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Datasheet for the decision of 11 November 2021

Case Number: T 0857/16 - 3.3.09

Application Number: 10718726.2

Publication Number: 2424384

IPC: A23L1/29, A23L1/305, A61K38/16

Language of the proceedings: EN

Title of invention:
METHOD FOR CONTROLLING THE DIGESTIVE COAGULATION OF PROTEINS

Patent Proprietor:
N.V. Nutricia

Opponents:
ABBOTT LABORATORIES
Société des Produits Nestlé S.A.
Fresenius Kabi Deutschland GmbH

Headword:
Digestive coagulation of proteins/NUTRICIA

Relevant legal provisions:
EPC Art. 54(3), 54(5), 56, 83, 84, 123(2)
EPC R. 80
RPBA Art. 12(4)
RPBA 2020 Art. 25(2)

Keyword:
Main request - Withdrawn
Auxiliary request 1 to 3, 5 to 7 and 9 to 11 - Sufficiency (no)
Auxiliary requests 4 and 8 - Added matter (yes)
Auxiliary requests 12 to 20 - Novelty (no)
Auxiliary request 21 - Clarity, Sufficiency, Novelty and Inventive Step (yes) - Added matter (no)

Decisions cited:
G 0002/08, T 0836/01, T 0304/08, T 1822/12, T 1972/14

Catchword:

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Case Number: T 0857/16 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 11 November 2021

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Appellant: (Opponent 1)	ABBOTT LABORATORIES 100 Abbott Park Road Abbott Park IL 60064 (US)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted on 15 February 2016 concerning maintenance of the European Patent No. 2424384 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

I. Appeals were filed by the three opponents and the patent proprietor against the decision of the opposition division finding that European patent No. 2 424 384 as amended according to auxiliary request 9 met the requirements of the EPC. As all parties are appellants, for the sake of simplicity, the board will continue to refer to them as patent proprietor and opponents.

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

III. The documents submitted during the opposition proceedings included:

D1: EP 1 972 346 A1
D2: US 2003/0104033
D3: WO 02/098242 A1
D5: US 5,021,245
D7: Caugant I. *et al.*, Journal of Diary Science, Vol. 77, 1993, pp. 533-540
D8: Yvon, M. *et al.*, Journal of Agriculture and Food Chemistry, vol. 40, 1992, pp. 238-244
D9: Chavan, U.D. *et al.*, Food Chemistry, Vol. 74, 2001, pp. 177-187
D10: WO 2010/126362 A1
D12: WO 2011/093693 A1
D13: Beaufrère B. *et al.*, Proteins, Peptides and Amino Acids in Enteral Nutrition, Vol. 3, 2000, pp. 121-133

D16: GB 1 507 380

D19: Gorrill A. *et al.*, The Journal of Nutrition, 1967, pp. 215-223

D20: Decuypere J.A. *et al.*, Journal of Animal Science, Vol. 53, 1981, pp. 1011-1018

D23: Calbet J.A.L. *et al.*, European Journal of Nutrition, Vol. 43(3), 2004, pp. 127-139

D28: van den Braak C. *et al.*, Clinical Nutrition, Vol. 32, 2013, pp. 765-771

D29: Hall. J.H. *et al.*, Brochure from Virginia Tech "Digestive system of the cow", 2009

D33: Guerin-Deremaux L. *et al.*, Brochure from Roquette "Is Nutralys a fast or a slow protein?", 1997

D35: Scanff P. *et al.*, Journal of Agriculture and Food Chemistry, Vol. 38(8), 1990, pp. 1923-1929

D36: Paul G.L., Journal of the American College of Nutrition, Vol. 28(4), 2009, pp. 464S-472S.

IV. In its decision, the opposition division found that:

- the subject-matter of the main request, filed as auxiliary request 1 by letter of 1 October 2015, did not meet the requirements of Articles 84 and 123(2) EPC. Claim 1 was drafted in the "further medical use" format but encompassed the treatment of conditions which were not medical. This rendered the claimed scope unclear. Furthermore, claim 1 contained added subject-matter because it envisaged the treatment of any kind of gastrointestinal disease, whereas the application as filed only disclosed the treatment of gastrointestinal diseases caused by the ingestion of a coagulating protein

- auxiliary request 1, filed during the oral proceedings, was not admitted on the ground that it contained unclear subject-matter

- auxiliary requests 2 to 8, filed by letter of 1 October 2015, were also considered to contain unclear subject-matter

- the subject-matter of auxiliary request 9 met the requirements of the EPC

V. The following requests were filed during the appeal proceedings:

- main request and auxiliary requests 1 to 11, filed with the statement setting out the grounds of appeal

- auxiliary requests 12 to 20, filed by letter of 7 January 2020

- auxiliary requests 21 to 23, filed as auxiliary requests 12 to 14 with the statement setting out the grounds of appeal

VI. The main request was withdrawn during the oral proceedings held before the board.

VII. Claim 1 of auxiliary request 1 reads:

"1. A nutritional composition that comprises anti-coagulating protein and coagulating protein, for use in the prevention or treatment of upper gastrointestinal complications resulting from coagulation of said coagulating protein in a human subject, wherein said anti-coagulating protein prevents or reduces

coagulation of said coagulating protein in the upper gastro-intestinal tract of said human subject, wherein the coagulating protein comprises caseinate and wherein the anti-coagulating protein is selected from pea and soy protein or a combination thereof."

