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Datasheet for the decision of 30 April 2021

Case Number: T 2005/16 - 3.3.09

Application Number: 11712031.1

Publication Number: 2544553

IPC: A23J3/10, A23L1/29, A23L1/305, A23C3/08

Language of the proceedings: EN

Title of invention:
CONTROLLING THE TEXTURE OF HIGH-PROTEIN NUTRITIONAL COMPOSITIONS COMPRISING MICELLAR CASEIN

Patent Proprietor:
N.V. Nutricia

Opponents:
Fresenius Kabi Deutschland GmbH
FrieslandCampina Nederland B.V.
Société des Produits Nestlé S.A.

Headword:
Compositions comprising high amounts of micellar casein/ NUTRICIA

Relevant legal provisions:
RPBA Art. 12(4)
EPC Art. 56, 83, 84, 123(2)

Keyword:

Main request: added subject-matter - (yes)
Auxiliary request 1: added subjet-matter - (yes)
Auxiliary request 2: clarity - (no)
Auxiliary request 3: added subject matter - (no); clarity, sufficency of disclosure, inventive step - (yes)
Partial reimbursement of the appeal at 25% - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 2005/16 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 30 April 2021

Appellant: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
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Respondent: (Opponent 2)	FrieslandCampina Nederland B.V. Stationsplein 4 3818 LE Amersfoort (NL)
Representative:	FrieslandCampina Nederland B.V. IP Department Bronland 20 6708 WH Wageningen (NL)
Respondent: (Opponent 3)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Rupp, Christian Mitscherlich PartmbB Patent- und Rechtsanwälte Sonnenstraße 33 80331 München (DE)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 1 July 2016 revoking European patent No. 2544553 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman A. Haderlein
Members: A. Veronese
E. Kossonakou

Summary of Facts and Submissions

I. The appeal was filed by the proprietor against the opposition division's decision to revoke European patent No. EP 2 544 553 B1.

II. With their notices of opposition, the three opponents had requested that the patent be revoked in its entirety on the grounds under Article 100(a) EPC (lack of novelty and lack of inventive step) and Article 100(b) and 100(c) EPC.

III. The documents submitted during the opposition proceedings included:

D1: E. De Kort et al., Dairy Sci. Technol., vol. 89, 2009, pp. 283-299
D4: WO 2009/072886 A1
D8: WO 2009/072885 A1

IV. The opposition division's decision was based, *inter alia*, on a main request and auxiliary requests 1 to 3, all filed during the oral proceedings before the opposition division.

V. The opposition division held, *inter alia*, that:

- the claims of the main request did not contain added subject-matter and did not extend the scope of protection; however, the subject-matter of claim 1 was not novel,

- claim 1 of auxiliary requests 1 and 2 contained added subject-matter,

- the claims of auxiliary request 3 were clear, did not contain added subject-matter and did not extend the scope of protection; however, the claimed subject-matter did not involve an inventive step over a combination of D4 or D8, the closest prior art, with D1.

VI. With its statement setting out the grounds of appeal the appellant filed a main request and auxiliary requests 1 to 4. With a letter dated 7 November 2017 it filed two amended versions of auxiliary requests 3 and 4, replacing the previously filed ones.

Claim 1 of the main request read:

"*1. A nutritional composition comprising 9 to 20 g of protein per 100 ml of the composition and having a pH of about 6 to 8, in which all or a major part of said protein comprises micellar casein, comprising two or more chelating agents selected from the group consisting of a phosphoric acid, citric acid, a soluble phosphate salt, a soluble citrate salt, and wherein the composition comprises an amount of about 1 to 120 $mEq \cdot L^{-1}$, preferably 10 to 80 mEq/L, more preferably 20 to 60 $mEq \cdot L^{-1}$ of two or more chelating agents, wherein the phosphoric acid is selected from the group consisting of uridine monophosphoric acid, cytidine monophosphoric acid, orthophosphoric acid, inositol hexaphosphoric acid, hexametaphosphoric acid, and the phosphate salt is selected from the group consisting of uridine monophosphate, cytidine monophosphate, orthophosphate, inositol hexaphosphate, hexametaphosphate.*"

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the range of 1 to 120 $mEq \cdot L^{-1}$ has been amended to 10 to 120 $mEq \cdot L^{-1}$.

