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Datasheet for the decision of 24 November 2020

Case Number: T 1312/16 - 3.3.09

Application Number: 10718723.9

Publication Number: 2424386

IPC: A23L33/17, A23L33/19, A61K38/16, A61K36/48, A61K38/01

Language of the proceedings: EN

Title of invention:

PEA-BASED PROTEIN MIXTURE AND USE THEREOF IN A LIQUID NUTRITIONAL COMPOSITION SUITABLE FOR ENTERAL FEEDING

Patent Proprietor:

N.V. Nutricia

Opponents:

Abbott Laboratories
Fresenius Kabi Deutschland GmbH
Société des Produits Nestlé S.A.
DF3 SAS(FR) / COSUCRA GROUPE WARCOING(BE)

Headword:

Pea-based protein mixture/NUTRICIA

Relevant legal provisions:

EPC Art. 56, 84

Keyword:

Claims - clarity - main request, auxiliary request 1 (no)
Inventive step - auxiliary request 2 (no)

Decisions cited:

G 0003/14

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Beschwerdekammern

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Case Number: T 1312/16 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 24 November 2020

Appellant: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
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Appellant: (Opponent 2)	Fresenius Kabi Deutschland GmbH Else-Kröner-Stasse 1 61352 Bad-Homburg v.d.H. (DE)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted on 2 May 2016 concerning maintenance of the European Patent No. 2424386 in amended form.**

Composition of the Board:

Chairman A. Haderlein
Members: F. Rinaldi
E. Kossonakou

Summary of Facts and Submissions

I. This decision concerns the appeals filed by the patent proprietor and opponents 1, 2 and 3 against the interlocutory decision of the opposition division finding that European patent No. 2 424 386 as amended met the requirements of the EPC.

II. Opponent 4 is a party as of right in the present appeal proceedings, but presented no arguments or requests.

III. As all the actively involved parties are appellants, they will continue to be referred to as patent proprietor and opponents.

IV. In their respective notice of opposition, opponents 1 to 4 had requested revocation of the patent based *inter alia* on Article 100(a) EPC, for lack of inventive step.

V. The documents submitted during the opposition proceedings included:

D5: EP 2 424 384 B1

D8: US 2003/0104033 A1

D9: I. Caugant et al., "In vivo and in vitro gastric emptying of milk replacers containing soybean proteins", Journal of Dairy Science, 77(2), 1994, 533-540

D10: EP 1 972 346 A1

D27: B. Beaufrère et al., "The 'fast' and 'slow' protein concept", Proteins, Peptides and Amino Acids in Enteral Nutrition, 3, 2000, 121-133

D30: J. L. Rombeau, M. D. Caldwell (editors), "Clinical nutrition: enteral and tube feeding", 2nd edn., Philadelphia: W. B. Saunders Company, 1990, 160-167

D34b: S. Kuyumcu et al., "A noncoagulating enteral formula can empty faster from the stomach: A double-blind, randomized crossover trial using magnetic resonance imaging", Journal of Parenteral and Enteral Nutrition, 1-8 (first published online, on: 3 April 2014)

D38: C.C.M. van den Braak et al., "A novel protein mixture containing vegetable proteins renders enteral nutrition products non-coagulating after in vitro gastric digestion", Clinical Nutrition, 32, 2013, 765-771

VI. In the decision under appeal the opposition division concluded that auxiliary request 1, filed as auxiliary request 3 on 10 February 2016 and renumbered at the oral proceedings on 11 March 2016, met the requirements of the EPC. Claim 1 of this request reads:

"A protein mixture comprising at least a source of intact pea protein and a source of a second intact vegetable protein, wherein the protein mixture comprises

- 20 to 40 weight% of casein,
- 20 to 40 weight% of whey protein,
- 13 to 25 weight% of intact soy protein, and
- 13 to 25 weight% of intact pea protein,

relative to the total protein in the protein mixture, wherein the sum of said proteins equals 100 weight%."

