knowledge), the skilled person would have been motivated to prepare synthetic compositions varying over time in accordance with the values in terms of lipids, phospholipids and proteins derivable from D3. The skilled person would hence have arrived at the claimed subject-matter without exercising inventive skills.

The arguments provided on 14 February 2025 regarding inventive step starting from D2 should be admitted into the appeal proceedings since they were filed in response to the communication pursuant to Article 15(1) RPBA.

XV. The arguments of the respondent, as far as relevant for the present decision, can be summarised as follows:

(a) D20 and the arguments based thereupon should not be admitted into the appeal proceedings because they were not relevant for the issues on file and there were no exceptional circumstances justifying their admittance at this late stage.

(b) The argument of the appellant regarding sufficiency of disclosure by analogy with the issue of enabling disclosure of D3 should not be admitted into the appeal proceedings. The patent provided guidance to prepare the claimed compositions and the achievement of the effect in terms of balanced growth and obesity prevention was not disputed *per se*.

(c) The main request fulfilled the requirements of Article 56 EPC.

D2 represented the closest prior art because it addressed the same purpose as the patent, namely the preparation of synthetic nutritional compositions for infants and mentioned the decrease of obesity. In contrast D3 did not disclose any synthetic compositions and focused on lipids without providing data on protein concentration. Starting from D2, the claimed subject-matter involved an inventive step for the reasons provided in the impugned decision.

The arguments of the appellant provided on 14 February 2025 regarding inventive step starting from D2 were not to be admitted into the appeal proceedings since there were no exceptional circumstances justifying their late filing.

Furthermore, the claimed subject-matter differed from D3 in that it related to synthetic compositions and a set thereof and in that D3 did not provide the protein concentration, let alone the combination of the claimed concentrations of the further components. According to the patent, the claimed compositions were especially adapted to promote balanced growth in infant of less than 3 months old and to prevent obesity in these children during infancy and later in life. Starting from D3, the objective technical problem resided in the provision of a nutritional intervention that ensured balanced growth and development in infants of specific age groups thereby reducing obesity in infancy and later in life. D3 did not provide any

motivation to formulate at least 2 distinct synthetic nutritional compositions for infants of less or more than 3 months, let alone with the present combination of concentrations of lipids, phospholipids and proteins. The appellant's argument of lack of inventive step starting from D3 in combination with D10 filed on 14 February 2025 should not be admitted into the appeal proceedings because it represented an amendment to the case of the appellant submitted without exceptional circumstances and it was not *prima facie* relevant to address the issue on file regarding the absence of teaching of protein concentration in the prior art.

Reasons for the Decision

1. Admittance of new item of evidence and related arguments

1.1 D20 and the arguments based thereupon were filed by the appellant with the letter of 14 February 2025 after notification of the communication of the Board under Article 15(1) RPBA. Their admittance is hence to be decided in accordance with Articles 13(1) and 13(2) RPBA.

1.2 The appellant argued that this document and the related arguments were filed in response to the preliminary opinion of the Board considering the calculation of the protein content from D3 performed by the opponent not appropriate (see paragraph 2.7 of the communication pursuant to Article 15(1) RPBA). Furthermore D20 would be highly relevant for the issue of patentability of the claimed subject-matter. According to the appellant, D20 would substantiate that the data provided in the

patent regarding the protein concentration was not correct. Accordingly there would be exceptional circumstances justifying the late-filing of D20 (Article 13(2) RPBA).

1.3 As argued by the respondent, the issue addressed by the Board in paragraph 2.7 of the communication pursuant to Article 15(1) RPBA was not newly raised by the Board but merely followed arguments of the respondent submitted already during the opposition proceedings and repeated in the appeal proceedings (see letter of the respondent in the opposition proceedings dated 15 July 2022, item (53) and reply to the statement of the grounds of appeal, item (65)). D20 was published in 2018, so that it could have been filed already in reply to these arguments. The Board further observes that D20 does not concern the calculation made by the appellant but rather the determination of the protein content according to the patent, which represents a different issue. The preliminary opinion of the Board cannot therefore represent exceptional circumstances justifying the filing of D20 at the present stage of the proceedings (Article 13(2) RPBA), which filing is furthermore detrimental to procedural economy (Article 13(1) RPBA).

