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**Datasheet for the decision
of 6 June 2023**

Case Number: T 0113/22 - 3.3.09

Application Number: 15813827.1

Publication Number: 3232819

IPC: A23L33/00

Language of the proceedings: EN

Title of invention:

INFANT NUTRITION WITH HYDROLYSED PROTEIN AND PALMITIC ACID

Patent Proprietor:

Société des Produits Nestlé S.A.

Opponent:

N.V. Nutricia

Headword:

Infant nutrition/NESTLÉ

Relevant legal provisions:

EPC Art. 84, 123(2), 111(1)
RPBA 2020 Art. 13(2)

Keyword:

Main request and auxiliary requests 1 and 2: clarity (no)
Auxiliary request 3: clarity - (yes); Added subject-matter (no)



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Case Number: T 0113/22 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 6 June 2023

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 14 October 2021
revoking European patent No. 3232819 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman F. Rinaldi
Members: A. Veronese
A. Jimenez

Summary of Facts and Submissions

- I. This decision concerns the appeal filed by the patent proprietor against the decision of the opposition division revoking the European patent.
- II. With its notice of opposition, the opponent had requested revocation of the patent in its entirety on the grounds under Article 100(a) EPC (lack of novelty and lack of inventive step) and 100(b) EPC.
- III. The decision of the opposition division was based on a main request, filed by letter dated 16 July 2021; auxiliary request 1, filed during the oral proceedings held before the opposition division and auxiliary request 2, originally filed as auxiliary request 1 by letter dated 16 July 2021.
- IV. In its decision, the opposition division found, *inter alia*, that the subject-matter of the main request and auxiliary requests 1 and 2 did not fulfil the requirements of Article 123(2) EPC.
- V. Claims 1 and 2 of the main request read:

"Partially hydrolysed protein and an oil mix comprising palmitic acid esterified to triacylglycerols, wherein the palmitic acid esterified in the sn-2 position of triacylglycerol is in the amount of from 20% to 60% by weight of total palmitic acid and palmitic acid esterified in the sn-1(3) position of triacylglycerol is in the amount of from 40% to 80% by weight of total palmitic acid; and wherein the ratio between the partially hydrolysed protein and the sn-2 palmitate is from 1.5:1 to 35:1 based on weight for use in an infant

formula for administration to an infant or young children to reduce calcium excretion, improve calcium homeostasis, increase calcium absorption, increase calcium retention, increase calcium utilization and/or reduce the formation of palmitic acid soaps by said infant or young child in a method for treatment of said infant or young child by therapy."

"2. Non-therapeutic use of partially hydrolysed protein and an oil mix comprising palmitic acid esterified to triacylglycerols, wherein the palmitic acid esterified in the sn-2 position of triacylglycerol is in the amount of from 20% to 60% by weight of total palmitic acid and palmitic acid esterified in the sn-1(3) position of triacylglycerol is in the amount of from 40% to 80% by weight of total palmitic acid; and wherein the ratio between the partially hydrolysed protein and the sn-2 palmitate is from 1.5:1 to 35:1 based on weight, in an infant formula for administration to an infant or young children, to reduce calcium excretion, improve calcium homeostasis, increase calcium absorption, increase calcium retention, increase calcium utilization and/or reduce the formation of palmitic acid soaps by said infant or young child."

VI. Claim 3 of the main request reads:

"Composition for use according to claim 1, or use according to claim 2, wherein the partially hydrolysed protein is partially hydrolysed whey protein."

VII. Claims 4 to 9 and 11 of the main request are worded like claim 3 and define the partially hydrolysed protein and the oil mixture.

- VIII. With its statement setting out the grounds of appeal, the appellant filed auxiliary requests 1 to 8. By its letter of 23 March 2023 in reply to the communication issued by the board in preparation for the oral proceedings, it filed auxiliary requests 9 to 13. During the oral proceedings, it renumbered auxiliary request 9 as auxiliary request 3.
- IX. Claims 1 to 9 of auxiliary requests 1 and 2 are identical to those of the main request.
- X. Auxiliary request 3 (filed as auxiliary request 9) differs from the main request in that claims 3 to 9 and 11 were amended by deleting the embodiment directed to the composition according to claim 1, leaving only the embodiment directed to the use according to claim 2.
- XI. The appellant's arguments can be summarised as follows.
- The opposition division's finding on added subject-matter was wrong because it was based on an unreasonably compartmentalised reading of the application as filed. Claims 1 and 2 were based on claims 1, 8, 12 and 13 and pages 10 to 12 as filed.
 - The application taught that a combination of partially hydrolysed proteins and an oil mix comprising palmitic ester esterified on the sn-2 position of the triglycerides induced the claimed effects. These ingredients were disclosed as active agents in the application as filed. The fact that palmitic acid was present also in the sn-1(3) position did not change this interpretation.

