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**Datasheet for the decision of 8 June 2021**

**Case Number:** T 1571/17 - 3.3.09

**Application Number:** 10701940.8

**Publication Number:** 2528456

**IPC:** A61K38/01, A61K36/47, A61K35/20, A23L1/30, A23L1/29, A23L1/305

**Language of the proceedings:** EN

**Title of invention:**
LIQUID ENTERAL NUTRITIONAL COMPOSITION SUITABLE FOR TUBE FEEDING

**Patent Proprietor:**
N.V. Nutricia

**Opponent:**
Société des Produits Nestlé S.A.

**Headword:**
Liquid enteral nutritional composition suitable for tube feeding/NUTRICIA

**Relevant legal provisions:**
EPC Art. 56
EPC R. 103(4)(a)

**Keyword:**

Inventive step - formulation of the technical problem - obvious combination of known features

Reimbursement of appeal fee - withdrawal of appeal

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**Case Number: T 1571/17 - 3.3.09**

# D E C I S I O N
# of Technical Board of Appeal 3.3.09
# of 8 June 2021

| | |
|---|---|
| **Appellant:** (Opponent) | Société des Produits Nestlé S.A.<br>Entre-deux-Villes<br>1800 Vevey (CH |
| **Representative:** | Elkington and Fife LLP<br>Prospect House<br>8 Pembroke Road<br>Sevenoaks, Kent TN13 1XR (GB) |
| **Respondent:** (Patent Proprietor) | N.V. Nutricia<br>Eerste Stationsstraat 186<br>2712 HM Zoetermeer (NL) |
| **Representative:** | Nederlandsch Octrooibureau<br>P.O. Box 29720<br>2502 LS The Hague (NL) |
| **Decision under appeal:** | **Interlocutory decision of the Opposition Division of the European Patent Office posted on 8 May 2017 concerning maintenance of the European Patent No. 2528456 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 the opponent against the opposition division's interlocutory decision that European patent No. 2 528 456 as amended met the requirements of the EPC.

In the following, the parties will be referred to by their party status before the opposition division.

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

III. The opposition division decided, among other things, that auxiliary request 1 (filed as auxiliary request 4 by letter dated 22 December 2016) met the requirements of the EPC.

IV. With its statement setting out the grounds of appeal, the patent proprietor filed a main request and four auxiliary requests.

V. At the oral proceedings, the patent proprietor withdrew its appeal and maintained auxiliary request 3 as the main request and auxiliary request 4. Auxiliary request 3 is the request which, according to the contested decision, met the requirements of the EPC.

VI. The relevant claims for this decision are thus:

Claim 1 of auxiliary request 3, which reads:

"Liquid enteral nutritional composition comprising:

(i) a protein fraction comprising more than 25 weight% and up to 80 weight% of vegetable protein comprising at least a source of intact pea protein, the protein fraction further comprising a dairy protein selected from the group of casein, including micellar casein and caseinate, and whey protein, the protein fraction comprising pea, soy, casein and whey protein, wherein the protein fraction consists of:
- 20 to 40 weight% of casein,
- 20 to 40 weight% of whey protein,
- 13 to 25 weight% of soy protein, and
- 13 to 25 weight% of pea protein,
relative to the total protein in the protein fraction, wherein the sum of said proteins equals 100 weight%;

(ii) a fat fraction comprising
(a) 8 to 15 weight% of linoleic acid (LA);
(b) 3.0 to 6.0 weight% of a combination consisting of the ω-3 poly-unsaturated fatty acids alpha-linolenic acid (ALA), docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA), wherein the amount of ALA > 2.5 weight% and the combined amount of DHA and EPA ≤ 2.5 weight%;
(c) 10 to 20 weight% of at least one medium-chain fatty acid (MCFA); and
(d) 35 to 79 weight% of at least one mono-unsaturated fatty acid (MUFA), wherein all relative amounts are calculated based on the total amount of fatty acids in the fat fraction."

In claim 1 of auxiliary request 4, it is specified that the soy protein is intact soy protein.

VII. The relevant documents for this decision are:

D1: EP 1 972 345 A1

D2: B. Beaufrère et al., "The 'fast' and 'slow' protein concept", Proteins, Peptides and Amino Acids in Enteral Nutrition, 3, 2000, 121-133

D16: J. L. Rombeau, M. D. Caldwell (editors), "Clinical nutrition: enteral and tube feeding", 2nd edn., Philadelphia: W. B. Saunders Company, 1990, 160-167

D21: US 2003/0104033 A1

D34: 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

D'43: EP 2 424 384 B1

D46: Applicant's letter dated 6 January 2012 (PCT-phase, Chapter II)

D47: J.A.L. Calbet et al., "Gastric emptying, gastric secretion and enterogastrone response after administration of milk proteins or their peptide hydrolysates in humans", European Journal of Nutrition, 43(3), 2004, 127-139

VIII. The patent proprietor's arguments, where relevant to the present decision, may be summarised as follows:

D1 was the closest prior art. The composition from D1 coagulated in the stomach. The technical problem was to reduce coagulation of casein beyond "dilution" effects which were achieved by replacing casein with a non-

coagulating protein. The solution was to use anti-coagulating vegetable proteins (soy and pea) and to increase the ratio of vegetable proteins to casein. The fact that soy protein and pea protein were anti-coagulating proteins, i.e. proteins that reduced coagulation of casein beyond "dilution" effects, was implicitly disclosed in the patent and demonstrated e.g. in D34, D'43 or D46.

