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Datasheet for the decision of 21 May 2026

Case Number: T 1182/24 - 3.3.09

Application Number: 16714300.7

Publication Number: 3277103

IPC: A23L33/18, A23L33/19, A23L33/00, A23L29/00

Language of the proceedings: EN

Title of invention:
MILK-BASED PROTEIN HYDROLYSATES AND COMPOSITIONS MADE THEREOF

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponent:
Arla Foods amba

Headword:
Milk-based protein hydrolysates/NESTLÉ

Relevant legal provisions:
EPC Art. 83, 54, 56, 100(a), 100(b)

Keyword:
Sufficiency of disclosure - (yes)
Novelty - (yes)
Inventive step - (yes)

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It can be changed at any time and without notice

Decisions cited:

Catchword:

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Case Number: T 1182/24 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 21 May 2026

Appellant: (Opponent)	Arla Foods amba Sønderhøj 14 8260 Viby J (DK)
Representative:	Zacco Denmark A/S Arne Jacobsens Allé 15 2300 Copenhagen S (DK)
Respondent: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	D Young & Co LLP 3 Noble Street London EC2V 7BQ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted/electronically transmitted on 15 July 2024 rejecting the opposition filed against European patent No. 3277103 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Haderlein
Members:	A. Zellner
	L. Basterreix

Summary of Facts and Submissions

I. The opponent lodged an appeal against the decision of the opposition division to reject the opposition (Article 101(2) EPC).

II. An opposition had been filed on the basis of Article 100(a) EPC for lack of novelty and lack of inventive step (Articles 54 and 56 EPC) and Article 100(b) EPC for lack of sufficiency of disclosure.

III. In the appealed decision, the opposition division held that the patent as granted met the requirements of Articles 83, 54 and 56 EPC. Novelty was acknowledged in view of documents D1 to D9. The opposition division considered each of documents D5 to D7 to be the closest prior art and found that the claimed subject-matter was also based on an inventive step.

IV. The following documents are referred to:

D2: US 2002/0192333 A1
D5: WO 96/13174
D6: WO 94/25580
D7: WO 2004/047566 A1
D9: WO 2012/042013 A1
D10: Medeiros et al., "*Bovine Milk Formula Based on Partial Hydrolysis of Caseins by Bromelain Enzyme: Better Digestibility and Angiotensin-Converting Enzyme-Inhibitory Properties*", International Journal of Food Properties 17:4, 21 November 2013, 806-17
D15a: Van der Ven, "*Biochemical and functional characterisation of casein and whey protein*

hydrolysates", doctoral thesis published on 4 June 2002

D18: Grzonka et al., "*Cysteine Proteases*", Industrial Enzymes, Springer Verlag, 2007, 181-95

D21: Budak et al. "*A genomic survey of proteases in Aspergilli*", BMC Genomics 15:523, 2014, 1-15

D23: Alcalase product sheet, Novozymes, 2002

D24: Neutrase product sheet, Novozymes, 2002

D25: Flavourzyme product sheet, Novozymes, 2002

D26: Merz et al., "*Flavourzyme, an Enzyme Preparation with Industrial Relevance: Automated Nine-Step Purification and Partial Characterization of Eight Enzymes*", J. Agric. Food Chern. 63(23), 2015, 5682-93

D28: EC 3.4.24.28 bacillolysin (neutrase), BRENDA The Comprehensive; Enzyme Information System

D33: Annex updated Table 1, submitted by the respondent on 23 December 2021

V. The main request (patent as granted) comprises four independent claims, which read as follows:

"1. A process for preparing a milk protein hydrolysate comprising hydrolysing a milk-based proteinaceous material with a microbial alkaline serine protease in combination with bromelain, a protease from Aspergillus *and a protease from* Bacillus*."*

"14. A composition comprising a milk-based protein hydrolysate obtained by the process of any preceding claim."