VII. With its statement setting out the grounds of appeal, the patent proprietor filed a main request, of which claim 1 reads:

"A protein mixture comprising more than 25 weight% and up to 50 weight% of intact vegetable proteins, the protein mixture further comprising 50 to 70 weight% of dairy proteins, relative to the total protein in the protein mixture, said protein mixture consisting of intact pea, intact soy, casein and whey protein, wherein 10-30 wt% is pea protein, relative to the total protein in the protein mixture."

VIII. Subsequently, by letter dated 8 May 2017, the patent proprietor filed auxiliary request 1. Claim 1 of this request is based on claim 1 of the main request (see point VII), the sole difference being that the term "consisting of" in the latter is replaced by the term "consisting essentially of".

IX. Auxiliary request 2 was filed with the statement setting out the grounds of appeal, as auxiliary request 1, and was renumbered when auxiliary request 1 was filed on 8 May 2017. This request is identical to the auxiliary request 1 which, according to the opposition division decision, met the requirements of the EPC (see point VI).

X. On appeal, the parties filed several documents. Only the following two are relevant to the decision:

D40: M. Yvon et al., "In vitro simulation of gastric digestion of milk proteins: comparison between in vitro and in vivo data", Journal of Agricultural and Food Chemistry, 40(2), 1992, 239-244

D42: P. Scanff et al., "In vivo gastric digestion of milk proteins: effects of technological treatments", Journal of Agricultural and Food Chemistry, 38(8), 1990, 1623-1629

XI. The arguments of the patent proprietor, where relevant to the present decision, may be summarised as follows:

Main request and auxiliary request 1 - clarity
The skilled person would have no difficulty in establishing the demarcation of the scope of claim 1. This applied to both requests.

Auxiliary request 2 - inventive step
D10 was silent on the issues of reducing coagulation of protein and gastric emptying. The technical problem solved by the subject-matter of claim 1 was to provide a protein mixture which at least met and preferably exceeded the WHO amino acid profile recommendations for complete nutrition but had reduced coagulation issues. D34b, D38, D9 and D5 demonstrated that the technical problem had been solved. However, the prior art did not suggest the solution described in claim 1. Even if one considered a less ambitious technical problem, the skilled person would not have arrived at the subject-matter of claim 1. D10 addressed the problem of providing a protein mixture which mimics egg proteins; the skilled person would not have modified it by adding soy protein.

XII. The arguments of the opponents, where relevant to the present decision, may be summarised as follows:

Main request and auxiliary request 1 - clarity
The amendment in claim 1 was open to examination under Article 84 EPC. The use of the terms "comprising" and

"consisting" gave raise to ambiguity as regards the scope of claim 1 in both requests.

Auxiliary request 2 - inventive step
The patent did not demonstrate that the technical problem of reducing coagulation had been solved. Moreover, there was no evidence that the protein mixture of D10 had coagulation issues, or that the protein mixture of claim 1 showed an improvement over D10. Rather, D5 showed that in the closest prior art no coagulation issues occurred. Therefore, the technical problem was to provide a further protein mixture. In light of D8 or D30, the solution would have been obvious to the skilled person.

XIII. Final requests:

The patent proprietor requested
that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the main request filed with the statement setting out the grounds of appeal, or auxiliary request 1, filed by letter dated 8 May 2017, or auxiliary request 2, filed as auxiliary request 1 with the statement setting out the grounds of appeal (effectively a request for dismissal of the opponents' appeals).

Opponents 1 to 3 requested
that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

1. The patent in suit relates, as set out in paragraph [0003], to a protein mixture which

- includes pea protein
- is suitable for use in an enteral nutritional composition
- mimics a normal healthy protein diet containing a mix of different vegetable and animal proteins and
- meets the WHO amino acid profile recommendations for complete nutrition.