IX. The opponent's arguments, where relevant to the present decision, may be summarised as follows:

There was no evidence that the composition of D1 coagulated. Moreover, the patent neither disclosed that soy protein and pea protein were anti-coagulating proteins nor foreshadowed the patent proprietor's technical problem. Instead, the problem was to provide a further enteral composition. The solution was obvious in view of e.g. D16 and D21. Moreover, the skilled person would expect that replacing casein with non-coagulating proteins would lead to a reduction in coagulation.

X. The parties' final requests were:

The patent proprietor requested that the opponent's appeal be dismissed or that the patent be maintained on the basis of auxiliary request 4.

The opponent requested that the decision under appeal be set aside and that European patent No. 2528456 be revoked.

## Reasons for the Decision

1. The patent relates to a liquid enteral nutritional composition comprising a pea-based protein fraction and a fat fraction. Among other things, the composition is said to minimise clinical complications that are associated with the administration of enteral nutrition in patients using tube feeding, e.g. reduced gastric emptying (paragraph [0001]).

2. *Auxiliary request 3 - inventive step*

2.1 The closest prior art

2.1.1 It is uncontested that D1 is the closest prior art.

2.1.2 D1 concerns a food product for enteral nutrition. It includes a protein mixture which contains 50% caseinate, 25% milk serum proteins (i.e. whey proteins) and 25% pea protein and a specified lipid mixture (claims 1 and 2 and paragraph [0025]).

2.1.3 It is uncontested that, in view of D1, the distinguishing features of claim 1 are:

- 13 to 25 weight% soy protein (none in D1)
- 20 to 40 weight% casein (50% in D1)
- 8 to 15 weight% of linoleic acid (17.1-22.8% in D1)

The patent proprietor explained that a direct consequence of the distinguishing features was that in claim 1 the ratio of vegetable proteins to casein was higher than in D1.

2.2 The technical problem

2.2.1 The patent proprietor's position was that the composition from D1 coagulated in the stomach. In its statement setting out the grounds of appeal, the patent proprietor formulated the technical problem as: "how to provide a liquid enteral composition which reduces stomach coagulation and improves gastric emptying".

2.2.2 Paragraph [0011] of the patent describes:

"[C]asein is coagulating in the stomach while whey proteins are not coagulating in the stomach. Hence, casein is regarded as a coagulation protein with slow gastric emptying properties and whey proteins are regarded as non-coagulating proteins with a much faster gastric emptying."

2.2.3 This is also known from the prior art. For instance D47, a publication in which gastric emptying of milk proteins is investigated, discloses that whey proteins remain soluble in the stomach whereas casein clots (page 133). D2, a publication on postprandial protein kinetics, discloses that whey proteins are more rapidly emptied from the stomach than casein because the latter clots at an acidic pH.

2.2.4 The parties agreed that replacing part of the casein within a composition (at a given total concentration of protein) with a non-coagulating protein (e.g. whey) leads to a reduction in coagulation, since the composition will include less coagulating protein (casein) and more non-coagulating protein. The parties referred to this phenomenon or effect as the "dilution" of casein by a different (non-coagulating) protein.

2.2.5 The opponent has shown (e.g. in its letter dated 8 May 2019) that soy protein and pea protein do not coagulate and this is not in dispute.

2.2.6 At the oral proceedings, the patent proprietor argued that the protein fraction of claim 1 achieved an effect going beyond the "dilution" of casein. While whey was a non-coagulating protein, soy protein and pea protein were "anti-coagulating" proteins, which meant that they actively decreased the coagulation of casein beyond the level that the skilled person would have expected to occur by "dilution".

On this basis the proprietor then formulated a "more appropriate" (i.e. more ambitious) technical problem, to reduce stomach coagulation of casein beyond "dilution" effects.

2.2.7 However, such a problem is neither explicitly disclosed in nor derivable from the patent in suit or the application as filed. In particular, there is no disclosure, either in the context of the examples of the patent or in the passages describing the vegetable proteins, that soy or pea protein are anti-coagulating proteins within the patent proprietor's definition of this term.

2.2.8 The patent proprietor argued that the anti-coagulating properties of soy protein and pea protein would be derivable from a sentence of the application as filed (page 3, lines 24 and 25) which reads:

"It is unknown whether or not other proteins are coagulating in the stomach or whether or not they may influence gastric emptying."

The same sentence is also found in paragraph [0011] of the patent.

However, the board cannot identify in this sentence any direct or implicit statement that soy protein and pea protein are anti-coagulating proteins. This sentence does not support the conclusion that soy protein and pea protein have advantageous properties for the coagulation of casein compared with whey proteins.