"17. Use of a milk protein hydrolysate obtained according to the process of any one of claims 1 to 13

in the preparation of an infant formula."

"18. The composition of any one of claims 14 to 16 for use in reducing or preventing food intolerance, cows' milk protein allergy (CMA), chronic diarrhea and malabsorption."

VI. The appellant's arguments can be summarised as follows.

- The claimed method was not sufficiently disclosed. The patent did not contain sufficient information on how the extent of hydrolysis according to claim 13 could be obtained, on the nature of the proteases and the conditions under which they were to be used or on how an effect could be achieved by using only four proteases, as claimed. Furthermore, there was no information on how a hypoallergenic composition according to claim 16 could be obtained.

- The process according to claim 1, the composition according to claim 14, the use according to claim 17 and the composition for use according to claim 18 were known from documents D1 to D9.

- The claimed process was not based on an inventive step considering document D5, D6, D7 or D2 as the closest prior art. The distinguishing feature was the presence of bromelain, and the technical problem was the provision of an alternative process, composition or use. The addition of bromelain was obvious for the skilled person.

VII. The respondent's arguments can be summarised as follows.

- The claimed process was sufficiently disclosed. The skilled person could easily follow the teaching of the patent. The extent of hydrolysis according to claim 13 was already achieved prior to ultrafiltration. Claim 16 did not require a specific value for beta-lactoglobulin. Conditions for hydrolysing milk-based proteinaceous material for the respective enzymes were known in the art. Claim 1 was not limited to the use of four enzymes.

- The claimed process, as well as the subject-matter of the other independent claims, was novel in view of the cited prior art. Multiple selections had to be performed to obtain the claimed combination of features. Different enzymes led to a different product composition of the hydrolysates obtained after the hydrolysis reactions.

- The claimed subject-matter was inventive for essentially the reasons given in the impugned decision. Documents D7 and D2 were not suitable as the closest prior art.

- The auxiliary requests should be admitted into the proceedings. They met all requirements of the EPC.

VIII. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

IX. The respondent (patent proprietor) requested that the appeal be dismissed. As an auxiliary measure, the respondent requested that the patent be maintained on the basis of auxiliary requests 1 to 20, filed with the reply to the statement setting out the grounds of appeal.

Reasons for the Decision

Main request (patent as granted)

Sufficiency of disclosure (Article 100(b) EPC)

1. The appellant submitted that the opposition division's finding that claims 1 to 16 of the patent as granted fulfilled the requirements of Article 83 EPC was erroneous. The appellant argued that the patent as granted did not disclose the invention, in particular according to claims 1, 13 and 16, in a manner sufficiently clear and complete for it to be carried out by the person skilled in the art.

2. According to the appellant, the contested patent did not provide sufficient information on how the extent of hydrolysis according to claim 13 could be obtained, in particular without an ultrafiltration step, since an ultrafiltration step performed after hydrolysis could not - even if applied - change the degree of hydrolysis obtained by the claimed process. The patent did not disclose sufficient information about the hydrolysis conditions, not even in the examples.

3. The appellant further argued that the contested patent did not provide sufficient information with respect to the nature or source of the proteases to be used, the conditions under which these were used - in particular the pH, and how an effect could be achieved by using four proteases, as claimed, rather than five, which were used in the examples. Furthermore, the appellant argued that the patent did not disclose how a hypoallergenic composition according to claim 16 could

be obtained.

4. The board is, for the following reasons, not convinced by the appellant's arguments.

4.1 Claim 1 of the main request relates to a process for preparing a milk protein hydrolysate. The process comprises hydrolysing a milk-based proteinaceous material. For the hydrolysis reaction, a combination of a microbial alkaline serine protease, bromelain, a protease from *Aspergillus* and a protease from *Bacillus* is used. The process does not exclude additional steps, nor does it exclude the use of additional enzymes. This was undisputed.