1.4 Moreover, as also brought forward by the respondent, D20 does not unambiguously substantiate that the data provided in the patent regarding the protein concentration are wrong. D20 reports on page 501 left column under "Total protein content in human milk" results of measurement of protein concentrations in samples following the MIR HMA technique (as used in the patent) and the BCA method. The results of this experiment indeed show that the concentrations obtained with the MIR HMA method were lower than those

determined with the BCA method, which according to the appellant is considered accurate and robust. However the conclusion of D20 is that the "instrument accuracy and precision needs to be checked at least once a week for routine analyses". According to the patent (see paragraph [0079] last sentence), a regular calibration as recommended in D20 was done in the experiments thereof. The Board therefore considers that there is no unambiguous evidence that the measurements made with MIR HMA technique in the patent are necessarily wrong.

As a result, the alleged high relevance of D20 does also not constitute exceptional circumstances according to Article 13(2) RPBA. Moreover, D20 and the related arguments do not resolve any issue on file (as *e.g.* the criticism of the calculation of the appellant of the protein concentration in D3) but rather raise a complete fresh case (alleged lack of accuracy of the measurements made in the patent), contrary to the requirements of Article 13(1) RPBA.

1.5 D20 and the appellant's related new arguments are therefore not admitted into the appeal proceedings (Articles 13(1) and 13(2) RPBA).

Main request

2. Sufficiency of disclosure

2.1 In the appeal proceedings, the appellant argued that example 1 of the patent and D3 provided data originating from the same clinical study. According to the appellant, the same approach regarding enabling disclosure should hence apply to the patent and D3. It would follow that, if the approach of the respondent stated during oral proceedings in opposition that D3

would not provide an enabling disclosure would be followed, the patent would also not sufficiently disclose the claimed invention. Nevertheless, the appellant indicated that they do not dispute that the skilled person could prepare synthetic compositions meeting the structural requirements of the claims (see *e.g.* submission dated 17 January 2024, page 1, 4th paragraph).

2.2 The Board observes that the issue raised by the appellant concerns the disclosure of D3 in the context of the inventive step discussion. Furthermore, even if the patent and D3 provide data originating from the same study, the disclosed data are not the same. In particular the patent focusses on the protein concentration while D3 does not disclose any information on the protein content.

2.3 Hence, independently of the issue of admittance of the appellant's objection, the Board considers that the issue of enabling disclosure of D3 is irrelevant in the present context.

2.4 Finally, the Board notes that the appellant did not provide in the appeal proceedings any further argument supporting an objection of lack of disclosure of the subject-matter of the present claims nor any explanation why the reasoning of the impugned decision would not be correct.

2.5 Accordingly, the main request meets the requirements of Article 83 EPC.

3. Inventive step

3.1 Closest prior art

3.1.1 In the appeal proceedings, the appellant primarily argued that the closest prior art would be D3 instead of D2 as considered in the impugned decision.

3.1.2 The main request relates to age-adapted synthetic nutritional compositions for infants, a set thereof and said compositions and set for use in ensuring balanced growth and preventing obesity. The claimed nutritional compositions are defined by specific concentrations of protein, lipid and specific phospholipids and the technical effect is linked to the protein content.

3.1.3 D3 reports results of a study aiming at characterising and quantifying human milk nutrients focusing on lipids in 50 women depending on the age and gender of the infants (see Abstract and tables 2 to 6). In particular the concentrations of lipids at 30, 60 and 120 days are provided in table 2 and the concentrations of phosphatidylcholine, phosphatidylethanolamine and phosphatidylinositol at 30, 60 and 120 days are provided in table 6 . However, as argued by the respondent, D3 does not explicitly disclose any synthetic nutritional composition nor any protein content.

The appellant mentioned the reference in the introductory part of the study (see page 771, left column) to formula feeding when breast feeding is not possible and hence the need to understand the nutrients composition of human milk. This general statement even in combination with the data of D3 cannot be seen as the unambiguous and direct disclosure of a specific

infant formula with a specific composition. Furthermore, the Board observes that D3 does not specifically refer to the reduction of the risk of obesity.

3.1.4 D2 aims at providing a synthetic infant nutritional composition which results in same growth and development as for breastfed children as well as in a reduction of obesity for the first months of life but also later in life (see page 5 lines 27 to 31, page 8 lines 12 to 18). The formula of D2 is defined *inter alia* by its protein and fat content (see *e.g.* pages 9 to 11). Hence D2 relates to the same type of product for the same purpose as the main request.

In this context the appellant argued that D2 explicitly stated that its purpose was not to be as close as possible in composition to breast milk but as close as possible in outcome for infants (see page 9 lines 10 to 13). According to the appellant, D2 would therefore be more remote than D3, which provided the composition of human milk being the gold standard in terms of infant nutrition according to the patent (see paragraph [0002] of the patent). The Board preliminarily concurs with the respondent that D2 has the same purpose as the main request but achieves it by different means (*i.e.* not by mimicking human breast milk), which does not disqualify D2 as closest prior art.