- This teaching could be combined with the features of the ratio between these active ingredients and the uses disclosed in claims 8 and 13 as filed. Thus, the combinations of the features in claims 1 and 2 did not create subject-matter extending beyond the content of the application as filed.
- Claims 10 and 11 did not create new subject-matter either because they were based on a combination of the teaching of claims 12 and 13 as filed with that of claims 15 and 16 and on page 23 as filed.
- Claims 3 to 9 were clear. It was evident that the "composition" mentioned in these claims was the combination of the oil mixture and the hydrolysed proteins mentioned in claim 1.
- The auxiliary requests addressed the objections raised, were to be admitted and were allowable. Auxiliary requests 9 to 13 overcame a clarity objection which the appellant did not have to address in the statement setting out the grounds of appeal. Therefore, these requests had to be admitted.
- The case had to be remitted to the opposition division for further prosecution on the basis of the main request or one of the auxiliary requests.

XII. The opponent's (respondent's) arguments may be summarised as follows.

- Claims 1 and 2 of the main request contained subject-matter extending beyond the content of the application as filed. New subject-matter was

generated by the rewording of these claims and by the combination of the following features:

- an oil characterised by the claimed pattern of esterification in the sn-2 and sn-1(3) positions
- the claimed ratio between the hydrolysed protein and the sn-2 palmitate
- the uses listed in these claims
- These features were disclosed in separate parts of the description and claims of the application as filed but not in combination. The purported uses concerned different embodiments which could not be combined. The definition of the active agents was changed compared to in the application.
- Dependent claims 10 and 11 of the main request contained added subject-matter because in the application as filed the uses specified in these claims were not correlated with those relating to calcium excretion, now specified in claim 1.
- Claims 3 to 9 were unclear because they referred to a composition which lacked an antecedent in claim 1.
- The same arguments applied to the auxiliary requests.
- If any request was found to meet the requirements of Article 123(2) EPC, the case was to be remitted for further prosecution.

The requests

XIII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution on the basis of:

- the main request, which had been considered by the opposition division, or, alternatively
- auxiliary requests 1 or 2 filed with the statement setting out the grounds of appeal or
- auxiliary request 3 filed as auxiliary request 9 with the letter of 23 March 2023 or
- auxiliary requests 4 to 9 filed as auxiliary requests 3 to 8 with the statement setting out the grounds of appeal or
- auxiliary requests 10 to 13 filed with the letter of 23 March 2023

XIV. The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. *Allowability of the amendments*

Claims 1 and 2

1.1 Claim 1 and 2 of the main request derive from claim 1 as originally filed. The originally filed claim 1, which was directed to "*A composition for use in formulaes for infants or young children comprising...*", was split into two claims which distinguish the therapeutic from the non-therapeutic uses of the ingredients in the original composition.

1.2 Amended claims 1 and 2 differ from claim 1 as originally filed in that:

- the wording "A composition for use in formulaes for infants and young children comprising partially hydrolysed protein and an oil mix comprising palmitic acid esterified to triacylglycerols... " has been changed to:

"Partially hydrolysed protein and an oil mix comprising palmitic acid esterified to triacylglycerols... for use in infant formula... in a method for treatment.... by therapy " in amended claim 1 and to

"Non-therapeutic use of partially hydrolysed protein and an oil mix comprising palmitic acid esterified to triacylglycerols...in an infant formula..." in amended claim 2

- a ratio between the partially hydrolysed protein and the sn-2 palmitate has been specified which was disclosed in claim 8 as filed
- uses relating to effects on calcium metabolism, which were disclosed in claims 12 and 13 as filed, have been indicated

1.3 The wording in amended claims 1 and 2 focuses on the ingredients in the originally disclosed composition rather than the composition comprising those ingredients. The appellant explained that it had reworded these claims to identify the partially hydrolysed protein and the oil mix as the active agents inducing the claimed therapeutic and non-therapeutic effects.