2.2.9 To conclude, the allegedly more appropriate (i.e. more ambitious) formulation of the technical problem introduced by the patent proprietor (see point 2.2.6) is not derivable from the patent or application as filed. Consequently, the alleged anti-coagulating effect of soy protein and pea protein cannot be used in the formulation of the technical problem (see Case Law of the Boards of Appeal of the EPO, 9th edition, 2019, Chapter I.D.4.4.2). Therefore, it is not necessary to examine whether the patent proprietor is correct that D34, D'43 or D46 demonstrate that soy protein and pea protein have anti-coagulating properties.

2.2.10 The opponent's position was that the patent proprietor had not demonstrated that the composition of D1 coagulated in the stomach. Notably, in example 1 of the patent, no comparison had been made with the composition of D1, a document acknowledged as prior art in the application as filed. Instead, the control composition used in example 1 showed numerous differences with respect to the composition of the invention; in particular, the protein fraction consisted of casein only. The opponent concluded that the technical problem was to provide a further enteral nutritional composition.

2.2.11 However, it is not relevant to decide whether the opponent's formulation of the technical problem is correct. Even if it was accepted, for the sake of argument, that the composition from D1 showed some coagulation and even if the patent proprietor's formulation of the technical problem presented in the statement setting out the grounds of appeal was retained (see point 2.2.1), it would have been obvious for the skilled person to obtain a reduction in coagulation with respect to D1. This will be outlined in the following.

2.3 Obviousness

2.3.1 At the oral proceedings the patent proprietor based its inventive-step argument solely on the presence of the anti-coagulating effect of soy protein and pea protein.

However, as explained above, this effect cannot be taken into consideration and casein is known to be a coagulating protein with slow gastric emptying properties. Therefore, the skilled person would expect that if a nutritional formula comprises less casein and more of a non-coagulating protein (at a given total concentration of protein), this would generally result in less coagulation. In other words, the skilled person would expect the effect referred to as "dilution".

2.3.2 In the written appeal proceedings, the patent proprietor had argued that the skilled person would have no motivation to add soy protein to the composition of D1 and reduce the content of casein. In its view, D1 addressed the problem of mimicking the amino acid profile of egg protein and adding soy protein would move the amino acid profile further away from egg protein.

2.3.3 However, this is not convincing. Egg protein is mentioned in D1 only as a standard reference protein (paragraph [0014]) and there is no disclosure in D1 that the invention's aim is to mimic egg protein. Contrary to the patent proprietor's argument, soy protein is not a protein with poor nutritional properties; blends of caseinate and soy protein are used in numerous enteral nutrition compositions, as exemplified in D16. Finally, D21 suggests providing enteral formulas with a blend of different vegetable and animal proteins containing e.g. soy protein isolate (e.g. paragraph [0036] and table 15).

2.3.4 With regard to the composition of the fat fraction, in particular the amount of linoleic acid, this distinguishing feature does not involve an inventive step either. Throughout the opposition proceedings, the patent proprietor had not argued that the fat fraction and in particular the amount of linoleic acid made an inventive contribution. The opposition division correctly concluded that "it is agreed with the opponent, and indeed clearly indicated in the contested patent in paragraph 59, that the selection of the fat fraction of the present application is merely the selection of the overlapping information contained in the guidelines provided by the sources mentioned in paragraph 71. No particular technical effect can be derived from this activity, nor has any been shown or made plausible by the proprietor, in particular in view of the fat fraction of D1" (decision under appeal, page 6). The board sees no reason to revisit this conclusion on appeal.

2.4 Therefore, the subject-matter of claim 1 of auxiliary request 3 does not involve an inventive step (Article 56 EPC).

3. *Auxiliary request 4 - inventive step*

3.1 Claim 1 of this request specifies that the soy protein is intact soy protein. According to the patent, "intact" means "non-hydrolysed" (paragraph [0031).

3.2 No technical effect for such a protein is described in the patent or demonstrated otherwise and the patent proprietor has not referred to any particular technical effect achieved by the non-disrupted primary structure of the soy protein either. Moreover, the prior-art document D21 explicitly suggests using intact vegetable proteins (paragraph [0036]). Therefore, intact soy protein does not make an inventive contribution.

3.3 Therefore, the subject-matter of claim 1 of auxiliary request 4 does not involve an inventive step (Article 56 EPC).

3.4 The opponent had requested that auxiliary request 4 not be admitted into the proceedings. In view of the fact that this request is not allowable, there is no need to decide on its admission into the proceedings.

4. *Partial refund of the appeal fee*

At the oral proceedings, the patent proprietor withdrew its appeal before the decision was announced. Its appeal fee is to be reimbursed at 25% under Rule 103(4)(a) EPC.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The patent is revoked.
3. The appeal fee of the patent proprietor is reimbursed at 25%.

The Registrar: The Chairman:


A. Nielsen-Hannerup A. Haderlein

Decision electronically authenticated