VIII. Claim 1 of auxiliary requests 2, 3, 5, 6, 7, 9, 10 and 11 differs from claim 1 of auxiliary request 1 in that the gastrointestinal complications and the amounts of proteins are more narrowly defined.

IX. Claim 1 of auxiliary request 4 reads:

"1. A nutritional composition that comprises coagulating protein, for use in preventing or reducing coagulation of said coagulating protein in the upper gastro-intestinal tract of a human subject suffering from upper gastrointestinal complications, said nutritional composition comprising anti-coagulating protein, wherein the nutritional composition comprises between 25-95 wt.% coagulating protein based on total weight of protein in the composition and between 5-75 wt.% anti-coagulating protein based on total weight of protein in the composition, and wherein the coagulating protein comprises caseinate and wherein the anti-coagulating protein is selected from pea and soy protein or a combination thereof."

X. Claim 1 of auxiliary request 8 is worded the same as claim 1 of auxiliary request 4, but the anti-coagulating protein is selected from pea protein or a combination of pea protein and soy protein.

XI. Claim 1 of auxiliary request 12 reads:

"*1. A nutritional composition that comprises anti-coagulating protein and coagulating protein, for use in the prevention of upper gastrointestinal complications resulting from coagulation of said coagulating protein in a human subject, wherein said anti-coagulating protein prevents or reduces coagulation of said coagulating protein in the upper-gastro intestinal tract of said human subject, wherein the coagulating protein comprises caseinate and wherein the anti-coagulating protein is selected from pea and soy protein or a combination thereof.*"

XII. Claim 1 of auxiliary requests 13 to 20 differs from claim 1 of auxiliary request 12 in that the gastrointestinal complications and the amounts of proteins are more narrowly defined.

XIII. Claim 1 (sole claim) of auxiliary request 21 reads:

"1. A non-therapeutic method for preventing or reducing coagulation of a coagulating protein comprised in a nutritional composition in the upper gastro-intestinal tract of a human subject, said method comprising administering said nutritional composition comprising anti-coagulating and coagulating protein to said subject, wherein the coagulating protein comprises caseinate and wherein the anti-coagulating protein is selected from pea and soy protein or a combination thereof."

XIV. The **proprietor's arguments** can be summarised as follows.

- All requests, including auxiliary requests 12 to 20 filed in reply to the board's communication, should be admitted.

- The claimed subject-matter was based on the teaching of the claims and pages 2 to 4 and 7 to 9 as originally filed.

- The invention was sufficiently disclosed and clearly defined. Example 1 of the patent showed that pea and soy protein reduced caseinate coagulation. The remarkable decrease in coagulates observed in Figure 1 was not due to dilution. At a concentration of 3%, caseinate coagulated upon digestion, as shown in D7 and D33. Reducing coagulation resulted in both prevention and treatment. The description provided sufficient information to carry out the invention. The opponent had not provided any evidence that the invention could not be carried out.

- The claimed subject-matter was novel over the cited documents. None of these disclosed the use of soy or pea protein to inhibit casein coagulation. The claimed therapeutic effects were not disclosed either. These technical features distinguished claim 1 of auxiliary request 1, relating to a therapeutic use, and claim 1 of auxiliary request 21, relating to a non-therapeutic use. Claim 1 of auxiliary request 21 related to a non-therapeutic method in which a product was used to achieve an effect and not to a process for manufacturing a product.

- The claimed subject-matter involved an inventive step starting from D1, D7, D19 or D20 as the closest prior art. D7, D19 and D20 related to the nutrition of animals, not humans. Furthermore, according to D7 and D20, coagulation was beneficial

rather than problematic. The digestive system of cows could not be compared to that of humans. The model used in D7 was not suitable for reproducing the human gastrointestinal system. D8 and D29 did not support extrapolation to humans either. D16 showed that milk protein formed clots and related to a different problem, food stability. The prior art did not hint in any way at the use of pea or soy protein to inhibit caseinate coagulation. D9 described the solubility profile of the pea protein, not its coagulating properties. Coagulation did not correlate with solubility.

XV. The **opponents' arguments** may be summarised as follows.

- None of the requests on file should be admitted.