Claims 4 and 6 of auxiliary request 2 read:

"*4. The nutritional composition according to any one of claims 1 to 3, wherein the composition is a liquid composition.*"

"*6. The composition according to claim 4, wherein the person is an elderly person, a person that is in a disease state, a person that is recovering from a disease state, a person that is malnourished, or a healthy person such as a sportsman or sportswoman or an active elderly.*"

Claim 1 of auxiliary request 3 read:

"*1. A nutritional composition comprising 9 to 20 g of protein per 100 ml of the composition and having a pH of about 6 to 8, in which all or a major part of said protein comprises micellar casein, comprising one chelating agent selected from the group consisting of disodium uridine monophosphate and disodium cytidine monophosphate.*"

VII. The appellant's arguments, where relevant for the decision, may be summarised as follows.

A basis for claim 1 of the main request and auxiliary requests 1, 2 and 3 could be found in claims 9 and 10, on page 10, line 7 and on page 8, lines 5-6 of the application as filed.

The examples in the patent showed that the claimed invention could be carried out by the skilled person. Compositions comprising proteins and chelating agents according to the invention having acceptable viscosity and turbidity were described. There was no evidence that these compositions could not be prepared and administered to the patients mentioned in the claims.

The claimed invention involved an inventive step. The compositions claimed in auxiliary requests 2 and 3 differed from those from the closest prior art (D4 or D8) in that they contained Na_2UMP or Na_2CMP. The patent showed that compositions comprising Na_2UMP were milky and had the same viscosity, regardless of the concentration of Na_2UMP. The same was to be expected with Na_2CMP, an analogue of Na_2UMP. The underlying problem was how to add phosphorus to a liquid micellar casein composition while transparency and viscosity remained unaffected. Neither the closest prior art, D4 or D8, nor D1 provided a hint at the claimed solution. The effects described in D1, observed with compositions comprising $CaCl_2$, could not be reasonably expected to occur in compositions comprising micellar casein.

VIII. The respondents' arguments, where relevant for the decision, may be summarised as follows.

The combination of features characterising claim 1 of the main request and of auxiliary requests 1 and 2 added subject-matter not disclosed in the application as filed. Claim 6 of auxiliary request 2 was unclear because it mentioned a patient not having an antecedent in claims 1-4, on which it was dependent.

The skilled person could not carry out the claimed invention. It would have been impossible to

simultaneously modulate the turbidity and the viscosity of the claimed compositions using the relevant chelating agents. Furthermore, compositions comprising the claimed amounts of proteins and chelating agents could not be prepared in liquid form. There was also no evidence that the claimed compositions could be administered to the patients mentioned in the claims.

The claimed invention did not involve an inventive step over D4 or D8, the closest prior art, in combination with D1. The claimed composition differed from those in D4 and D8 in that specific chelating agents were used. According to respondents 2 and 3 the underlying problem was that of including phosphorus compounds in a nutritional composition rich in casein without influencing its viscosity. The proposed solution was obvious in view of D1, which taught that phosphorus agents influenced the viscosity and transparency of micellar casein compositions. According to respondent 3 the aforementioned problem was not solved across the entire scope claimed. Therefore, the problem was that of providing an alternative composition. Its solution was obvious over D4 or D8 combined with D1.
Respondent 3 added that other documents could be considered as the closest prior art or could be combined with the closest prior art; therefore, if inventive step were acknowledged starting from D4 and D8, the case would have to be remitted to the opposition division for reconsideration in view of the additional documents cited.

IX. In a communication dated 27 October 2020 issued in preparation for oral proceedings the board gave the preliminary opinion that the decision under appeal was to be set aside and that the patent could be maintained on the basis of auxiliary request 3. All parties agreed

that this decision could be taken in writing. In particular, in its letter dated 25 November 2020 the appellant withdrew its request for oral proceedings. Subsequently, the oral proceedings were cancelled.

The requests

X. The appellant requested that the decision be set aside and that the patent be maintained on the basis of the main request or, alternatively, on the basis of one of auxiliary requests 1 and 2, each filed with the statement setting out the grounds of appeal, or alternatively, on the basis of one of auxiliary requests 3 and 4, filed by letter dated 7 November 2017. It also requested a partial refund of the appeal fee under Rule 103(4)(c) EPC.

XI. Opponents 1, 2 and 3 (respondents 1, 2 and 3) requested that the appeal be dismissed.

Reasons for the Decision

Main request

1. *Added subject-matter*

1.1 The opposition division decided that the combination of the feature "two or more chelating agents" with the specific chelating agents listed in claim 1 created new subject-matter extending beyond the content of the application as filed.

