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**Datasheet for the decision
of 27 March 2014**

Case Number: T 0775/12 - 3.3.09

Application Number: 03795909.5

Publication Number: 1575377

IPC: A23L1/30, A23L1/29

Language of the proceedings: EN

Title of invention:

NUTRITIONAL FORMULA COMPRISING L(+) LACTIC ACID

Patent Proprietor:

Nestec S.A.

Opponent:

N.V. Nutricia

Headword:

Relevant legal provisions:

RPBA Art. 12(2)

EPC Art. 123(2), 84, 56

Keyword:

New objection under Article 123(2) EPC (not admitted)

Claims - clarity - main request (yes)

Inventive step - main request (yes)

Decisions cited:

Catchword:



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Case Number: T 0775/12 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 27 March 2014

Appellant:
(Patent Proprietor)

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 27 January 2012
revoking European patent No. 1575377 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman:

W. Sieber

Members:

M. O. Müller

E. Kossonakou

Summary of Facts and Submissions

- I. This decision concerns the appeal filed by the proprietor of European patent No. 1 575 377 against the decision of the opposition division to revoke it.
- 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) and that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC).

The documents submitted during the opposition proceedings included:

- D1: A. Ballabriga et al, "Metabolic response of prematures to milk formulas with different lactic acid isomers or citric acid", Helvetica Paediatrica Acta 1970, 1, 1969, pages 25 to 34;
- D2: G. Boudras et al, "Effect of Feeding Yoghurt Versus Milk in Children With Acute Diarrhea and Carbohydrate Malabsorption", Journal of Pediatric Gastroenterology and Nutrition 33, 2001, pages 307 to 313;
- D5: US 5,972,393;
- D7: US 6,475,539 B1;
- D9: US 6,423,354; and
- D10: US 4,212,893.

III. The opposition division's decision, announced orally on 16 November 2011 and issued in writing on 27 January 2012, was based on a main and first to fourth auxiliary requests.

The main request was rejected for lack of novelty.

Independent claims 1 and 5 of the first auxiliary request, which is the only request relevant to the present decision, read as follows:

"1. A powdered nutritional formula comprising a protein source, a carbohydrate source and a lipid source, wherein the pH of the formula, in its liquid state, is in the range of 3.5 to 6, wherein the formula comprises lactic acid and whereby at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid, characterized in that the formula is directly acidified with L(+)-lactic acid and contains 0.5-3% of L(+)-lactic acid based on the dry weight of the formula."

"5. A method of preparing the powdered nutritional formula according to any of claims 1-4, comprising the steps of

- hydrating the protein source and/or the carbohydrate source,
- adding diluted L-(+) lactic acid to hydrated carbohydrate source and/or the hydrated protein source in an amount of 0.5-3% of L(+)-lactic [sic] acid based on the dry weight of the formula until a pH of about 3.5 - 6 is obtained; and
- drying the obtained mixture."

In the opposition division's view, the only difference between the subject-matter of claim 1 of the first auxiliary request and closest prior art document D2 was the fact that the claimed formula was powdered. No effect had been shown to result from this difference. The objective technical problem was therefore an alternative nutritional formula that had bacteriostatic activity, which was provided without fermentation and had no adverse effects in infants. The patent and D2 solved this problem by directly acidifying with L(+) lactic acid, and D5 and D7 both disclosed acidified formulations which were powdered. The claimed powdered formulae were hence obvious. The same argument applied to the process of independent claim 5. More specifically, the only difference was a drying step to prepare the powdered formulae, and there was no prejudice in the prior art against this.

The second and third auxiliary requests were considered not to meet the requirements of Article 56 EPC either, and the fourth auxiliary request was rejected for not meeting the requirements of Article 123(3) EPC.

IV. On 30 March 2012, the proprietor (hereinafter "the appellant") filed an appeal and, on the same day, paid the prescribed fee. The statement setting out the grounds of appeal was filed on 6 June 2012 together with a main and first to fifth auxiliary requests as well as

D11: Declaration of N. J. Krebs, signed 5 June 2012.