- The recasting of the claims infringed Rule 80 EPC.

- All requests contained added subject-matter as follows: the treatment of subjects affected by disorders not induced by casein coagulation; the formulation of claims in the medical and non-medical format and the addition of an undisclosed disclaimer directed to a non-therapeutic method; and the selection of "upper gastrointestinal complications" and its combination with the other claimed features.

- The claims were unclear, and the invention insufficiently disclosed. The composition could not prevent diseases induced by its own administration. It was impossible to distinguish therapeutic from non-therapeutic uses and define gastrointestinal complications. The claimed composition was not as such suitable for preventing protein coagulation

and treating or preventing gastrointestinal disorders, let alone if other ingredients were present. The effect in example 1 of the patent was only due to caseinate dilution.

- The claimed subject-matter lacked novelty over D1, D2, D3, D5, D6, D10, D12, D16, D19, D20 and D36. Preventing coagulation did not distinguish the claimed subject-matter from the prior art. Claim 1 of auxiliary request 12 defined a mechanism of action which occurred when carrying out the treatments of the prior art, in particular the treatment disclosed in D12. Claim 1 of auxiliary request 21 defined a non-therapeutic method not limited by the intended purpose.

- The claimed subject-matter did not involve an inventive step starting from D1, D7, D19 or D20 as the closest prior art. In particular, starting from D1 as the closest prior art, the problem was the provision of a further use for the claimed composition. Starting from D7, the problem was the provision of an alternative use of anti-coagulating protein or a further patient population in which coagulation had to be prevented. There was no evidence that soy and pea protein prevented coagulation. Thus, this problem had not been solved.

- D7 taught that soy protein reduced casein coagulation in pre-ruminant calves. D9 taught that pea protein was not a coagulating protein. D8, D29 and D35 showed that the calf abomasum was a model for the human stomach. D16 taught that milk protein precipitation was inhibited by vegetable protein (e.g. soy), and D19 taught that no curd was formed

in calves fed with diets in which milk protein was partially replaced by soy protein. D13 and D33 taught that casein was a "slow" coagulating protein, whereas pea and soy were "fast" non-coagulating proteins. It was thus obvious to replace caseinate with soy or pea protein to prevent caseinate coagulation and complications associated with coagulation.

The requests

XVI. The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of:

- auxiliary requests 1 to 11, filed with the statement setting out the grounds of appeal

- auxiliary requests 12 to 20, filed with the letter dated 7 January 2020

- auxiliary requests 21 to 23, originally filed with the statement of grounds of appeal as auxiliary requests 12 to 14

XVII. The opponents requested that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

1. The main request was withdrawn during the oral proceedings before the board. Thus, the first relevant request is auxiliary request 1.

2. The admissibility of auxiliary requests 1 to 20 was contested. In view of the following conclusions

concerning these requests, there is no need to discuss this issue.

Auxiliary requests 1, 2, 3, 5 to 7 and 9 to 11

3. *Sufficiency of disclosure*

3.1 The idea underlying the opposed patent is to include an anti-coagulating protein in a nutritional composition comprising a coagulating protein to prevent the coagulation of the coagulating protein when the composition is ingested by a human subject (see paragraphs [0007], [0036] and [0038]). According to claim 1, the nutritional composition can be used to treat and prevent gastrointestinal complications induced by protein coagulation.

3.2 The board considers it credible that gastrointestinal complications induced by protein coagulation after ingestion can be prevented by preventing the coagulation of the coagulating protein present in the composition. However, the idea that a condition induced by the ingested composition can be treated by administering that same composition is at odds with the principle underlying the invention.

3.3 The proprietor argued that in cases in which protein coagulation is not completely prevented and a subject still suffers from gastrointestinal complications, but to a lesser extent, the invention related to a treatment rather than a prevention. Treatment had to be considered in a broad sense and to encompass alleviation of a disease.

3.4 This argument is not convincing. The idea that a sub-optimal prevention of coagulation changes the nature of

the intervention, namely from the prevention of a complication to its treatment, is not logical. Considering how the invention is carried out and the underlying mechanism of action, it is not credible that the purported therapeutic effect extends beyond prevention of gastrointestinal complications.

3.5 For these reasons it is concluded that, as far as it relates to a therapeutic treatment, the invention defined in claim 1 of auxiliary request 1 is not sufficiently disclosed. Claim 1 of auxiliary requests 2, 3, 5 to 7 and 9 to 11 relates, like claim 1 of auxiliary request 1, to a therapeutic treatment. Thus, the same conclusions apply to these requests.

