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Datasheet for the decision of 24 May 2022

Case Number: T 0277/19 - 3.3.09

Application Number: 07787372.7

Publication Number: 2046143

IPC: A23L29/10, A23L29/212

Language of the proceedings: EN

Title of invention:
STABILISER SYSTEM FOR LIQUID NUTRITIONAL COMPOSITIONS

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponent:
Fresenius Kabi Deutschland GmbH

Headword:
Stabiliser system for liquid nutritional compositions/NESTLÉ

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

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It can be changed at any time and without notic

Keyword:
Inventive step - main request and auxiliary requests 1 to 3 - (no)
Amendment after summons - auxiliary requests 4 and 5 - exceptional circumstances (no)

Decisions cited:
T 1187/16, T 2610/16, T 0042/17

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Case Number: T 0277/19 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 24 May 2022

Appellant: (Opponent)	Fresenius Kabi Deutschland GmbH Else-Krömer-Strasse 1 61352 Bad Homburg (DE)
Representative:	Fresenius Kabi Deutschland GmbH Patent Department Pharmaceuticals Division Borkenberg 14 61440 Oberursel (DE)
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)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 13 November 2018 rejecting the opposition filed against European patent No. 2046143 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Haderlein
Members:	M. Ansorge
	J. Hoppe

Summary of Facts and Submissions

I. The opponent (appellant) lodged an appeal against the opposition division's decision rejecting the opposition.

II. With its notice of opposition, the opponent had requested that the patent be revoked on the ground for opposition under Article 100(a) EPC (lack of inventive step), *inter alia*.

III. The opposition division decided, *inter alia*, that the subject-matter of claim 1 of the patent as granted involved an inventive step in view of D3 as the closest prior art.

IV. In the present decision, reference is made to the following documents:

D3: US 3,950,547
D12: G. Eisenbrand, P. Schreier, "Römpp Lexikon Lebensmittelchemie", second edition, 2006, entry "Stärke", pages 1100 and 1101

V. Claim 1 of the patent as granted (main request) reads as follows:

"A liquid nutritional composition comprising partially hydrolysed protein, fat and from 0.1 to 10 grams per litre of an emulsifier with a hydrophilic lipophilic balance value of less than 5, from 0.1 to 10 grams per litre of an emulsifier with a hydrophilic lipophilic balance value of more than 5 and from 0.01 to 20 grams per litre of a low amylose starch, having an amylose content of less than 50% by weight."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the feature "wherein the emulsifier with a hydrophilic lipophilic balance value of less than 5 is a fatty acid monoglyceride or a fatty acid diglyceride and wherein the emulsifier with a hydrophilic lipophilic balance value of more than 5 is a citric acid ester of mono- and/or diglycerides, a diacetyl tartaric acid ester of mono- and/or diglycerides or lecithin" has been added to the end of claim 1.

Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the feature "having an amylose content of less than 50% by weight" has been replaced with "having an amylose content of less than 30% by weight".

Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 1 in that the feature "having an amylose content of less than 50% by weight" has been replaced with "having an amylose content of less than 30% by weight".

Claim 1 of auxiliary request 4 differs from claim 1 of the main request in that the feature "from 0.01 to 20 grams per litre of a low amylose starch" has been replaced with "from 2.0 to 10.0 grams per litre of a low amylose starch".

Claim 1 of auxiliary request 5 reads as follows:

"A method of stabilising a liquid nutritional composition including partially hydrolysed protein and fat, comprising adding to the composition from 0.1 to 10 grams per litre of an emulsifier with a hydrophilic lipophilic balance value of less than 5,

from 0.1 to 10 grams per litre of an emulsifier with a hydrophilic lipophilic balance value of more than 5 and from 0.01 to 20 grams per litre of a low amylose starch, having an amylose content of less than 50% by weight."

VI. The board issued a communication pursuant to Article 15(1) RPBA indicating its preliminary opinion that the subject-matter of claim 1 of the main request and auxiliary requests 1 to 3 did not involve an inventive step in view of D3 as the closest prior art.

VII. The parties' relevant arguments, submitted in writing and during the oral proceedings, are reflected in the reasons for the decision below.

VIII. Requests

The appellant requested that the decision be set aside and that the patent be revoked in its entirety.