Claim 1 of the first auxiliary request, which is the only request relevant to the present decision, reads as follows:

"1. A method of preparing a powdered nutritional formula comprising a protein source, a carbohydrate source and a lipid source, wherein the pH of the formula, in its liquid state, is in the range of 3.5 to 6, wherein the formula comprises lactic acid and whereby at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid, comprising the steps of

- hydrating the protein source and the carbohydrate source;
- adding the lipid source;
- adding diluted L-(+) [*sic*] lactic acid to the hydrated carbohydrate source, the hydrated protein source and the lipid source until a pH of about 3.5 - 6 is obtained, the lactic acid addition taking place in-line; and
- drying the obtained mixture."

V. A response was filed by the opponent (hereinafter "the respondent") with its letter of 24 December 2012.

VI. On 17 July 2013, the parties were summoned to oral proceedings. In the annex to the summons, the board gave its preliminary opinion *inter alia* on the clarity, novelty and inventive step of the first auxiliary request.

VII. By its letter of 30 September 2013, the appellant withdrew all previous requests and filed a new main and first and second auxiliary requests. The sole claim 1 of the new first auxiliary request was identical to

claim 1 of the previous first auxiliary request (see point IV above).

VIII. On 27 March 2014, oral proceedings were held before the board. At the beginning of the oral proceedings, the appellant withdrew its main request and made the previous first auxiliary request its new main request. Furthermore, amended pages of the description in line with the new main request were filed during the oral proceedings.

IX. The appellant's arguments, in as far as relevant for the present decision, can be summarised as follows:

- Main request - new objection under Article 123(2) EPC

During the oral proceedings, the respondent raised for the first time an objection under Article 123(2) EPC against claim 1 of the main request. The appellant requested that this objection not be admitted into the proceedings. Claim 1 of the main request was identical to claim 1 of the first auxiliary request filed with the statement of grounds of appeal. Therefore, the respondent could already have raised this objection in its response to the grounds of appeal. Since this attack was however presented only at the oral proceedings before the board, it was not in line with Article 12(2) RPBA and therefore should not be admitted. Regardless of this, the combination of the four process steps in claim 1 was based on the application as filed, namely claims 2 and 7 to 9, page 10, line 7, page 13, lines 27 and 34, and page 14, line 12, of the application as filed. Both in-line addition

and drying were disclosed in the cited passages in a general way and were not linked to any specific process embodiments. It was thus allowable to isolate these two features and to combine them with the remaining process features as disclosed in the application as filed.

- Main request - amendments - Article 84 EPC

The respondent's objection that the feature of in-line addition in claim 1 rendered this claim unclear was not correct. In-line addition meant that the lactic acid was added by a continuous process step, and this was clear for a person skilled in the art. It was also not true that essential features were missing in the claim that were necessary to avoid precipitation in the resulting nutritional formula.

- Main request - inventive step

In the same way as the opposed patent, D7 was directed to the preparation of acidified nutritional formulae that had the advantage of a reduced microbial contamination and did not show protein precipitation. D7 therefore represented the closest prior art. The claimed process differed from that of D7 in that the lactic acid was added in-line. The problem solved by this in-line addition was the provision of a more economical process that led to acidified nutritional formulae without any protein precipitation and without the need to use a stabiliser. That the claimed in-line addition led to a more economical process was proven by the patent, according to which the process of

example 3, where the lactic acid was added in-line, was more efficient and allowed for a higher turnover than that of examples 1 and 2, where the lactic acid was added batch-wise. Furthermore, due to this in-line addition a high concentration of lactic acid, which led to protein precipitation, was avoided. D7 taught that a stabiliser was essential to avoid protein precipitation. A similar teaching was present in D9 and D10. Therefore, the skilled person would not have expected on the basis of D7, D9 or D10 that protein precipitation could be avoided without the presence of a stabiliser. As regards the process of D5, this was a fermentation process. If the skilled person had applied the teaching of D5 to that of D7, he would have replaced the direct addition of lactic acid in D7 by this fermentation process. Finally, the only explicit disclosure of the way in which the acid was added in D7 was of a batch-wise addition. Therefore the reference to conventional equipment and process technology in D7 did not imply that D7 taught a continuous process.