3.1.5 Accordingly, the Board considers that D2 represents a better starting point for the assessment of inventive step.

3.2 Inventive step starting from D2

3.2.1 Neither in their statement of the grounds of appeal nor in their letter of 17 January 2024 did the appellant provide any argument against the finding of the opposition division that the claimed subject-matter would be inventive starting from D2. Only in the letter of 14 February 2025 did the appellant address the reasoning of the opposition division and the respondent regarding inventive step starting from D2.

3.2.2 As argued by the respondent, pursuant to Article 12(3) RPBA, the appellant has the duty to set out their complete appeal case in their statement of the grounds of appeal.

3.2.3 The attack starting from D2 provided with the letter of 14 February 2025 represents therefore an amendment to the case of the appellant, which admittance is to be assessed according to *inter alia* Article 13(2) RPBA.

3.2.4 Contrary to the opinion of the appellant expressed during the oral proceedings, the observation in the preliminary opinion of the Board regarding the absence of any objection from the side of the appellant against the finding of the opposition division that the claimed subject-matter involved an inventive step starting from D2 cannot justify the filing of such arguments at this late stage of the proceedings. The reasoning starting from D2 as closest prior art formed the basis of the impugned decision and was further followed by the respondent in their reply to the statement of the grounds of appeal. The appellant chose not to address them earlier in the appeal proceedings. The communication pursuant to Article 15(1) RPBA cannot

have provided any new trigger to file the present arguments.

3.2.5 Moreover, the appellant has not relied on any further potential exceptional circumstances to justify the filing of these arguments at this late stage of the proceedings.

3.2.6 The appellant's objection of lack of inventive step provided with the submission of 14 February 2025 based on D2 is therefore not admitted into the appeal proceedings (Article 13(2) RPBA).

3.2.7 In the absence of further arguments against the conclusion of the opposition division that the claimed subject-matter would be inventive starting from D2, the Board sees no reason to differ from the impugned decision.

3.3 Inventive step starting from D3

3.3.1 Even when starting from D3 for the assessment of inventive step, the argument of lack of inventiveness of the appellant was not convincing.

3.3.2 The Board observes that D3 does not explicitly disclose the protein content of the analysed human milk.

Furthermore, as argued by the respondent, the calculation suggested by the appellant on page 6 of the statement of grounds of appeal based on the energy density, lipid and lactose content disclosed in Table 2 of D3 is not appropriate to unambiguously determine the content of protein from the data of D3.

First of all, D3 provides the mean results obtained from the various analysed individual samples. The calculated protein content would hence be an estimated mean value.

Moreover, despite being the major digestible carbohydrate in human milk, lactose is not the sole one as human milk usually also contains glucose and galactose. It follows that the amount of lactose cannot be considered to provide the total of amount of carbohydrates entering into the energy density. In this context the appellant did not provide any evidence in support of their argument that the quantity of glucose and galactose would be so low as to have a negligible impact on the calculation.

3.3.3 The objective problem to be solved can be formulated as the provision of synthetic nutritional compositions for infants or young children.

3.3.4 For the reasons detailed above (see point 3.3.2) regarding the calculation of the protein content in D3, even if one was to consider that the skilled person would have been motivated to prepare a synthetic infant formula by combining the values obtained for the different nutrients in D3, the skilled person would still not have arrived at the present narrow range of protein content in each of the claimed compositions (for infants of less than 3 months old and of more than 3 months old).

3.3.5 The appellant further referred to D10 in their letter of 14 February 2025. They explained that D10 represented the common general knowledge relied upon by the appellant and concerning the fact that human breast milk constituted the leading considerations for

determining the values of the components of an infant formula.

The respondent requested this argument based on D10 not to be admitted into the appeal proceedings because it was late filed and not *prima facie* relevant and because no exceptional circumstances for its filing at this stage of the proceedings had been brought forward.

The Board considers that the present argument does not represent an amendment to the appellant's case but rather a refinement of arguments already provided since D10 was merely filed to support a commonly accepted standard already relied upon by the appellant. In any case, this argument does not overcome the fact that the skilled person would not have found in D3 the presently claimed protein concentrations.

3.3.6 The Board therefore considers that D3 either alone or in combination with D10 does not render the claimed subject-matter obvious.

3.3.7 As a result, the main request fulfils the requirement of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

B. Atienza Vivancos A. Jimenez

Decision electronically authenticated