- 1.4 The opposition division decided that amended claims 1 and 2 created new subject-matter because the parts of the application focusing on a combined use of hydrolysed protein and sn-2 palmitate (page 10, lines 22 to 25, page 11, lines 5 to 10 and page 12, lines 17 to 34) were silent as to the ratio between the hydrolysed protein and sn-2 palmitate and the uses listed in the claims. Since the combination of these features was not disclosed in the application, the amendments created originally undisclosed subject-matter.
- 1.5 The respondent endorsed this view during the appeal. Furthermore, it submitted that according to the application as filed, only the palmitic acid esterified in the sn-2 position of the triacylglycerols in the oil mix was an active agent, not that esterified in the sn-1 position. Page 2 as filed taught that sn-1 palmitate induced an increase rather than a decrease of calcium excretion. Thus, the rewording of the claims created originally undisclosed subject-matter.
- 1.6 The board does not concur with this view and agrees with the appellant that the arguments of the opposition division and the respondent are based on an unreasonably compartmentalised reading of the application as filed.
- 1.7 The skilled person reading claims 1, 8, 12 and 13 as filed would understand first that the composition defined in claims 1 to 8, which comprises the partially hydrolysed protein and the oil mixture defined in these claims, is meant to induce the uses specified in claims 12 and 13. Furthermore, the skilled person reading these claims in combination with the aforementioned

passages on pages 10 to 12 would also understand that the hydrolysed protein and the oil mixture comprising triacylglycerols esterified by the specified amount of palmitic acid in the sn-2 position are the active agents of the composition. Moreover, they would learn that as long as the triacylglycerols in the oil contain the claimed amount of palmitate in the sn-2 position, the triacylglycerols can also contain palmitate in the sn-1(3) position in the given amount. In other words, according to the teaching of the application as filed, the sn-1(3) substitution does not disqualify the oil mixture containing these triacylglycerols as the "active agent".

- 1.8 For these reasons, neither the change in wording adopted in claims 1 and 2 nor the addition of the features disclosed in claims 8 and 12 as filed, which define the ratio between the active agents and the intended uses, creates originally undisclosed subject-matter.
- 1.9 The respondent also argued that the "reduction of calcium secretion" was disclosed in claim 12 as filed as a separate embodiment from the other uses (e.g. improvement of calcium homeostasis and increase of calcium absorption), which were disclosed in claim 13 as filed. In its opinion, the combination of these uses in amended claims 1 and 2 created new subject-matter.
- 1.10 This argument is not convincing either. Despite being mentioned in different claims as filed, all these uses relate to improvements of calcium metabolism. Listing them in one single claim, rather than in separate claims, does not create new subject-matter.

Claims 10 and 11

- 1.11 Claims 10 and 11 of the main request depend on claims 1 and 2 and define the use of the agents for improving different aspects of calcium metabolism which were disclosed in claims 12 and 13 as filed.
- 1.12 Dependent claims 10 and 11 further specify the use of the claimed agents respectively for:
- improving sleep duration, improving sleep quality and quantity in the infant, improving infant and parent quality of life and reducing maternal anxiety - these aspects were disclosed in claim 15 as filed
 - increasing bone mineralisation, bone strength and bone mineral density in the infant - these aspects were disclosed in claim 16 as filed
- 1.13 The opposition division and the respondent argued that since claims 15 and 16 as filed did not depend on claims 12 and 13 as filed, the combination of the uses in amended claims 10 and 11 with those of claims 1 and 2 created subject-matter extending beyond the content of the application as filed.
- 1.14 This argument fails to convince. It is clear from page 23 of the application as filed that the various uses mentioned in claims 10 and 11 are mediated by an improvement in calcium metabolism triggered by the mechanisms specified in claims 1 and 2. Thus, by referring to claims 1 and 2, claims 10 and 11 do not create originally undisclosed subject-matter.

1.15 For these reasons, it is concluded that claims 1, 2, 10 and 11 comply with the requirements of Article 123(2) EPC.

2. *Clarity of claims 3 to 9 and 11*

2.1 As mentioned above, claim 1 as filed, which was directed to "A composition for use in formulaes for infants or young children comprising...", was split into two claims, using a wording which identifies the partially hydrolysed protein and the oil mix as the active agents inducing the claimed therapeutic and non-therapeutic effects. Amended claim 1 has been re-worded using the format of Article 54(5) EPC, whereas claim 2 has been formulated as a use claim.

2.2 However, claims 3 to 9 and 11, which according to one embodiment depend on claim 1, have not been adapted to the wording of this claim. In fact, they still refer to the "composition" defined in claim 1 as filed. Therefore, although claims 3 to 9 and 11 formally depend on claim 1, they have a different claim category.

2.3 The scope of a claim directed to a product, like claim 1 as filed, differs from that of a claim drafted under Article 54(5) EPC or as a use claim. This creates doubts as to the scope of claims 3 to 9 and 11, which are still directed to a "composition".

2.4 The appellant argued that the skilled person would understand that the composition of claims 3 to 9 and 11 is made up of the combination of the protein mixture and the oil mix defined in claim 1. However, this argument does not resolve the uncertainty relating to

claim scope caused by mixing claims of different categories.