1.2 According to the appellant a basis for claim 1 could be found in claims 9 and 10 and on page 10, lines 7-10 of that application, which states: "By using two or more

chelating agents according to the invention any type of compositions can be produced, having any desired viscosity, transparency and phosphorous content".

1.3 The board does not agree with the appellant. As noted by the respondents, several features disclosed in separate parts of the application as filed must be selected and combined in order to arrive to the composition of claim 1, namely:

- a nutritional composition having a pH of 6 to 8 and comprising 9 to 20g/100ml of protein, the "major amount" of this protein being micellar casein, as disclosed in claim 10 as filed

- a combination of two or more chelating agents, as disclosed on page 10, lines 7-10 as filed

- specific amounts of the relevant chelates, as disclosed in claim 14 as filed

- specific phosphoric acids, which are specified in claim 2 as filed.

1.4 This combination of features is not directly and unambiguously disclosed in the application as filed. It is noted that:

- claim 14 as filed, which specifies the amount of chelating agent/s, refers back to claims 9-13; however, none of these claims mentions the specific phosphoric acids from claim 1 of the main request; furthermore, none of these claims refers back to claim 2 as filed, in which these acids are listed

- claim 14 as filed relates to the concentration of a composition comprising one or more and not two or more chelating agents

- claims 1 and 2 as filed relate to the control of the properties of a composition comprising 6 to 20g/100ml of a micellar casein and not, as in claim 1 of the main request, 9 to 20g/ml of a protein, the "major amount" of which is micellar casein.

1.5 By selecting the amount of protein defined in claim 9 as filed, the specific phosphate acids of claim 2 as filed and by singling out the presence of two or more chelating agents in the specific concentration of claim 14 as filed, subject-matter has been created which extends beyond the content of the application as filed (Article 123(2) EPC).

Auxiliary request 1

2. *Added subject-matter*

2.1 Claim 1 of auxiliary request 1 differs from that of the main request on account of the range defining the amount of chelating agent(s). According to the appellant the new value of 10 to 120 mEq/ml is obtained by combining the ranges disclosed in claim 14 as filed; however, for the same reasons as presented above when dealing with the main request, the combination of features of claim 1 of auxiliary request 1 creates originally undisclosed subject-matter (Article 123(2) EPC).

Auxiliary request 2

3. *Clarity*

3.1 Claim 6 of auxiliary request 2 is dependent on claim 4 and mentions a "person" who is not defined in claim 4 or in any of the preceding claims. Therefore, claim 6 is unclear. This lack of clarity was not present in the claims as granted. Therefore, auxiliary request 2 is not allowable (Article 84 EPC).

Auxiliary request 3

4. Claim 1 of this requests differs from claim 1 of the main request in that the composition comprises one chelating agent selected from disodium uridine monophosphate (Na_2UMP) or disodium cytidine monophosphate (Na_2CMP), which are the preferred chelating agents according to page 8, lines 5-6 as filed, and in that the amount of these agents is not specified. The dependent claims have been adapted. The amendments overcome the objections under Articles 84 and 123(2) EPC, which led to finding that the previous requests are not allowable. This has not been disputed.

5. *Sufficiency of disclosure*

5.1 The respondents argued that the skilled person could not carry out the claimed invention because the purported technical effect of the invention, namely the modulation of both the turbidity and the viscosity of the claimed compositions, could not be achieved across the entire scope of the claims using the relevant chelating agents, let alone combinations of these. Foods were typically turbid and it would have been impossible to prepare compositions comprising the

claimed high amounts of proteins and chelating agents in liquid form. There was also no evidence that the claimed compositions could be administered to the patients mentioned in the claims.

The respondents' arguments are not persuasive.

5.1.1 The claims define a nutritional composition, as such. They do not require any particular effect to be achieved. In particular, no mention is made of modulation of the turbidity or viscosity of the composition. For the requirement of sufficiency of disclosure to be fulfilled, it is necessary for the skilled person to be provided with enough information to prepare a composition suitable for nutritional purposes which comprises the claimed nutritional ingredients and one chelating agent selected from Na_2UMP or Na_2CMP. The issue of whether the aforementioned non-claimed technical effect can be achieved is not relevant.

5.1.2 There is no evidence that the skilled person would not be able to prepare the claimed compositions by relying on the information in the patent and common general knowledge. The patent describes several liquid compositions comprising high amounts of micellar casein and phosphate agents, including Na_2UMP. It is true that a liquid composition could not be prepared when a high amount of hexametaphosphate (SHMP) was used, due to gelification (paragraph [0101]); however, the skilled person would understand that, if a liquid composition has to be prepared, the amount of the chelating agent(s) should not reach a level inducing gel formation. Furthermore, the use of SHMP is no longer foreseen in the claims of auxiliary request 3.