4.2 To carry out the claimed process, the skilled person has to be able to provide a milk-based proteinaceous material. The contested patent provides detailed information on such a material (see paragraphs [0037] to [0045]). The contested patent also provides detailed information on the respective enzymes (see paragraphs [0046] to [0064]). This was also undisputed.

4.3 Further, the skilled person has to be able to hydrolyse the starting material with a combination of enzymes falling under the definition of claim 1. Paragraphs [0065] to [0081] and [0085] to [0090] of the patent in dispute provide this information.

4.4 Finally, the information provided in the contested patent, in addition to the skilled person's common general knowledge, must allow the skilled person to obtain a milk protein hydrolysate. At least example 2 of the patent provides this information.

4.5 The appellant argued, by reference to Table 3 of document D26, that Flavourzyme™, which comprised the exoprotease LAP2 and was the only exoprotease used in the example of the patent, had an optimum pH of 9.5 and substantially reduced activity at pH 8.5 or 10.5. According to the patent in dispute, however, the preferred pH range was 7.0 to 8.0. Neither the patent nor document D33 provided sufficient information on the reaction conditions, in particular with respect to pH.

4.6 This argument, however, is not sufficient to establish that the results obtained in the example of the patent in dispute cannot be reproduced, even if the optimum pH of a particular enzyme may be outside the pH range used in the example. Furthermore, as submitted by the respondent, documents D23 and D24 (see Reaction parameters, Activity) as well as D25 (see Description) disclose optimum pH ranges for respective enzymes within the range of paragraph [0065] of the patent.

4.7 In summary, the process according to claim 1 is sufficiently disclosed.

4.8 Claim 13 is dependent on any of claims 1 to 12. It additionally requires that the extensively hydrolysed protein hydrolysate, i.e. the product obtained by the claimed process, be *"an extensively hydrolysed product wherein the extent of hydrolysis (NPN/TN %) is greater than 95%, preferably greater than 99%".* As shown in Table 1 of the contested patent, this can be achieved. The contested patent thus provides the skilled person with sufficient information on how to obtain a hydrolysate according to claim 13.

4.9 The appellant argued that the extent of hydrolysis according to claim 13 could only be achieved after

ultrafiltration. Such a step, however, was not mandatory and not part of the process according to claims 1 or 13. Furthermore, this step would not alter the result of the hydrolysis reaction but would merely remove non-hydrolysed protein from the final hydrolysate.

4.10 This argument is not convincing. As stated above (see point 4.1), the process of independent claim 1 does not exclude further steps, such as ultrafiltration. Furthermore, document D33 discloses that the hydrolysis rate NPN/TN% of example 1 of the patent is already greater than 95% before ultrafiltration.

4.11 The appellant argued that NPN/TN% was not a valid parameter for evaluating the rate of hydrolysis because a lower value could be achieved by ultrafiltration.

4.12 As indicated above, however, the NPN/TN% of below 95% was already achieved before an ultrafiltration step (see point 4.10).

4.13 The appellant argued that in the example of the contested patent, five different enzymes were used. There was no information, however, on how the results of this example could also be achieved by a process which uses only four enzymes, as required by claim 1.

4.14 This argument is not convincing. Claim 1 is not limited to a process consisting of the hydrolysis step recited in the claim but can contain additional steps. In addition, paragraph [0018] of the contested patent, as well as claim 2, refer to the preferred use of two proteases from *Aspergillus*. Furthermore, there is no experimental evidence that a process using the combination of four enzymes according to claim 1, i.e.

one comprising only one rather than the preferred two proteases from *Aspergillus*, would not lead to a milk protein hydrolysate. The board is convinced that a skilled person is able to successfully implement the process as claimed when following the information given in the contested patent.

4.15 The appellant argued that the proteases used in the process according to claim 1 were not sufficiently defined in the patent.

4.16 This argument is not convincing. As mentioned above, the description of the patent in suit provides sufficient information on the nature of the enzymes (see paragraphs [0046] to [0064]).