The protein mixture is described as, among other things, suitable for the promotion of gastric emptying (paragraph [0015]). Coagulation (i.e. clotting) of proteins in the stomach is believed to cause delayed gastric emptying (paragraph [0017]).

2. *Main request - clarity*

2.1 Claim 1 of the main request relates to a protein mixture which

- comprises more than 25 weight% and up to 50 weight% of intact vegetable proteins
- comprises 50 to 70 weight% of dairy proteins
- consists of intact pea, intact soy, casein and whey protein

It is uncontested that the values in weight% relate to the total protein in the protein mixture.

2.2 This combination of features is not based on a straightforward combination of granted claims. Moreover, the term "consisting of" is derived from the description. Therefore, the amendment is open to examination under Article 84 EPC (G 3/14).

2.3 According to claim 1, the only proteins which make up the protein mixture are: intact pea and intact soy protein (both vegetable proteins) and casein and whey (both dairy proteins).

2.4 The skilled person reading this claim is left in doubt as to the scope of this claim. There are two contradictory requirements in claim 1, namely:

(1) the protein mixture consists of only four proteins
(2) the proteins making up the protein mixture do not add up to 100 weight% if the protein mixture comprises more than 25 weight% but less than 30 weight% of intact vegetable proteins: some 5 weight% of protein is not accounted for.

2.5 Therefore, one conclusion that the skilled person may arrive at is that the value specified as 25 weight%, which refers to intact vegetable proteins, is too low: rather, it should read 30 weight%. Another conclusion may be that the value specified as 70 weight%, which refers to the dairy proteins, is incorrect: rather, it should read 75 weight%. It is thus unclear whether claim 1 covers compositions comprising more than 70 weight% of dairy proteins or compositions comprising less than 30 weight% of intact vegetable proteins.

2.6 The patent proprietor argued that this clarity objection only amounted to a theoretical exercise and that the skilled person would understand that claim 1

was limited to protein mixtures consisting of intact pea, intact soy, casein and whey protein.

This argument is not convincing because undefined boundaries of a claim do not merely amount to a theoretical exercise. Although the compounds of the protein mixture are clearly defined, the percentage composition of the protein mixture is not.

2.7 On this basis already, claim 1 fails to clearly define the matter for which protection is sought. The requirement of Article 84 EPC is not fulfilled.

3. *Auxiliary request 1 - clarity*

3.1 Claim 1 of auxiliary request 1 differs from claim 1 of the main request only in that the term "consisting essentially of" replaces the term "consisting of". However, this does not change the assessment that claim 1 is ambiguous in respect of the amounts of protein. Moreover, the term "essentially", at least in the present context, does not have a well-defined meaning, and therefore adds further ambiguity to the scope of the claim.

3.2 Thus, claim 1 fails to clearly define the matter for which protection is sought. The requirement of Article 84 EPC is not fulfilled.

Auxiliary request 2 - inventive step

4. In the decision under appeal, the opposition division regarded D10 as the closest prior art. This was not contested by the parties. Nor is the board of a different opinion.

4.1 D10 relates to a protein mixture and the use thereof in the preparation of a food product intended for oral or enteral nutrition (paragraph [0001]). The protein mixture of D10 is "similar to that of the protein considered nutritionally as standard reference proteins (egg proteins)" (paragraph [0009]). Table 1 shows its amino acid profile.

4.2 Claim 2 of D10 discloses a protein mixture which contains 50% caseinate, 25% milk serum proteins (i.e. whey protein) and 25% pea protein. This mixture represents the closest prior art.

5. The distinguishing features of claim 1 over the mixture of claim 2 of D10 are the following:

- 20 to 40 weight% of casein (50 weight% in the protein mixture of D10) and
- 13 to 25 weight% of intact soy protein (D10 does not disclose soy protein).

This was not a contentious issue.