The respondents argued that there was no evidence that Na_2CMP could be used to carry out the invention. None of the tested compositions comprised this agent; however, as noted by the appellant, Na_2CMP is an analogue of Na_2UMP. Therefore, it is reasonable to assume that it is also suitable for preparing compositions according to the invention.

5.1.3 No evidence has been provided that the claimed compositions cannot be administered to the persons mentioned in claims 4 and 5 either. The respondents' allegations are mere speculations and do not raise serious doubts, based on verifiable facts, that the invention cannot be carried out.

5.2 For these reasons, it is concluded that the requirement of sufficiency of disclosure is fulfilled (Article 83 EPC).

6. *Inventive step*

6.1 The claimed invention relates to a nutritional composition comprising high amounts of micellar casein. As explained in the patent, the presence of high amounts of this protein and the necessary levels of phosphates may have undesired effects on the viscosity and transparency of nutritional compositions; see paragraphs [0001], [0004], [0005] and [0034]. The invention is intended to prevent these effects.

6.2 Claim 1 of auxiliary request 3 encompasses the subject-matter of the auxiliary request 3 filed before the opposition division, which does not involve an inventive step according to the decision under appeal. The opposition division decided that D4, or in the alternative D8, represents the closest prior art. This

choice was not disputed by the parties and the board does not see any reason to deviate from it.

6.3 D4 and D8 disclose nutritional compositions comprising high amounts of micellar casein and acknowledge the problem of formulating compositions having an acceptable viscosity. The pH and the amount of micellar casein present in the compositions described in these documents correspond to those indicated in claim 1. D4 and D8 teach that a certain calcium-ion activity is beneficial to maintain an acceptable viscosity and that the use of citric acid, typically added to control the pH and calcium-ion activity, can be problematic.

6.4 However, D4 and D8 do not envisage the inclusion of phosphate acids or their salts in a nutritional composition comprising high amounts of micellar casein. Therefore, the composition from claim 1 differs from those disclosed in D4 and D8 in that it comprises disodium uridine monophosphate (Na_2UMP) or disodium cytidine phosphate (Na_2CMP).

6.5 As shown in the patent in suit, contrary to other chelating agents, Na_2UMP can be added to a composition comprising high amounts of micellar casein without inducing any significant change of viscosity and turbidity; see figures 3 and 8 and compare the results observed when adding Na_2UMP, the claimed organic orthophosphate, disodium orthophosphate (Na_2HPO_4, an inorganic orthophosphate), sodium phytate (SP, an organic polyphosphate), hexasodium hexametaphosphate (SHMP, an inorganic polyphosphate) and trisodium citrate (TSC, an organic salt).

6.6 As stated in paragraph [0034] of the patent, using Na_2UMP or Na_2CMP, "a liquid micellar casein composition

is obtained with a substantially unaffected transparency and viscosity, yet providing the necessary phosphorous and counter ions for a nutritional composition." (emphasis added by the board).

6.7 The respondents argued that this effect could not be achieved in compositions comprising fats and other nutritional components, which were typically opaque. The tested compositions did not contain fats.
This argument is not persuasive; it is reasonable to assume that, even if a composition is not transparent due to the presence of fat, the addition of the claimed phosphates would not further increase its opacity and viscosity. Therefore, in this case too, it would be advantageous to use the selected compounds. No evidence of the contrary was provided by the respondents.

6.8 The respondents have also observed that no tests were performed using Na_2CMP; however, as noted by the appellant, this nucleotide is an analogue of Na_2UMP and can be expected to share with it the relevant properties when used according to the invention.

6.9 Therefore, it is concluded that the data in the patent make it credible that Na_2UMP and Na_2CMP can be added to a nutritional composition comprising high amounts of micellar casein so as to provide the phosphorus content necessary for nutrition without inducing disadvantageous changes in viscosity and transparency.

6.10 Accordingly, the underlying objective technical problem can be formulated as proposed by the opposition division and the appellant, namely that of adding phosphorus to a liquid micellar casein composition while the transparency and viscosity of the composition remains unaffected.

6.11 According to the opposition division and the respondents the proposed solution was obvious because the skilled person confronted with this problem would have found a hint to the claimed solution in D1.