The respondent (proprietor) finally requested that the appeal be dismissed (main request), or as an auxiliary measure, that the patent be maintained in amended form on the basis of one of auxiliary requests 1 to 3, filed with the reply to the grounds of appeal, or on the basis of one of auxiliary requests 4 and 5, filed by letter dated 25 April 2022.

Reasons for the Decision

MAIN REQUEST

1. Inventive step

1.1 The parties agreed that D3 was the closest prior art document in the case at hand. The board does not see any reason to deviate from this starting point.

1.2 D3 relates to a dry dietary food composition, for consumption mixed with water as an aqueous emulsion having improved stability, comprising, by dry wt., about from 3 to 40% of a nutritionally balanced peptide mixture, or amino acid supplemented peptide mixture, said peptide mixtures having a total amino acid profile sufficient to support normal human physiological functions; about from 2 to 35% lipid, said lipid containing sufficient linoleic acid or esters thereof, to provide said composition with a linoleic acid source content of at least 0.4%; about from 7.5 to 90% carbohydrate; about from 1 to 16% of a gelatinised high amylose starch, containing at least 50%, by wt., amylose; and about from 0.05 to 10% of a water-lipid emulsifying agent, and wherein said composition has a weight ratio of said high amylose starch to said lipid of at least 0.25, and wherein the total high amylose starch content of said composition is 16% or less and the total starch content is 20% or less and the total free amino acid content of said composition is less than 5% (see claim 1 of D3), as well as an aqueous emulsion thereof (see claim 27 of D3).

Example 6 of D3 (which is considered to be the closest prior art by both parties) relates to a specific emulsion in line with the teaching of D3, comprising, *inter alia*, a specific mixture of emulsifying agents, i.e. Span 60 and Tween 60, fulfilling the hydrophilic lipophilic balance values of the emulsifiers and its amounts as required in claim 1 of the main request.

1.3 The parties also agreed that the subject-matter of claim 1 of the main request differed from Example 6 of D3 on account of the feature "from 0.01 to 20 grams per litre of a low amylose starch, having an amylose content of less than 50% by weight".

1.4 However, the parties disagreed as to whether an effect resulting from the distinguishing feature over D3 was demonstrated and consequently the parties had different views on how to formulate the objective technical problem to be solved.

1.5 For the following reasons, no effect can be acknowledged over Example 6 of D3.

1.5.1 Whilst the respondent agreed that there was no direct comparison between a composition within the scope of claim 1 and a composition according to Example 6 of D3, it submitted that it was only required to convincingly demonstrate that the technical effect had its origin in the distinguishing feature, and this could be done without necessarily reworking the prior art (i.e. Example 6 of D3) precisely. In its view, Example 2 of the patent was suitable for demonstrating an effect resulting from the distinguishing feature over Example 6 of D3, wherein composition A in Table 2 of the patent exemplified an example in line with the patent, demonstrating improved emulsion stability, and

the comparative example next to composition A in Table 2 of the patent was sufficiently representative of Example 6 of D3.

1.5.2 For the reasons outlined below, a comparison of composition A in Example 2 of the patent and the comparative example next to it in Table 2 is not suitable for demonstrating improved emulsion stability over D3.

The liquid nutritional compositions used in composition A in Example 2 as well as the comparative example (directly next to composition A in Table 2, allegedly representative of Example 6 of D3) are not precisely defined. There is no information given in Example 2 as to which partially hydrolysed whey protein and which fat were used. In addition, no information is given in Example 2 as to which amounts of partially hydrolysed protein and fat were present in the nutritional compositions. Moreover, different emulsifiers were used in Example 2 of the patent and in Example 6 of D3. Therefore, it cannot be acknowledged that the comparative example for Example 2 of the patent (directly next to composition A in Table 2) is representative of Example 6 of D3. For this reason, it cannot be used to demonstrate any improvement over D3.

1.5.3 Furthermore, as can be taken from Table 7 of D3, the liquid nutritional composition according to Example 6 of D3 provides stable emulsions. When the emulsifier mixture of Span 60 and Tween 60 is used (see Example 6, Table 7, of D3), a stability rating of 100 can be achieved, which is rated as the best emulsion stability.

1.5.4 In view of the above, an improved emulsion stability cannot be acknowledged over D3.

1.6 Therefore, the objective technical problem to be solved is that of providing an alternative liquid nutritional composition.