4.17 The appellant argued that the conditions under which the enzymes (proteases) are used in the claimed process were not sufficiently disclosed.

4.18 This argument is also not convincing. As indicated above, the description of the patent in suit provides information on these conditions (see paragraphs [0065] to [0070]). The appellant has not shown which of the conditions would not lead to success.

4.19 The appellant argued that the skilled person was not able to provide a composition according to claim 16, i.e. a hypoallergenic composition.

4.20 The board is not convinced. The contested patent discloses in paragraphs [0089] to [0097] the preparation of a composition having residual beta-lactoglobulin (BLG) below the limit of the detection kit and thus a BLG below 0.01 mg/g. The appellant has not provided any data showing that these results cannot

be obtained.

5. For these reasons, the board concludes that the appellant's arguments do not show that the claimed invention is not sufficiently disclosed and that the ground for opposition under Article 100(b) EPC does not prejudice the maintenance of the patent.

Novelty (Articles 100(a) and 54 EPC)

6. The appellant submitted that the process according to claim 1, the composition according to claim 14, the use according to claim 17 and the composition for use in reducing or preventing food intolerance according to claim 18 were already known and that the opposition division's conclusion to acknowledge novelty was erroneous. According to the appellant, documents D7 and D2 disclosed a process according to claim 1 of the contested patent, and the composition according to claim 14 was disclosed in documents D7, D2, D1, D3a, D4, D5, D6, D8 and D9.

7. The board observes the following.

Claim 1

7.1 It is correct that document D7 discloses milk protein-based hydrolysates, such as whey protein isolates (see D7, page 4, lines 27 and 34, and page 6, line 8, to page 10, line 29). It is also correct that D7 discloses enzymes according to claim 1 (see D7, page 10, lines 3 to 20). However, to arrive at the claimed process, the skilled person has to select four enzymes out of a long list of enzymes disclosed in D7. Contrary to the submission of the appellant, these four enzymes are not disclosed in combination. The claimed process is thus

novel in view of the disclosure of D7.

7.2 It is also correct that document D2 discloses enzymes according to claim 1 of the main request (see paragraph [0018]). The combination of four enzymes according to claim 1 is, however, not disclosed in D2 (see the examples).

7.3 The process of claim 1 of the main request is, for these reasons, novel.

Claim 14

7.4 According to the appellant, the composition according to claim 14 of the main request, i.e. a product defined by way of a product-by-process claim, was not different from a composition prepared according to the process disclosed in document D7. The appellant argued that the enzymatic hydrolysis of milk protein disclosed in D7 made use of the same combination of endopeptidase and exopeptidase (Flavourzyme™) enzymes as claim 14 and that it was followed by an ultrafiltration step. The process of D7 thus inevitably led to the composition of claim 14. Concerning the respondent's argument that according to document D15a different proteases produced different hydrolysates having distinct peptide profiles, the appellant argued that the disclosure of D15a related to the hydrolysis using a single protease, not four or five proteases as required by process claim 1 of the main request. As a consequence, D15a could not be used as proof that the composition of claim 14 of the main request was different from the composition disclosed in D7.

7.5 The board is not convinced and endorses the argument of the opposition division and the respondent. Document

D15a discloses that different proteases have different specificities (see Table 2 on page 6). The board is therefore convinced that the use of different enzymes for hydrolysing milk-based proteinaceous material leads to different product compositions. The board sees no reason why this principle should not apply when a combination of different enzymes is used. The board thus concludes that the products obtained when the combination of enzymes according to claim 1 of the main request is used differ from compositions obtained by the use of different enzyme combinations (see the first paragraph on page 124 of D15a). Since the process for preparing a milk protein hydrolysate using the combination of enzymes according to claim 1 of the main request is novel due to the enzyme combination (see paragraph 7.3 above), the composition according to claim 14 of the main request is also novel for the same reason.

7.6 The appellant argued that the composition according to claim 14 of the main request was not novel in view of the disclosure of documents D1 to D6, D8 and D9.