6. The technical problem

6.1 Starting from D10, the patent proprietor regarded the technical problem as providing a protein mixture which at least meets and preferably exceeds the WHO amino acid profile recommendations for complete nutrition but has reduced coagulation issues (cf. patent in suit, paragraph [0017]).

6.2 Before assessing whether the composition of claim 1 successfully solves this problem, it is necessary to determine the meaning of reduced coagulation issues in the context of the patent.

6.2.1 During the oral proceedings, the patent proprietor submitted that, in the patent in suit, coagulation related to the formation of insoluble particles, i.e. casein coagulate of a certain size. As explained in example A of the patent in suit, the particles are formed by the gastric digestion of a protein solution in an artificial stomach juice. The size of the particles is established by pouring the solution through metal sieves and weighing the resulting fractions. Furthermore, the proprietor explained that the insoluble particles relevant to assessing coagulation were those having a size greater than 1 mm.

6.2.2 D38, a document published after the effective date of the patent, confirms that insoluble particles affect the speed of gastric emptying, and that digestible solids have to be broken down into particles of < 1-2 mm prior to being emptied from the stomach (page 769, right-hand column). Thus, gastric digestion which leads to insoluble particles below a certain size is not relevant because it does not affect gastric emptying. Based on this disclosure, opponent 1 argued that the cut-off value of the particle size determining coagulation may be even higher, i.e. greater than 2 mm.

6.2.3 Irrespective of the precise value (greater than 1 mm or greater than 2 mm), it can be concluded that, in the context of the patent in suit, the size of the coagulate is what matters to decide whether coagulation occurs. It follows that reduced coagulation issues, in this context, refers to a reduction in the formation of coagulate having a certain particle size.

6.3 The next step is to examine whether the ambitious formulation of the technical problem as reducing coagulation issues within the above meaning can stand.

6.3.1 In the patent in suit there is no disclosure on how mixtures of proteins coagulate, let alone the mixture of claim 1.

6.3.2 In the experimental section of the patent (example A, and figures 1 and 2), the coagulation of 6% (w/v) solutions of individual proteins (sodium caseinate, calcium caseinate, whey, intact pea, and intact soy) is investigated. The experiments are carried out as outlined above (point 6.2.1). It is manifest from the results that sodium and calcium caseinate form coagulate. Instead, the solutions of whey, pea and soy do not include particles having a size greater than 0.25 mm.

6.3.3 However, there is no experimental evidence on the coagulation of protein mixtures comprising casein and intact vegetable proteins.

6.3.4 In view of this, it is not possible to infer from the patent in suit that the protein mixture described in claim 1 leads to reduced coagulation issues (as understood in the context of the patent) when compared with the protein mixture known from D10.

6.4 At this juncture, it is observed that casein is known to coagulate or clot at an acidic pH (D9, D40, D42). Furthermore, whey protein is emptied from the stomach more rapidly than casein (D27, page 124). Similarly, the patent in suit acknowledges that casein forms a gel in the stomach, which slows the digestion (paragraph [0046]).

6.4.1 Therefore, it would normally be credible that if a nutritional formula comprised less casein and more of a protein that does not tend to coagulate, this would generally result in less coagulation; but, as explained above, to assess whether coagulation issues occur the relevant point is whether coagulate with particles of a certain size is formed.

6.4.2 With this in mind, it is not relevant to decide whether the coagulation of casein is solely pH-dependent (as the patent proprietor argued) or whether it is also concentration-dependent (as the opponents argued). Answering these questions would not make it possible to draw a conclusion as to whether there was a reduction in coagulation issues (as understood in the context of the patent).

6.4.3 These considerations underline the fact that in the absence of experimental results no conclusion can be drawn as to whether reduced coagulation issues occur.

6.5 To support its argument that the protein mixture of claim 1 resulted in reduced coagulation issues, the patent proprietor referred to D34b and D38. Both documents discuss the coagulation of protein mixtures. D34b, like D38, is not a prior-art document.