X. The respondent's arguments, in as far as relevant for the present decision, can be summarised as follows:

- Main request - new objection under Article 123(2) EPC

An objection under Article 123(2) EPC had been raised against the previous main request, and the objection raised against the current main request could thus not be a surprise to the appellant. This objection should therefore be admitted into the proceedings. The objection was based on the

fact that the combination of the four process steps in claim 1 of hydrating a protein source and a carbohydrate source, adding a lipid source, adding diluted L(+) lactic acid in-line until a certain pH is reached and drying the obtained mixture to obtain a powder was not based on the application as filed. More specifically, claim 7 as filed contained only two of these four steps, and compared to page 10, lines 13 to 26, of the application as filed, present claim 1 represented an intermediate generalisation.

- Main request - amendments - Article 84 EPC

The feature in claim 1 of adding the lactic acid in-line rendered claim 1 unclear, since essential features were missing in the claim that were necessary in order to prepare products that had the advantages mentioned in D11, such as being devoid of any precipitated protein.

- Main request - sufficiency of disclosure and novelty

During the oral proceedings, the respondent explained that the objection made in the written proceedings under Article 83 EPC was not maintained. The respondent furthermore stated that it did not have any novelty objections.

- Main request - inventive step

D7 constituted the closest prior art. The claimed process differed from the one in D7 in that the lactic acid was added in-line. It was stated in the patent itself that the product of example 3,

where the lactic acid was added in-line, was the same as that obtained in examples 1 and 2, where the acid was added batch-wise. The claimed in-line addition of the lactic acid thus did not lead to any advantageous product properties. The appellant's argument that stabilisers could be avoided by the claimed process was irrelevant since the claim covered processes where stabilisers were present. D7 already disclosed that any conventional process technology could be used. In-line addition of an acid was conventionally known, and therefore this process step was obvious. Finally it was stated in the patent that the acid may be added in-line or batch-wise, which implied that both process variants were totally equivalent. To replace the batch-wise addition of the acid in D7 by in-line addition was thus a trivial matter which could not contribute to inventive step.

- XI. The appellant requested that the decision under appeal be set aside and that the European patent be maintained on the basis of claim 1 of the main request (originally filed with letter dated 30 September 2013 as first auxiliary request) and the amended description pages 2 to 10 filed at the oral proceedings.

- XII. The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.
2. *Main request - new objection under Article 123(2) EPC*
 - 2.1 The sole claim 1 of the main request refers to a method of preparing a powdered nutritional formula, the process comprising the four steps of hydrating a protein source and a carbohydrate source, adding a lipid source, adding diluted L(+) lactic acid in-line until a certain pH is reached and drying the obtained mixture to obtain a powder (for the exact wording of claim 1, see points IV and VII above).
 - 2.2 During the oral proceedings before the board, the respondent raised the objection that this combination of process steps was not based on the application as filed.

The appellant requested that the respondent's objection, raised for the first time at the oral proceedings, not be admitted into the proceedings.

 - 2.2.1 Claim 1 of the main request is identical to claim 1 of the first auxiliary request filed with the statement of grounds of appeal (letter of 6 June 2012). In its response to the statement of grounds of appeal (letter of 24 December 2012), the respondent did not raise any objection under Article 123(2) EPC against this claim of the first auxiliary request.
 - 2.2.2 Pursuant to Article 12(2) RPBA, the response to the statement of grounds of appeal shall contain the respondent's complete case. This response shall set out

clearly and concisely the reasons why it is requested that the decision under appeal be upheld, and should specify expressly all the facts, arguments and evidence relied on.

These requirements are not met in the present case. More specifically, the respondent's objection under Article 123(2) EPC against claim 1 of the main request and the related arguments were presented for the first time at the latest possible point in time, namely during the oral proceedings before the board. The respondent did not give any reason why this objection was not raised with its response to the statement of grounds of appeal, and no reason is apparent to the board. In particular, since claim 1 of the main request had already been on file when the response to the statement of grounds of appeal was filed (see point 2.2.1 above), this objection could, and should, have been raised at that point in time, pursuant to Article 12(2) RPBA.

The respondent argued that an objection under Article 123(2) EPC had already been raised against the previous main request and thus the present objection could not be a surprise to the appellant. However, the previous objection was that the term "in-line" in product claim 1 contravened Article 123(2) EPC. That objection is entirely different from the present one, i.e. that the combination of the four process steps in independent process claim 1 is not based on the application as filed. Thus, the respondent's argument must fail.