3.6 For these reasons, auxiliary requests 1 to 3, 5 to 7 and 9 to 11 are not allowable (Article 83 EPC).

Auxiliary requests 4 and 8

4. *Added subject-matter*

4.1 Claim 1 of auxiliary requests 4 and 8 relates to a composition for use in preventing or reducing the coagulation of a coagulating protein in subjects suffering from gastrointestinal disorders. This claim encompasses the treatment of subjects suffering from upper gastrointestinal complications not necessarily induced by protein coagulation. The treatment of these subjects is not disclosed in the application as filed.

4.2 The parts of the application as filed mentioning subjects suffering from upper gastrointestinal complications make it clear that the complications arise from delayed gastric emptying caused by coagulation of proteins in the upper gastrointestinal

system (see page 1, lines 5 to 6 and 11 to 15 and page 9, lines 18 to 20). The gist of the originally disclosed invention is, in fact, to reduce protein coagulation in the upper gastrointestinal tract and prevent the complications induced by that coagulation.

4.3 This means that according to the teaching of the application as filed, the treated subjects are those whose gastrointestinal complications arise because of protein coagulation. However, in claim 1, the aetiology of the gastrointestinal complications is not limited in any way. This adds originally undisclosed subject-matter.

4.4 Auxiliary requests 4 and 8 are thus not allowable (Articles 123(2) EPC).

Auxiliary requests 12 to 20

5. *Novelty*

5.1 Claim 1 relates to a nutritional composition comprising caseinate and pea or soy protein for use in the prevention of upper gastrointestinal complications resulting from coagulation of caseinate in a human subject. Examples of such complications, listed in claim 5, are aspiration pneumonia, reflux, vomiting, nausea, bloating and delayed gastric emptying.

5.2 During the proceedings, the parties gave opposing views as to whether the expression "prevention of gastrointestinal complications" limits the claim to medical treatments by therapy within the meaning of Article 53(c) EPC or whether non-medical conditions also fall within this definition. It was, however, not disputed that this expression encompasses medical

treatments and that as far as these treatments are concerned, claim 1 is to be construed as a purpose-limited product claim in accordance with Article 54(5) EPC.

5.3 Article 54(5) EPC allows patent protection of substances or compositions already known as medicines, provided their use in a method under Article 53(c) EPC be specific and not comprised in the state of the art. Where it is already known to use a medicament to treat an illness, Article 54(5) EPC does not exclude that this medicament be patented for use in a different treatment by therapy of the same illness (see G2/08, answer to question 1).

5.4 The opponents contended that the subject-matter of claim 1 of auxiliary request 12 lacks novelty over D12, a document relevant under Article 54(3) EPC, on the ground that D12 discloses the same composition, for treating the same illness, by carrying out the same treatment method.

5.5 D12 discloses a nutritional composition comprising a specifically designed pea-based protein fraction, which is well tolerated and minimises complications associated with reduced gastric emptying (see page 1 lines 6 to 13). These complications, which are classified as "upper digestive tract complications", include reduced gastric emptying, retention, reflux, vomiting, aspiration and pneumonia (see page 2, lines 9 to 17). All are said to be linked to reduced gastric emptying.

5.6 The composition defined in claim 8 of D12 comprises 20 to 40% wt casein protein, 13 to 25% wt soy protein, 13 to 25% wt pea protein and 20 to 40% wt whey protein.

Page 12, lines 8 to 11 specifies that within the context of the invention, in one embodiment, "casein" is caseinate and preferably is calcium caseinate.

5.7 D12 states that it was known from the existing literature that different proteins can influence gastric emptying in different ways and that casein is considered a coagulating protein with slow gastric emptying properties. Furthermore, it states that whey was considered a non-coagulating protein with fast gastric emptying and that it was previously unknown whether "other proteins" (e.g. pea and soy protein) influence gastric emptying (see page 3, lines 19 to 24). The composition proposed in D12 to prevent the aforementioned gastrointestinal complications comprises pea protein as the only mandatory ingredient. The next preferred protein is soy protein (see claims 1 and 8). Thus, D12 teaches that pea and soy, like whey, are proteins which minimise complications associated with reduced gastric emptying otherwise induced by casein and caseinate.

5.8 Example 1 of D12 reports the results of a clinical trial comparing a composition containing casein as the sole source of protein with one according to the invention in which 75% of the casein protein has been replaced by soy protein, pea protein and whey protein. The results show that there is a reduction in the incidence of nausea and vomiting, i.e. of upper gastrointestinal complications according to claim 5 of auxiliary request 12 (see D12, page 42, lines 1 to 14). These results confirm that, as explained in the aforementioned pages 2 and 3 of D12, casein protein induces upper gastrointestinal complications and that these complications can be prevented if soy, pea and

whey proteins are included in the composition replacing part of the casein.

5.9 According to the proprietor, the subject-matter of claim 1 was novel over D12 because D12 did not mention the prevention or reduction of coagulation of a coagulating protein in the upper gastrointestinal tract of a human and did not disclose the anti-coagulating effect of pea and soy either.