6.12 D1 describes a study aimed at determining the calcium-binding capacity of different inorganic and organic orthophosphates and polyphosphates. The influence of chelating agents such as citric acid and phosphates on the calcium activity of casein micelles in dairy compositions is acknowledged on page 284. According to the authors, the binding capacity of these agents can be used to influence the stability of casein micelles in dairy systems, for example. After analysing the results, the authors conclude that the calcium-binding capacity of phosphate provides "useful information to understand the interaction of calcium, phosphate and casein micelles for the development of, for example, medical nutrition"; see page 297.

6.13 The respondents argued that the skilled person would have taken the teaching of D1 into account. The tests described in D1, which included turbidity measurements, were conducted substantially in the same way as those described in the patent in suit. The results indicated that of all the chelating agents tested, Na_2UMP provided the weakest binding with calcium. From this information the skilled person would have expected Na_2UMP to cause the smallest increase in viscosity when added to micellar casein. Therefore, as decided by the opposition division, starting from D4 or D8, it would have been obvious to select this compound to solve the underlying technical problem.

These conclusions are not persuasive.

6.14 First of all, D4 and D8 only mention in passing the possible relevance of calcium-ion activity for viscosity and the use of citric acid to control calcium-ion activity. The problems associated with the presence of a high micellar casein content are solved in D4 and D8 by subjecting the composition to an evaporation step (D4) or using a micellar-casein/casein mixture (D8). The problem of controlling transparency is not mentioned at all.

6.15 Furthermore, as stressed by the appellant, the tests described in D1 do not provide any conclusive information regarding the effect of phosphate chelators on the stability of casein micelles. The tests, including those in which sediment and turbidity were measured, were conducted using compositions comprising calcium chloride rather than micellar casein. The authors consider that the results provide "useful information" relating to heat stability of nutritional compositions comprising micellar casein; however, D1 does not mention anything regarding any influence of phosphate salts on the viscosity and transparency of compositions comprising high amounts of micellar casein. D1 teaches that Na_2UMP binds less strongly to calcium ions compared with other phosphates. Nonetheless, no reasonable prediction can be made from the results regarding the effects of phosphate chelating agents on complex casein micellar systems, let alone on their viscosity and transparency. These properties are not even mentioned in D1. For these reasons, the board does not share the respondents' arguments as endorsed in the opposition division's decision that the skilled person would have used Na_2UMP with a reasonable expectation of success when

attempting to solve the aforementioned technical problem.

6.16 As explained in paragraphs [0105] and [0109] of the patent, micellar casein is made of a complex structure comprising loosely and strongly bound calcium ions. This supramolecular structure differs substantially from the simple calcium chloride system studied in D1. Therefore, the finding that different chelators influence the viscosity and transparency of complex micellar systems in very different manners is new, relevant and unexpected technical teaching. Without this teaching, the skilled person would not have had a reasonable expectation of solving the underlying problem. In particular, the skilled person would not have had any reason to select Na_2UMP or Na_2CMP as phosphorus sources in a nutritional composition without inducing detrimental effects on its viscosity and transparency.

6.17 Accordingly, the claimed subject-matter involves an inventive step over D4 or D8, alone or in combination with D1.

6.18 Respondent 1 also mentioned other documents as being relevant and, possibly, as being alternative starting points for discussing inventive step. It also referred generically to arguments discussed during the opposition proceedings; however, respondent 1 did not present any reason as to why these documents should be more suitable than D4 or D8 as the closest prior art or should be more relevant than D1.

6.19 The problem-solution approach as applied in proceedings before the EPO and cemented in established case law requires the most relevant prior art document to be

selected as a starting point. If an attack from this most promising basis fails, it is considered that documents of lesser apparent relevance will have considerably diminished chances of success. In the absence of any detailed or convincing arguments in support of the alternative lines of attack, the board does not consider it appropriate to consider them further. Along the same line of thought, respondent 1's conditional request to remit the case to the opposition division for further consideration, should the claimed subject-matter be found to involve an inventive step over D4 or D8 in combination with D1, is to be rejected.

7. Partial reimbursement of the appeal fee

The appellant withdrew its request for oral proceedings within one month of notification of the communication issued by the board in preparation for oral proceedings and no oral proceedings took place. Therefore, the appeal fee is to be reimbursed at 25% pursuant to Rule 103(4)(c) 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 with the order to maintain the patent as amended according to the claims of auxiliary request 3 filed with the letter dated 7 November 2017, and a description to be adapted accordingly.

3. The appeal fee is reimbursed at 25%.

The Registrar: The Chairman:

A. Nielsen-Hannerup A. Haderlein

Decision electronically authenticated