7.7 Concerning documents D1 to D4 and D8, the appellant referred to its submissions during the opposition proceedings.

7.8 The board sees no reason to deviate from the opposition division's conclusion and concludes that the composition according to claim 14 of the main request is novel over D1 to D4 and D8.

7.9 Concerning document D5, the appellant argued, by reference to pages 1 and 2 and example 1, that hydrolysis products obtained with mixtures of endoproteases and exopeptidases were known, and that

these known processes led to compositions falling within the scope of claim 14.

Concerning document D6, the appellant argued, by reference to claims 1, 3, 6 and 10, that the hydrolysis of whey protein using a combination of exopeptidase (Flavourzyme™) and endopeptidases, resulting in a degree of hydrolysis greater than 80%, implied that the product composition fell within the scope of claim 14 of the main request.

Concerning document D9, the appellant argued, by reference to the summary, the examples, pages 1 and 2, and claims 1 and 9, that the document disclosed essentially the same conditions as the patent in suit and that the compositions obtained were therefore also essentially the same.

7.10 The board is not convinced and concurs with the conclusion of the opposition division.

Documents D6 and D9 do not disclose an enzyme composition comprising bromelain, unlike the composition used in the process according to claim 1 of the main request. The board is convinced that the hydrolysate resulting from a process not comprising bromelain is different from a composition according to claim 14 of the main request (see point 7.5 above).

Document D5 does not disclose the use of bromelain in the enzyme composition. Document D5 furthermore discloses that the hydrolysis rate of the method according to the invention was between 36 and 55%, which is not an extensive hydrolysate (see page 1, lines 27 to 31 of D5 and paragraphs [0007], [0029] and [0073] of the patent in dispute). The board is

therefore not convinced that the product obtained in D5 falls within the scope of claim 14 of the main request.

7.11 The respondent further argued that the claimed process differed from the process disclosed in document D6 (example 2) additionally in that the enzyme preparation comprised a microbial alkaline serine protease. The board notes that D6 discloses the use of the Flavourzyme™ enzyme preparation (see page 2, lines 17 to 23). Even if, as submitted by the appellant by reference to document D26, "Flavourzyme" comprises an alkaline protease 1 (ALP1 in Table 3), there is no evidence that the Flavourzyme™ composition of D26 is identical to the Flavourzyme™ composition of document D6 (see page 2, lines 17 to 23). The alkaline serine protease ALP1 (size 29.0 kDa) is missing from the preparation of D6. Furthermore, the composition used in example 2 of D6 does not include a protease from *Bacillus*.

7.12 During the oral proceedings, the appellant submitted, by reference to paragraphs [0014] and [0074] of the patent, that the respondent had admitted in the patent in dispute that its product Alfaré® performed essentially in the same way as the enzyme preparation of claim 1 of the main request. The appellant argued that, since the use of the known enzyme preparation Alfaré® led to a peptide weight distribution similar or substantially identical to that achieved with a hydrolysate made with porcine pancreatin or the enzyme combination used in the patent, a hydrolysate according to claim 14 was also known.

7.13 This submission, irrespective of whether it is admissible, as objected to by the respondent, is not convincing. There is no evidence that the enzyme

composition Alfaré® is identical to the composition of claim 1 of the main request, and the description of the patent simply states that the results after hydrolysis are similar or substantially identical. There is no disclosure, however, of the composition of Alfaré® or the conditions under which it was used. It is thus rather unlikely, and not shown in any way, that the product obtained when using the known composition Alfaré® leads to an identical composition when using it to hydrolyse milk-based proteinaceous material.

7.14 The board concludes, for these reasons, that the product composition according to claim 14 of the main request is different from the composition obtained in a process as disclosed in document D5.

Claims 17 and 18

7.15 Claims 17 and 18 refer to the composition according to claim 14. Since the board concluded that such a composition is novel, the use according to claim 17 and the composition for use in reducing or preventing food intolerance according to claim 18 are, as a consequence, also novel.