1.7 Even when assuming, for the sake of argument, that the objective technical problem should also include a reference to the stability of the emulsion, i.e. to provide an alternative liquid nutritional composition having excellent emulsion stability, as argued by the respondent, the claimed subject-matter does not involve an inventive step in view of D3.

1.8 With respect to the question of obviousness, the respondent argued that a skilled person, when faced with the problem of providing a liquid nutritional composition containing partially hydrolysed protein and fat with excellent emulsion stability, would turn to the examples in D3 and specifically to Table 1, which related to "stability against separation"; however, Table 1 clearly demonstrated that the compositions containing "normal starch" are unstable or less stable emulsions. Accordingly, the skilled person would not be motivated by Table 1 to add another starch to a composition containing high amylose starch, let alone a "normal starch", with the expectation of solving the above problem. D3 clearly provided the skilled person with teaching leading away from using starch with an amylose content of less than 50% by weight to stabilise a liquid nutritional composition. Therefore, the skilled person would avoid the possible presence of up to 4% additional starch, which is permitted by claim 1 and column 4, lines 37 to 64 of D3.

1.9 The board is not convinced by the respondent's line of argument in this respect.

1.10 First, in Table 1 of D3 a different emulsifier system is used compared with Example 6 of D3, which represents the closest prior art. Consequently, it cannot be derived from Table 1 that the specific emulsifier mixture of Span 60 and Tween 60 used in Example 6 of D3 leads to phase separation or unstable emulsions, keeping in mind that a stability rating of 100 can be achieved for certain mixtures of Span 60 and Tween 60 (see Table 7 of D3), which is rated as the best emulsion stability.

1.11 Second, in the broadest sense, the composition in claim 1 of D3 comprises about 1 to 16% of a gelatinised high amylose starch, wherein the total starch content is 20% or less. Therefore, another starch may be present in addition to the amount of about 1 to 16% of a gelatinised high amylose starch. In this context, it is noted that claim 1 of D3 contains the feature "for consumption mixed with water as an aqueous emulsion having improved stability", which also indicates that the aqueous emulsion obtained from the dry composition in claim 1 of D3 has improved stability.

Furthermore, column 4, lines 50 to 59, of D3 provides the teaching that, where starch is used as a carbohydrate source, the total starch content of the diet should not exceed 20% by weight, on a dry basis, and the total high amylose starch content (including that added in addition to the carbohydrate) should not exceed 16% in order to maintain the proper viscosity of the emulsion, with suitable starches including e.g. potato starch.

In other words, there is unambiguous teaching in D3 that other starches, such as potato starch, may be added to the composition of D3. Potato starch is a low amylose starch having an amylose content in the range required in claim 1 of the main request (and even the more limited amylose content as defined in claim 1 of auxiliary requests 2 and 3). This is supported by composition A in Example 2 of the patent and by the common general knowledge as represented in D12 (see the table on page 1101 of D12). The cited passage in D12 indisputably represents common general knowledge. D12 was used by both parties in their line of argument. Moreover, the respondent did not dispute the admittance of D12. Therefore, the board exercised its discretion to admit this document into the proceedings under Article 13(1) RPBA 2020 (Article 25(1) RPBA 2020).

Therefore, there is an incentive in D3 itself to add potato starch, for instance, to the composition in D3 in the amounts required in claim 1 and with the required amylose content.

1.12 The respondent argued that even when considering, on the basis of the teaching in column 4 of D3 or claim 1 of D3, the addition of a low amylose starch to gelatinised high amylose starch, this would have led to a total starch or a starch mixture to be classified either as high amylose starch (having an average amylose content of above 50% by weight) or as low amylose starch (having an average amylose content below 50% by weight); however, as this mixture of low amylose starch and high amylose starch was to be classified as a low amylose starch, this would have been in conflict with the wording of claim 1 of D3 and would thus have gone against the teaching of D3.

Therefore, a skilled person would not have considered this option.

The board does not agree with the respondent's interpretation or calculation of the average low amylose content of the starch mixture, since this is not in line with the wording of claim 1 and the teaching of D3. There is no doubt that claim 1 of D3 allows that, for instance, (i) low amylose starch may be added in a quantity of 4% and gelatinised high amylose starch may be added in a quantity of 16% or (ii) low amylose starch may be added in a quantity of 19% and gelatinised high amylose starch may be added in a quantity of 1%. A skilled person would not calculate an average amylose content of this mixture and conclude that it is to be classified either as low amylose starch or as high amylose starch. This would be a misinterpretation of the teaching of D3, so this line of argument by the respondent must fail. Likewise, the wording of claim 1 of the main request does not require the average amylose content of the total starch content to be below 50%. Instead, it only requires the presence of 0.01 to 20 grams per litre of a low amylose starch having an amylose content of less than 50% by weight, but is otherwise not restricted (cf. "comprising").