6.5.1 D34b does not describe the composition of the protein mixtures investigated. In particular, the proportions of whey, casein, soy and pea protein are not disclosed.

6.5.2 D38 examines the coagulation behaviour of casein-dominant compositions (in which the protein composition is not specified) and of an enteral composition which comprises 25% caseinate, 35% whey, 20% pea and 20% soy

protein in the protein blend (P4 blend). The tests are carried out in essentially the same way as in the patent in suit. No coagulate having a size of greater than 0.25 mm is detected for the P4 blend.

6.5.3 However, this protein mixture is near the bottom end of the casein concentration of claim 1 (20 to 40 weight%). It does not make it possible to draw conclusions at the higher end of the claimed range. This is the critical end of the range because, as explained above, casein is known to coagulate in the stomach.

6.5.4 It follows from this that D34b and D38 cannot support the view of the patent proprietor that the technical problem of reducing coagulation issues is solved over the entire scope of claim 1.

6.6 Another question was whether the composition of D10 showed coagulation (the position of the patent proprietor) or not (the position of the opponents). In this context, the parties referred to D5.

6.6.1 D5 is a patent in the name of the patent proprietor. It is not prior art for the patent in suit. In example 1, coagulation properties of protein solutions at 6% (w/v) are studied, essentially using the methods described in the patent in suit and in D38. The protein solutions have the following composition:

- 100% sodium caseinate
- protein mixtures of sodium caseinate and pea protein (ratios of 85:15, 70:30 and 60:40) and
- protein mixtures of sodium caseinate and soy protein (ratios of 70:30 and 50:50)

6.6.2 The results in figure 1 show that no coagulate is detected for the protein mixture of sodium caseinate and soy protein (50:50). The highest amount of coagulate (sum of wet particles > 2 mm and between 1 mm and < 2 mm) corresponds to the protein solution of 100% sodium caseinate, followed by the protein mixture of sodium caseinate and pea protein (85:15). Some coagulate is detected for the protein mixtures of sodium caseinate and pea protein (70:30 and 60:40) and for the protein mixture of sodium caseinate and soy protein (70:30).

6.6.3 The patent proprietor argued that the protein mixture of D10 was a composition which comprised 2/3 casein and 1/3 pea protein. In its view, D5 demonstrated that a protein mixture having a similar composition (ratios of sodium caseinate to pea protein 70:30 and 60:40) led to a certain amount of coagulate. Therefore, the patent proprietor concluded that the composition of claim 1 was less prone to coagulation, i.e. resulted in reduced coagulation issues, as compared with the protein mixture of D10.

6.6.4 This is not convincing. The protein mixture of D10 is a blend of 50% caseinate, 25% pea protein and 25% whey. Whey is known in the art as a milk protein that is emptied from the stomach more rapidly than casein (D27, page 124). Hence, of the results in figure 1 of D5, the correct comparison for the protein mixture of D10 is, rather, a protein mixture which includes 50 weight% of casein (i.e. the coagulating protein) and 50% of proteins that do not show coagulation. For such a protein mixture, figure 1 of D5 shows that there are no coagulation issues as understood in the context of the patent.

6.6.5 Thus, if any conclusion at all can be drawn from the results of D5, it is that a composition which is comparable to the one in D10 does not show any coagulation issues.

6.6.6 To conclude, D5 does not support the patent proprietor's ambitious formulation of the technical problem either.

6.7 The patent proprietor referred in writing to D9. In its view, this showed that incorporating soybean protein prevented casein from clotting.

6.7.1 However, D9 is not suitable for demonstrating that the subject-matter of claim 1 results in reduced coagulation issues with respect to D10 either.

6.7.2 The aim of D9 is to examine the gastric digestion of milk replacers, i.e. blends of milk and soy protein, in pre-ruminant calves. The *in vitro* gastric emptying was studied after digestion with chymosin, an enzyme exclusively produced in newborn ruminants. Therefore, it is not convincing that experiments on gastric emptying in calves, under conditions simulating the calf's abomasum, could support any conclusion on the technical problem under examination.