8. The subject-matter of the main request is, for these reasons, novel. The opposition division's assessment of novelty is therefore correct, and the ground for opposition pursuant to Articles 100(a) and 54 EPC does not prejudice the maintenance of the patent.

Inventive step (Articles 100(a) and 56 EPC)

9. The opposition division held that the main request met the requirements of Article 56 EPC, taking either

document D5 or D6 as the closest prior art.

10. The appellant argued based on the disclosure of any of documents D5, D6, D7 and D2 as the closest prior art.

10.1 With respect to documents D5 and D6, the appellant concurred with the opposition division concerning the distinguishing feature, i.e. the presence of bromelain. The appellant disagreed, however, with the definition of the technical problem. According to the appellant, the objective technical problem should not contain any reference to halal products and should only amount to the provision of an alternative process. The appellant concluded, by reference to documents D18 and D10, that the use of bromelain was obvious for the skilled person to provide an alternative process for preparing milk protein hydrolysate. Regarding the disclosure of document D6, the appellant additionally submitted that the reference to cheese flavour observed in the hydrolysates was not relevant for the assessment of inventive step.

10.2 With respect to documents D2 and D7 as the closest prior art, the appellant also based its inventive-step objection on bromelain as the only distinguishing feature and argued lack of inventive step essentially as for documents D5 and D6.

11. The board concludes the following.

The contested patent

11.1 The patent relates to compositions comprising milk-based protein hydrolysate and a process for their preparation using enzymes from microbial and plant origin, avoiding the use of porcine-derived enzymes

while maintaining hypoallergenic properties (see paragraphs [0001], [0002] and [0012]). It also addresses the problem of allergenicity, in particular when using cow's milk as the milk source, and the hydrolysis of cow's milk protein by enzymes as a known solution to this problem (see paragraphs [0004] to [0006]). Furthermore, the preparation of extensively rather than partially hydrolysed protein hydrolysates is preferred(see paragraphs [0007], [0029] and [0073]). To address these problems, the patent suggests enzyme combinations comprising a microbial alkaline serine protease, bromelain, a protease from *Aspergillus* and a protease from *Bacillus*, which may replace porcine enzymes (see paragraphs [0014] and [0017]).

Closest prior art

11.2 Document D2 is not a suitable starting point since it discloses the use of pancreatin as a possible protease (see paragraph [0018] and claim 3) rather than as a particular combination of non-porcine proteases, and thus concerns a different purpose from the patent, which is directed to enzymes of microbial and plant origin, thus avoiding porcine-derived enzymes. Moreover, D2 also teaches towards a low degree of hydrolysis and thus away from the contested patent (see paragraph [0034]).

11.3 Document D7 is not a suitable starting point since it discloses the preferred use of trypsin from porcine pancreas (see claim 6 and example 1) and is thus not directed to milk protein hydrolysate prepared by using non-porcine enzymes.

11.4 Both parties concurred with the opposition division that documents D5 and D6 are suitable as closest prior-

art documents. The board sees no reason to differ. In the following, the board deals with D6, similar considerations applying to D5.

Distinguishing feature

11.5 The parties also argued, in line with the opposition division, that the claimed process differed from the processes disclosed in D6 in that bromelain was used in the enzyme preparation. The board sees no reason to differ (see example 2 of D6).

11.6 In addition, example 2 of D6 uses the Flavourzyme™ enzyme combination but neither an alkaline serine protease nor a protease from *Bacillus* (see point 7.11 of this decision).

The technical effect

11.7 The description of the contested patent does not provide a direct comparison to any method disclosed in D6. Table 1 of the contested patent (see also document D33) shows, however, that hydrolysis of whey isolate using four enzymes according to claim 1, and a further protease from *Aspergillus*, leads to a hydrolysate with a high degree of hydrolysis (NPN/TN%>= 95%) and low antigenicity (NLG < 0.1 mg/g). The board is not convinced by the appellant's argument that similar results cannot be obtained when using an enzyme preparation not comprising the further protease from *Aspergillus*.