2.2.3 The board therefore decided not to admit the present objection under Article 123(2) EPC and related arguments into the proceedings (Article 13(1) RPBA).

2.3 In these circumstances, there is no need to decide on the validity of the present objection. The board would however like to note that even if the objection and related arguments had been admitted into the proceedings, the objection would have been without merit. More specifically, the three steps of hydrating the protein and carbohydrate source, adding the lipid source and adding the diluted L(+) lactic acid until a certain pH is reached are based on claims 7 to 9 as filed. The feature in the third step that the lactic acid addition takes place in-line is based on page 10, line 7, page 11, line 31, and page 12, lines 27 to 28, of the application as filed. The drying step (fourth step of the claimed process) is based on page 13, lines 27 and 34, of the application as filed. The step of drying implies that the resulting formula is powdered. Regardless of this, the feature of the resulting formula being powdered is clearly and unambiguously derivable from the back-reference of claim 7 to *inter alia* claim 2 as filed. Both in-line addition and drying are disclosed in the cited passages in a general way and are not linked to any specific process embodiments. The isolation of these two features and their combination with the remaining process features disclosed in the application as filed therefore do not contravene Article 123(2) EPC.

3. *Main request - amendments - Article 84 EPC*

3.1 Claim 1 of the main request differs from the corresponding granted claim 6 in that the lactic acid is added in-line. In the respondent's view, this feature did not meet the requirements of Article 84 EPC since essential features were missing in the claim that were necessary in order to prepare products that had

the advantages mentioned in D11, such as being devoid of any precipitated protein.

- 3.2 According to Article 84 EPC the claims must be supported by the description. In the present case, it cannot be deduced from the description that certain features of the in-line addition are essential to obtain the desired products. The fact that no such features are present in claim 1 thus does not mean that this claim lacks support in the description. Therefore, this requirement of Article 84 EPC is met by claim 1.

Furthermore, as not disputed by the respondent, the feature of in-line addition means that the acid is added by a continuous - as opposed to batch-wise - process step, and how such a process step is performed is known to the skilled person. This feature is therefore clear, such that the further requirement of Article 84 EPC of the claims being clear and concise is met as well.

No further objections have been raised by the respondent, and the board is satisfied that the amendments in claim 1 meet the requirements of Article 84 EPC.

4. *Main request - sufficiency of disclosure and novelty*

- 4.1 The respondent mentioned in passing in its written response to the statement of grounds of appeal with regard to the main and auxiliary requests then on file that the requirements of Article 83 EPC were not complied with (first paragraph of page 3 of its letter of 24 December 2012). During the oral proceedings, the respondent explained that this objection was not maintained in respect of the new main request.

The respondent furthermore stated during the oral proceedings that it did not have any novelty objections.

The board too is satisfied that the invention as claimed is sufficiently disclosed and that the subject-matter of the sole claim 1 of the main request is novel over the cited prior art.

5. *Main request - inventive step*

5.1 The invention underlying the opposed patent concerns a process for preparing nutritional formulae that are acidified to prevent growth of pathogens while avoiding protein precipitation (page 2, lines 5 to 7 and 39 to 41).

5.2 In the same way, D7 aims at acidified nutritional formulae that have the advantage of a reduced microbial contamination and do not show protein precipitation (column 1, lines 43 to 48). As agreed upon by both parties during the oral proceedings, D7 can therefore be considered to represent the closest prior art.

D7 (column 15, line 25, column 19, line 46, to column 20, line 19, and column 20, lines 51 to 54) discloses a process of preparing a nutritional formula comprising the steps of

- mixing pectin with water, a calcium source and minerals and adding a carbohydrate to form a carbohydrate/mineral slurry and mixing a source of protein with water to form a protein slurry;
- combining the aqueous carbohydrate/mineral slurry with the protein slurry and subsequently with an oil blend;

- homogenizing the resulting blend;
- acidifying the blend with an edible acid to obtain a pH of about 4.0 to 4.35 with the edible acid being, e.g., lactic acid (column 15, line 25); and
- drying the resulting beverage and supplying it in the form of a powder (column 20, lines 51 to 54).

The step of mixing the pectin with water, a source of calcium and minerals and adding a carbohydrate to form a carbohydrate/mineral slurry and of mixing the source of protein with water to form a protein slurry corresponds to the first step of the claimed process.