5.10 However, this is irrelevant. As noted by opponent 1, as in the case underlying decision T 1972/14 (see point 1.1 of the Reasons), the identification of the mechanism of action underlying the method of treatment disclosed in D12 does not confer novelty to claim 1. Furthermore, as noted by opponent 2, mentioning this mechanism of action in the case at issue does not result in the identification of a new clinical situation and the definition of a new group of patients, as was the case, for example, in decision T 836/01 (see point 10 of the Reasons).

5.11 For these reasons, it is concluded that the subject-matter of claim 1 of auxiliary request 12 lacks novelty over the teaching of D12.

5.12 Claim 1 of auxiliary requests 13 to 20 defines more specifically the upper gastrointestinal complications being treated and the amounts of proteins present in the composition. However, these limitations do not further distinguish the claimed subject-matter from the teaching of D12. In particular, the complications include vomiting, which is disclosed in D12.

5.13 For these reasons, it is concluded that the subject-matter of auxiliary requests 12 to 20 lacks novelty

over D12 and is not allowable (Articles 100(a) EPC and 54(3) EPC).

Auxiliary request 21

6. *Admission and Rule 80 EPC*

6.1 Auxiliary request 21 was filed with the proprietor's statement setting out the grounds of appeal, thus at the earliest stage of the appeal proceedings. It contains only one claim, claim 1, directed to a non-therapeutic method for preventing or reducing coagulation of a coagulating protein in a human.

6.2 Claim 1 derives from claim 8 of the main request underlying the decision under appeal, filed as auxiliary request 1 by letter of 1 October 2015. Current claim 1 differs from earlier claim 8 in that it specifies that the coagulating protein is caseinate. This amendment addresses objections of lack of sufficiency raised during the opposition proceedings and does not substantially change the case because caseinate was a characterising feature of the method defined in the other requests, e.g. auxiliary request 4, also filed on 1 October 2015. All other claims were deleted. This results in a considerable simplification of the case. Thus, there is no reason to consider auxiliary request 21 inadmissible (Article 12(4) RPBA 2007 and Article 25(2) RPBA 2020).

6.3 The patent as granted did not contain a claim directed to a non-therapeutic method. The opponents argued that the insertion of this new claim infringed Rule 80 EPC. However, the addition of an independent claim directed to a non-therapeutic method during the opposition proceedings was in reaction to the objection that

granted claim 1 encompassed both therapeutic and non-therapeutic uses and lacked novelty over the prior art (see e.g. page 5 of the notice of opposition of opponent 1). The claims were re-formulated in reply to this objection to distinguish these two embodiments of the invention and establish novelty over the cited prior art. Therefore, the amendment is occasioned by a ground for opposition and does not infringe Rule 80 EPC.

7. *Added subject-matter*

7.1 According to the opponents, claim 1 adds originally undisclosed subject-matter because it contains an undisclosed disclaimer which has no basis in the application as filed.

7.2 This is not correct. The following sections of the application provide basis for the claimed subject-matter: page 2, lines 21 to 29 and claims 1, 2, 7, 8 and 9 as filed. These sections teach that the invention concerns the administration of an anti-coagulating protein for preventing coagulation of a coagulating protein and that both proteins are included in a nutritional composition. Moreover, they teach that the invention can be carried out for non-therapeutic purposes (see page 2, line 27 referring to a non-therapeutic treatment). Healthy subjects who may benefit from the treatment and a sports drink are mentioned (e.g. page 10, line 21). It is also clear that humans are the preferred subjects of the treatment (claim 9 and page 9, line 27) and that the preferred proteins are caseinate, pea and soy (see claims 7 and 8).

7.3 Opponent 1 argued that claim 1 encompasses uses, such as the prevention of bloating and delayed gastric emptying, which involve both therapeutic and non-therapeutic effects and that the "insertion of the term non-therapeutic infringes Article 123(2) EPC because " *it is not saved by the necessity to meet Article 53(c) EPC*" (grounds of appeal, page 3, last paragraph). This argument is not convincing, at least for the aforementioned reason that the claimed non-therapeutic method is based on page 2, lines 27 to 28 of the application as filed. Therefore, claim 1 does not contain added subject-matter (Article 123(2) EPC).

8. *Sufficiency of disclosure and clarity*

8.1 The reasons for the finding that the invention defined in claim 1 of auxiliary request 1 is not sufficiently disclosed do not apply because that claim was deleted and the sole claim of auxiliary request 21 does not relate to the treatment referred to in that claim.

8.2 According to the opponents, the invention defined in claim 1 of auxiliary request 21 is also insufficiently disclosed. Focusing on the wording of claim 1, the opponents argued, first of all, that the administration of a composition comprising a coagulating protein cannot be used for preventing or reducing the coagulation of a coagulating protein contained in the same composition. For this same reason, they considered that claim 1 also lacked clarity.