6.7.3 Thus, D9 is not relevant.

6.8 During the oral proceedings, the patent proprietor proposed a less ambitious technical problem, which was to provide a further protein mixture while maintaining the coagulation profile of D10.

However, there is no evidence which compares the coagulation profile of D10 with that of the subject-

matter of claim 1. Therefore, it is not appropriate to include any aspect relating to coagulation into the formulation of the technical problem.

6.9 Thus, the objective technical problem is to provide a further protein mixture which at least meets and preferably exceeds the WHO amino acid profile recommendations for complete nutrition. There is no doubt that claim 1 solves this problem.

7. Obviousness

7.1 Starting from D10, the skilled person tasked with providing a further protein mixture would look for enteral nutritional compositions which comprise a suitable protein mixture, with a mix of different vegetable and animal proteins.

7.2 The skilled person would consider D8. It concerns an enteral formula having a protein system that contains a stabilising protein and caseinate. The formula has a reduced rate of creaming and an enhanced shelf life (paragraph [0001]). These are basic requirements that enteral nutritional compositions have to meet. The patent in suit confirms this too (paragraph [0003], lines 46 to 48).

7.2.1 The protein system of D8 comprises a stabilising protein, which may be whey, soy, corn, potato, rice or pea. The vegetable protein is preferably intact. Furthermore, D8 suggests that the stabilising protein is an admixture of whey and one or more vegetable proteins (paragraphs [0036] and [0039]). In the examples of D8, protein mixtures of casein and soy protein in a ratio of 80 to 20 are described. Moreover, D8 instructs the skilled person that the quantity of

stabilising proteins can be increased to 60 w/w % based on the total protein content of the formula (claim 1; paragraph [0010]).

7.2.2 Therefore, the skilled person looking for further protein mixtures would find, in D8, the suggestion that some of the casein of the formula of D10 be replaced by intact soy protein and that the amount of this protein be modified. In doing so, the skilled person would provide a protein mixture falling within the scope of claim 1, without exercising any inventive skills.

7.2.3 For completeness, it is observed that blends of caseinate and soy protein are known for use in enteral nutrition compositions. D30 confirms this knowledge: it lists several pages of commercial compositions which comprise these two proteins. This supports the view that the skilled person would consider replacing some of the casein in the protein mixture of D10 by soy protein.

7.2.4 The patent proprietor argued that D10 was concerned with providing a protein mixture which mimicked egg protein. It maintained that the skilled person would not add soy protein to the composition of D10 in view of its poor nutritional properties.

7.2.5 However, the cysteine content of the protein mixture of D10 (table 1) is about half that in egg protein. Hence, it is manifest that D10 does not provide an amino acid profile which mimics that of egg protein. Rather, D10 simply aims to provide an amino acid composition which is similar in nutritional terms to standard reference proteins. Moreover, in the experimental section of D10, the protein mixture containing caseinate (50%), pea

protein (25%) and milk serum protein (25%) is compared with casein as the control, not egg protein.

7.2.6 The argument that soy protein has poor nutritional properties is not convincing either. The WHO amino acid profile recommendations for complete nutrition referred to in paragraph [0003] of the patent in suit are not difficult to achieve. Opponent 1 explained that the WHO recommendation was merely 0.6 g cysteine per 100 g protein and that the protein mixture of D10 easily achieved this value. It also presented conclusive calculations that, starting from D10, protein mixtures according to both claim 1 and the WHO requirement were feasible. The calculations were not contested. This confirms that using soy protein would not go against the teaching of D10. On the contrary, the skilled person has some leeway in how the protein mixture can be modified while still meeting WHO requirements.

8. Thus, the subject-matter of claim 1 does not involve an inventive step (Article 56 EPC).

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:

A. Nielsen-Hannerup A. Haderlein

Decision electronically authenticated