The step of combining the carbohydrate/mineral slurry with the aqueous protein slurry and subsequently with the oil blend (a lipid source) corresponds to the second step of the claimed process.

The step of acidifying the blend e.g. with lactic acid to obtain a pH of about 4.0 to 4.35 corresponds to the third step of the claimed process, except for the feature of in-line addition of the acid.

Finally, the step of drying the resulting beverage and supplying it in the form of a powder corresponds to the last step of the claimed process.

In the above-discussed description of the process in columns 19 and 20 of D7, it is not disclosed how the lactic acid is added. The only disclosure present in this respect can be found in column 25, lines 50 to 52, where it is stated that the acid (in this case citric and phosphoric acid) is added "to the batch", which rather indicates that the acid addition occurs batch-wise. As agreed upon by both parties during the oral

proceedings, the claimed process therefore differs from that of D7 in that the lactic acid is added in-line.

- 5.3 One of the problems addressed in the opposed patent is the provision of a process that is more economical (page 2, lines 42 to 43).
- 5.4 As a solution to this problem the patent in suit proposes a process according to claim 1 which is characterised in that the lactic acid is added in-line instead of the batch-wise addition of D7.
- 5.5 It is stated on page 9, lines 26 to 27, of the patent that the process according to example 3, where the lactic acid is added in-line, is more efficient and allows for a higher turnover than that of examples 1 and 2, where the lactic acid is added batch-wise. In view of this statement, it is credible that the above problem is solved over D7. This problem therefore constitutes the objective technical problem.
- 5.6 It remains to be examined whether the skilled person confronted with this problem of providing a more economical process would have replaced the batch-wise addition of D7 by an in-line addition of the lactic acid.
 - 5.6.1 Neither D7 nor any of the further cited prior art documents makes any reference to a continuous production process, let alone to a continuous process where specifically the acid is added in-line. Even less so is there any suggestion in the cited prior art that by using such an in-line addition of the acid, the process could be made more economical. Consequently, the skilled person looking for a more economical process would have had no reason to add the acid in the

specific process disclosed in D7 in-line as required for the process of claim 1. The claimed process is thus not obvious.

- 5.6.2 The respondent referred in this respect to column 19, lines 34 to 36, of D7, where it is stated that the beverage according to the invention of D7 can be prepared using conventional equipment and process technology known to those skilled in the art. In the respondent's view, in-line addition was conventionally known and thus obvious in view of this statement in D7.

The board however does not agree. As set out above, the only explicit disclosure of the way in which the acid is added in D7 is a batch-wise addition. Therefore the reference to conventional equipment and process technology would be read by the skilled person rather as a reference to a conventional batch-wise process using conventional equipment.

- 5.6.3 The respondent further argued that according to page 5, lines 32 to 33, of the patent, in-line addition was equivalent to batch-wise addition and hence obvious.

The board does not agree with this argument either. The patent states in the cited passage that "[f]or example, it was found that L+ lactic acid may be added in-line or batch-wise...". The fact that both in-line and batch-wise addition are possible does not necessarily imply that they are equivalent. On the contrary, as can be deduced from page 9, lines 26 to 27, of the patent, in-line addition is more efficient and has a higher turnover than batch-wise addition (see point 5.5 above).

5.7 The process of the sole claim 1 of the main request is therefore inventive.

5.8 Since the decision is thus in favour of the appellant, there is no need to discuss the merits of the appellant's further argument, namely that an additional problem solved by the in-line addition of the acid over D7 is the avoidance of protein precipitation without the need to use a stabiliser.

5.9 Finally, since both parties agreed during the oral proceedings that D7 - rather than D1 or D2 - was the closest prior art, and since the board agrees with this, there is no need to discuss inventive step starting from D1 or D2 as the closest prior art.

6. *Adaptation of the description*

6.1 After the board had announced its opinion on the main request, the appellant submitted adapted description pages 2 to 10. The respondent had no objection and the board too is satisfied that the amended description meets the requirements of the EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent as amended in the following version:
 - Description, pages 2 to 10, as filed during the oral proceedings;
 - Claim 1 of the main request, filed with letter dated 30 September 2013 as first auxiliary request.

The Registrar:

The Chairman:



M. Cañueto Carbajo

W. Sieber

Decision electronically authenticated