8.3 Focusing on the literal wording of claim 1, this conclusion could appear correct. Nevertheless, when construing the claim from the perspective of a skilled person, technically nonsensical readings should be avoided. From this perspective, it is clear that it is

the anti-coagulating protein present in the composition, rather than the composition as such, which is used to prevent or reduce the coagulation of the coagulating protein comprised in the composition. Therefore, this argument is not convincing and neither leads to the conclusion that the invention of claim 1 is not sufficiently disclosed, nor that claim 1 lacks clarity.

8.4 The opponents argument that claim 1 lacks clarity because the boundary between therapeutic and non-therapeutic application is not clear is not convincing either. From the perspective of a skilled person, it is possible to distinguish therapeutic from non-therapeutic applications. Healthy subjects who can benefit from the treatment are mentioned on page 10, line 21 of the application as filed. In these subjects, it is possible to achieve a non-therapeutic effect without necessarily inducing a therapeutic one.

8.5 The opponents have also contended that the invention is not sufficiently disclosed because pea and soy protein, which are labelled each as an "anti-coagulating protein" in claim 1, are not suitable for preventing the coagulation of caseinate, the coagulating protein. They noted that according to paragraphs [0007] and [0008] of the patent, reduction and prevention of coagulation means that coagulation occurs to a far lesser extent compared to what would be expected based on the amount of coagulating protein present in the composition and that a "synergistic effect" has to take place. In their opinion, the tests in example 1 and Figure 1 of the patent show that coagulation is not prevented.

8.6 The tests of example 1 were conducted as follows: compositions comprising only caseinate or a combination of caseinate and either pea or soy protein were subjected to gastric digestion using an *in-vitro* model of the human stomach. The total number of proteins was constant (6% w/v), but their ratio was varied. The following compositions were tested:

- 100% sodium caseinate
- sodium-caseinate to pea protein 85:15 (w/v)
- sodium-caseinate to pea protein 70:30 (w/v)
- sodium-caseinate to pea protein 60:40 (w/v)
- sodium-caseinate to soy protein 70:30 (w/v)
- sodium-caseinate to soy protein 50:50 (w/v)

8.7 After gastric digestion, the samples were sieved to yield fractions comprising protein coagulates having different particle sizes.

8.8 Figure 1 shows the weight of the coagulates having a diameter of between 1 and 2 mm and bigger than 2 mm, retrieved after digestion of the tested compositions. As shown in this figure, the weight of the coagulate particles decreases progressively as the ratio of pea or soy protein to caseinate is increased.

8.9 According to the opponents, this progressive decrease correlated only with the reduction in the amount of caseinate. It was due to the replacement of caseinate, which coagulated during digestion, with pea or soy protein, which did non coagulate. The effect did not extend beyond dilution and did not qualify as "prevention or reduction of coagulation" as defined in the patent.

8.10 Referring for example to D13 and D33, the opponents noted that it was well known that caseinate coagulated during digestion and was digested slowly, thus it was considered a "slow protein", whereas pea protein did not readily coagulate and was digested fast. Soy protein was similar to pea protein and could not be expected to coagulate either. These properties of the tested proteins explained the results.

8.11 Opponent 2 also filed graphs obtained by plotting the results of Figure 1 using different scales (see letters dated 28 February 2019 and 6 February 2020). In its opinion, these graphs confirmed the direct correlation between the recovered coagulate and the amount of caseinate initially present in the composition; the absence of coagulates in the sample containing a 50:50 ratio of caseinate to soy protein was also not surprising. In this sample, the concentration of caseinate was 3%, below its minimum gelling concentration, and coagulation could not occur. These results showed that pea protein and soy protein did not materially affect the aggregation of caseinate.

8.12 The board does not agree with these conclusions. Figure 1 shows that the replacement of 15% and 30% caseinate with pea protein affords a decrease in the total number of particles having a diameter larger than 1 mm of around 37% (from around 31.5 to 20 g) and 75% (from around 31.5 to 8 g), respectively. The decrease in the number of particles having a diameter larger than 2 mm is even sharper: around 63% (from 24 to 9 g) and 87% (from 24 to 4 g), respectively. Similar results are obtained replacing 30% caseinate with soy protein. No particles having a diameter larger than 1 mm are found when 50% caseinate is replaced with soy protein.

8.13 The board considers it credible that this decrease in coagulated particles far exceeds that which could be attributed to dilution. This decrease and the total absence of coagulated particles larger than 1 mm in the samples comprising a 1:1 ratio of caseinate to soy protein (3% w/v of each protein) are due to the influence of soy and pea protein on the coagulation process of caseinate. As explained by the proprietor with reference to D7 (table 1 and results) and D33 (results), at a concentration of 3%, caseinate would coagulate when subjected to digestion; the conditions to which a protein is subjected during digestion are more complex than those occurring when it is simply diluted below its gelling concentration.