The claimed nutritional composition is thus an obvious alternative in view of D3.

In view of the above, the subject-matter of claim 1 of the main request does not involve an inventive step in view of D3 as the closest prior art.

AUXILIARY REQUESTS

2. In the written proceedings, the respondent did not provide arguments as to why the nutritional composition in claim 1 of auxiliary requests 1 to 3 might be suitable for overcoming the inventive-step objection raised in view of D3 as the closest prior art. During the oral proceedings, it argued that the auxiliary requests led to a further distinction over D3, for instance, with the subject-matter of claim 1 of auxiliary request 2 being more in line with the examples in the patent and in claim 1 of auxiliary request 3, with the claimed scope being narrowed.

The board does not find the respondent's line of argument convincing in this respect.

With respect to auxiliary request 1, the appellant referred to Example 6 of D3, which mentions fatty acid mono and diglycerides (Atmos 150 VS, HLB = 3.2, and Atmul 124, HLB = 3.5) as well as a diacetyl tartaric acid ester of mono- and diglycerides (Emcol AA-45, HLB = 15). In the absence of any counter-argument from the respondent, using Atmos 150 VS or Atmul 124 in combination with Emcol AA-45 is considered to be obvious to a skilled person having knowledge of D3.

With respect to auxiliary requests 2 and 3, it is noted that potato starch is a low amylose starch having an amylose content in the range required in claim 1 of auxiliary requests 2 and 3 (see point 1.11 above).

Therefore, it is concluded that the subject-matter of claim 1 of auxiliary requests 1 to 3 also lacks an inventive step in view of D3 as the closest prior art.

3. Article 13(2) RPBA

3.1 The respondent filed auxiliary requests 4 and 5 in response to the communication pursuant to Article 15(1) RPBA and requested that these claim requests be admitted into the proceedings.

3.2 The appellant requested that these claim requests not be admitted into the proceedings (Article 13(2) RPBA).

3.3 The respondent argued that the board's preliminary opinion outlined in the Article 15(1) RPBA communication indicated for the first time in the entire proceedings that claim 1 as granted lacked an inventive step. Therefore, the submissions filed on 25 April 2022 represented the first opportunity for the respondent to respond to the board's preliminary opinion and auxiliary requests 4 and 5 represented a *bona fide* attempt to overcome the inventive-step objection.

3.4 For the following reasons, the board does not share the respondent's view.

It is true that the board concluded in its preliminary opinion in the Article 15(1) RPBA communication, in contrast to the opposition division, that the claimed subject-matter lacked an inventive step in view of D3 as the closest prior art; however, the board merely gave its opinion on the appellant's inventive-step objection, which was raised at the very beginning of the appeal proceedings in the grounds of appeal, which was submitted more than three years ago. Indisputably, no new aspects were raised from the board's side.

As the appeal proceedings are intended for reviewing the impugned decision, the parties have to expect that the board might express a preliminary opinion that is different from that of the opposition division (T 42/17, point 4.4 of the Reasons; T 1187/16 point 3.2 of the Reasons; T 2610/16, point 3.3 of the Reasons). Filing claim requests in response to the board's preliminary opinion, which merely assesses objections raised from the very beginning of the appeal proceedings, therefore does not qualify as exceptional circumstances and cannot justify these claim requests possibly being taken into account (see the case law cited above). Instead, according to Article 12(3) RPBA 2020, or Article 12(2) RPBA 2007 where applicable, the grounds of appeal and the reply must already contain a party's complete case. For the respondent, this implies the need to respond immediately in its reply to the objections raised by the appellant, instead of waiting until the board sets out its preliminary opinion.

In view of the above, the board exercised its discretion not to take into account auxiliary requests 4 and 5 (Article 13(2) RPBA).

4. As none of the claim requests forming part of the appeal proceedings fulfilled the requirements of the EPC, the patent has to be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

T. Buschek A. Haderlein

Decision electronically authenticated