- 2.5 Thus, claim 3 to 9 and 11 do not clearly define the matter for which protection is sought and do not fulfil the requirements of Article 84 EPC.

Auxiliary requests 1 and 2

3. *Clarity*

- 3.1 Claims 1 to 9 of auxiliary requests 1 and 2 are identical to those of the main request. Thus, the conclusion that claims 3 to 9 lack clarity apply equally to auxiliary requests 1 and 2. Accordingly, these requests are also not allowable.

Auxiliary request 3

4. *Admittance*

- 4.1 Auxiliary request 3 was filed as auxiliary request 9 in reaction to the communication issued by the board in preparation for the oral proceedings. It differs from the main request in that the embodiment directed to a "composition" in claims 3 to 9 and 11 was deleted.
- 4.2 The appellant submitted that this amendment was made in direct response to the board's preliminary opinion in the communication that claims 3 to 9 of the main request were unclear. It is true that the clarity issue was raised by the respondent during the opposition proceedings. However, in its preliminary opinion, the opposition division considered that these claims were clear.

- 4.3 Therefore, there was no reason for the appellant to file a request addressing this issue during the proceedings before the opposition division. This clarity issue was not addressed in the opposition division's decision either. Hence, the appellant had no reason to address it when filing its statement setting out the grounds of appeal.
- 4.4 As it later turned out, the respondent raised the clarity objection again in its reply to the statement of grounds of appeal.
- 4.5 Under these circumstances, the board considers it appropriate to give the appellant the opportunity to address this objection in the appeal proceedings. The deletion of the reference to a "composition" in dependent claims 3 to 9 and 11 directly addresses the clarity issue raised by the respondent and taken up in the board's communication under Article 15(1) RPBA. This amendment is simple and not detrimental to procedural economy.
- 4.6 During the oral proceedings, the respondent argued that auxiliary request 3 should not be admitted because it raised new issues. It noted that after the deletion of the embodiment directed to a "composition" in claims 3 to 9 and 11, the dependent claims only related to the uses in claim 2, which were said to be non-therapeutic. This despite the fact that, in its opinion, some of the uses set out in claim 9 were necessarily medical. Therefore, new issues of clarity and added subject-matter were created by the amendment.
- 4.7 This argument fails to convince the board. The same issues were present in the auxiliary requests filed by the appellant with its statement setting out the

grounds of appeal. For instance, auxiliary request 3 filed with that statement (renumbered as auxiliary request 4) included claims on increasing bone mineralisation, bone strength and bone mineral density or on preventing or reducing the risk of constipation in the infant. These uses were also defined as non-therapeutic. However, the respondent did not raise any objection against these claims in its reply to the statement setting out the grounds of appeal. The board considers that these objections could and should have been raised with that reply. Since they were filed at a very late stage of the appeal proceedings, the board decided to disregard them.

4.8 For these reasons, the board considers that there are exceptional circumstances which justify that auxiliary request 3 be taken into account. Accordingly, this request is admitted into the appeal proceedings (Article 13(2) RPBA 2020).

5. *Allowability of the amendments and clarity*

5.1 As mentioned above, auxiliary request 3 addresses the clarity objection which led to the finding that the main request was not allowable. The embodiment considered unclear has in fact been deleted.

5.2 As stated in paragraph 4.6 above, during the oral proceedings before the board, the opponent raised an objection of added subject-matter against claim 9 of auxiliary request 3. This can be considered a separate and additional objection against claim 1 of auxiliary request 3. However, this objection raised for the first time at the oral proceedings constitutes an amendment of the respondent's case. It is irrelevant that the objection was formally raised for a set of claims filed

after the summons to oral proceedings since, as mentioned in paragraph 4.7, the issue had already been present in the previously filed claims. There are no exceptional circumstances for allowing amendments in the respondent's case at such a late stage of the appeal proceedings (Article 13(2) RPBA 2020). The respondent should have raised these objections in its reply to the statement setting out the grounds of appeal. Therefore, this objection has been disregarded.

5.3 No further objections of lack of clarity or added subject-matter were raised against the claims of this request. Therefore, the claims of auxiliary request 3 are considered to fulfil the requirement of clarity and not to contain added subject-matter for the same reasons presented when discussing the main request.

6. *Remittal*

6.1 The decision under appeal only dealt with added subject-matter under Article 123(2) EPC. The parties agreed that should any request be considered to meet the requirements of this article, the case be remitted to the opposition division for further prosecution for the other grounds for opposition raised to be examined.

6.2 In view of these circumstances, the board considers that there are special reasons to remit the case to the opposition division for further prosecution (Article 111(1) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division for further prosecution.

The Registrar:

The Chairman:



M. Schalow

F. Rinaldi

Decision electronically authenticated