8.14 The opponents contended that D7 and D33 were not relevant because they did not indicate the size of the particles present in the coagulate. Furthermore, they argued that the results in Figure 1 of the patent were meaningless because the number of particles having a diameter of less than 1 mm was not given. Coagulation could have occurred, resulting in particles of smaller size, which were not shown. Pepsin, one of the hydrolytic enzymes used for the tests could also have cleaved caseinate, preventing the growth of larger particles. Prevention of coagulation could only be shown by adding incremental amounts of pea or soy protein to a fixed amount of caseinate. No such test had been performed.

8.15 These arguments are not persuasive. D33 teaches that 3% casein coagulates when subjected to digestion in a model simulating human digestion and that this coagulate causes delayed gastric emptying. It is thus reasonable to assume that the coagulates mentioned in

D33 have substantially the same size (at least 1 mm) as those which according to the patent induce delayed gastric emptying. This confirms that the total absence of coagulates observed when 50% caseinate is replaced with soy protein results from the presence of soy protein and is not due to dilution.

8.16 Although it cannot be ruled out that particles having a smaller size were formed during the tests and that some caseinate was hydrolysed by pepsin, the overall picture of the results in example 1 is that pea protein and soy protein inhibit caseinate coagulation. The most credible explanation for the total absence of coagulates of at least 1 mm in the last sample and for the remarkable decrease in their amounts in the others, which far exceeds that which could be explained by dilution, is that pea and soy protein inhibit the coagulation of caseinate.

8.17 It is not disputed that other tests and experimental settings could have been envisaged to further assess the effects of soy or pea protein and explore the underlying mechanism of action. However, it was on the opponents to show that, as they allege, these proteins do not materially affect the coagulation of caseinate during the digestion process. It was also on them to show that low amounts of pea or soy protein (e.g. 5%, mentioned in claim 5) are not suitable for inducing the effect mentioned in the patent. To the extent that the claims could encompass significantly lower or even insignificant amounts of these proteins, the skilled person would not consider carrying out these embodiments of the invention or would not consider them to be covered by claim 1.

8.18 For these reasons, it is concluded that the invention can be carried out by the skilled person and that claim 1 fulfils the requirement of sufficiency of disclosure and clarity (Articles 83 and 84 EPC).

9. *Novelty*

9.1 Lack of novelty of claim 1 was disputed over D1, D2, D3, D5, D10, D12 and D36.

9.2 Referring to decisions T 304/08 and T 1822/12, the opponents argued that the purpose of the method defined in claim 1, namely the prevention or reduction of coagulation of the coagulating protein, does not limit the scope of the claim or, at most, only indicates that the method is suitable for achieving this effect.

9.3 The board does not share this view. In the decisions cited, the claims were directed to a process for producing a product: in T 304/08, an adsorbent treated with a surface-active agent having reduced malodour; in T 1822/12, a food having a reduced concentration of acrylamide and moisture content. In these cases, the respective boards, referring to decisions G 2/88 and G 6/88, decided that the purpose of the claimed method was only limiting to the extent that the method had to be suitable for achieving that specified purpose.

9.4 In the current case, although claim 1 literally refers to a method, the claimed invention does not relate to a method for manufacturing a product but instead to the use of a product to obtain an effect. As mentioned above (point 8.3), claim 1 is not to be construed as relating to a method in which a composition comprising a coagulating protein is administered to inhibit the coagulation of that same coagulating protein. This

reading would be illogical. Instead, claim 1 is to be construed as relating to the use of an anti-coagulating protein present in a composition in a non-therapeutic method in which the anti-coagulating protein prevents the coagulation, in the human gastrointestinal tract, of a coagulating protein included in that composition.

9.5 Thus, the effect of preventing coagulation indicated in the claim is a characterising feature of claim 1 and cannot be disregarded. None of the aforementioned cited documents mentions this use.

9.6 D1 (claim 1) discloses a nutritional composition for enteral nutrition comprising caseinate and pea protein. D3 (table 1) and D5 (claim 6) disclose nutritional compositions comprising caseinate and soy protein. However, none of these documents mentions coagulation.

9.7 D2 (table 2 and example 5) discloses nutritional compositions comprising caseinate and soy protein which do not cream or coagulate during storage. No mention is made of coagulation in the gastrointestinal tract.

9.8 D10 has the same filing date and claims priority from the same earlier priority document as the patent in suit. No reference is made to coagulation in that earlier document. D10 is thus not relevant under Article 54(3) EPC.

9.9 D12 and D36 teach that pea and soy protein do not coagulate during digestion. However, they do not directly and unambiguously disclose the claimed use.

9.10 Therefore, the subject-matter of claim 1 is novel over the prior art.

10. *Inventive step*

10.1 In their statement setting out the grounds of appeal, the opponents referred to each of D1, D7, D19 and D20 as the closest prior art. Since the claimed invention relates to a nutritional composition for human use, the board considers that a document focusing on the preparation of a nutritional composition for use in humans should be selected as the closest prior art. D1 is the only of the aforementioned documents relating to human nutrition. D7, D19 and D20 relate to animal feeds for calves and pigs. Furthermore, as noted by the proprietor, contrary to the teaching of the opposed patent, casein coagulation and the consequent curd formation during digestion are regarded in the prior art as beneficial, not problematic. D7 teaches that the decrease in coagulation is associated with reduced body gain and digestibility in calves (page 534, first paragraph). D20 teaches that curd formation (induced by coagulation) is necessary for the rearing of calves and pigs (page 1016, right column, first paragraph).

10.2 For these reasons, D7, D19 and D20 do not represent the closest prior art. D1 is thus the closest prior art.

10.3 The claimed subject-matter differs from the teaching of D1 by the use of the anti-coagulating protein to prevent or reduce the coagulation of caseinate. The technical effect induced by this difference is that the composition is easily digestible and that digestive comfort is improved (see paragraphs [0003], [0038] and [0043] of the opposed patent).

10.4 The underlying problem is the provision of a non-therapeutic method involving a further use of pea and/

or soy protein in a nutritional composition comprising caseinate administered to a human subject.

10.5 For the reasons discussed above when dealing with the issue of sufficiency of disclosure, it is credible that pea protein and soy protein prevent the coagulation of caseinate. This makes it also credible that the underlying problem has been solved.

10.6 According to the opponents, the proposed solution was obvious. It was well known that caseinate coagulated during digestion, whereas pea or soy protein did not. The different coagulating properties of these proteins were known, for example, from D9, D13, D23, D33 and D36. Therefore, the skilled person confronted with the underlying problem would have considered administering a composition including pea or soy protein rather than caseinate, or at least would have replaced part of it, to prevent caseinate coagulation.

10.7 This argument is not convincing. Claim 1 relates to the use of an "anti-coagulating" protein in the context of a method for preventing or reducing coagulation of a coagulating protein. This indicates that the protein interacts with and effectively prevents or reduces the coagulation of the coagulating protein. The prior art neither mentions this effect nor provides any pointer to the use of pea and soy protein for this effect.

10.8 The opponents have also argued that D7, D19 and D20 hinted at the claimed solution because they disclosed the anti-coagulating properties of pea and soy protein. These documents investigate the effects of the partial replacement of casein and milk protein with soy or pea protein in nutritional compositions for calves and pigs. The opponents considered that animals, such as

calves, could be used as models for nutrition in humans. In particular, the abomasum of pre-ruminant calves was considered a model for the human stomach (see D8, D29 and D35). Furthermore, D7 was an article published in a renowned journal, "The Journal of Dairy Science", whose audience included specialists in the field of human nutrition. Its teaching would not have remained unnoticed by the skilled person.

10.9 These facts are true, but the conclusions drawn are not convincing. As mentioned above, contrary to the teaching of the opposed patent, these documents regard the inhibition of coagulation as detrimental in the feeding of the observed animals. Thus, these documents teach away from using pea or soy protein to prevent caseinate coagulation during the digestive process in animals and other subjects, such as humans.

10.10 The opponents argued that D16 pointed to the use of soy protein for preventing coagulation during digestion. Nonetheless, this document concerns the manufacture of a nutritional composition having excellent stability. Furthermore, as noted by the proprietor, D16 teaches that the milk protein comprised in the composition forms clots and therefore does coagulate. The clots are stabilised in a stable network. This is what promotes the stability and digestibility of the composition. Thus, D16 does not relate to preventing coagulation either.

10.11 Finally, the opponents contended that D28 showed that at the relevant date, the skilled person would have used the claimed anti-coagulating proteins for the claimed purpose. However, D28 is a document stemming from some of the inventors identified in the patent which was published almost three years after the

relevant date. Therefore, neither is this document part of the state of the art, nor can it provide an independent view of the common knowledge of the skilled person before the relevant date.

10.12 For these reasons, it is concluded that the subject-matter of claim 1 involves an inventive step (Articles 56 and 100(a) 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 on the basis of:

   - the sole claim of auxiliary request 21, originally filed as auxiliary request 12 with the statement setting out the grounds of appeal

   - a description to be adapted

   - Figure 1 of the patent specification

The Registrar: The Chairman:

A. Nielsen-Hannerup A. Haderlein

Decision electronically authenticated