The objective technical problem

11.8 The technical problem can therefore be seen in the provision of a process for preparing an extensive milk

protein hydrolysate comprising hydrolysing a milk-based proteinaceous material with an enzyme preparation, where the hydrolysate is hypoallergenic and can be prepared avoiding porcine enzymes.

11.9 The appellant submitted that not every claimed hydrolysate led to a product enjoying halal status because the process according to claim 1 did not exclude further steps, such as hydrolysis with a porcine-derived enzyme.

11.10 It is correct that claim 1 does not exclude such a step. However, the process, as shown by the experimental results of the patent in suit, does not rely on the presence of porcine-derived enzymes and is therefore suitable for avoiding the use of porcine enzymes.

The claimed solution

11.11 To solve the technical problem, a process is provided which comprises hydrolysing a milk-based proteinaceous material with a combination of a microbial alkaline serine protease, bromelain, a protease from *Aspergillus* and a protease from *Bacillus*.

11.12 The appellant argued that the problem was not solved over the entire scope of the claim.

11.13 It is correct that the experimental data provided in the contested patent do not directly show whether a combination of four, rather than five, enzymes leads to the same result. It is also correct that there are no experimental data on whether other proteases or other combinations of enzymes can achieve the claimed technical effects. However, there is also no evidence

that omitting the further protease from *Aspergillus* would not lead to the claimed technical effects. Claim 1 also requires the presence of at least one protease from *Aspergillus*. In view of the above, the board concludes that the problem is solved over essentially the entire scope claimed.

Non-obviousness of the claimed solution

11.14 The appellant argued, by reference to documents D18 and D10, that the skilled person would include bromelain in the enzyme preparation of document D6. According to the appellant, this was because the enzyme was well known in the dairy industry,and the skilled person would add it to the enzyme preparation disclosed in D6 as a routine measure to provide an alternative process.

11.15 The board notes that document D10 suggests, as submitted by the appellant, the use of bromelain because of its lower cost compared to trypsin and pepsin and because of its higher temperature stability compared to rennet (see page 810, penultimate paragraph). The board further notes that document D6, while postulating a degree of hydrolysis of up to 80% (see page 3, lines 20 to 23), effectively discloses a method in which the degree of hydrolysis is at a relatively low level of at most about 65% for milk-based proteinaceous material (see page 3, lines 2 to 6 and Figures 1 and 3) and that document D10 also discloses the use of bromelain as a proteolytic enzyme for the development of a functional bovine milk with **partially** hydrolysed proteins (see page 807, third paragraph). The board is not convinced that the skilled person would add bromelain to the enzyme preparation of D6 in the expectation to solve the technical problem of providing a process for preparing an **extensive** milk

protein hydrolysate, in particular because of the different degree of hydrolysis to be expected.

11.16 The appellant also argued, by reference to documents D10 and D18, that the skilled person would include bromelain in the enzyme preparation of document D6 for another reason. D6 taught a method for hydrolysing a protein with a proteolytic enzyme to obtain a hydrolysate with reduced allergenicity (page 7, lines 2 to 7) and a high degree of hydrolysis (page 3, lines 20 to 23). Use of the additional enzyme bromelain would further increase the degree of hydrolysis.

11.17 The board is not convinced. There are no data that support the appellant's argument. Therefore, the claimed process is also based on an inventive step taking document D6 as the closest prior art, essentially for the same reasons given in point 11.15.

11.18 Furthermore, even if the skilled person decided to add bromelain to the enzyme preparation disclosed in example 2 of D6, they would still not arrive at the claimed process because although D6 suggests adding further enzymes, such as a neutral protease from *Bacillus* or an alkaline protease derived from *Bacillus*, D6 does not suggest adding both these enzyme types together since claims 9 and 10 of D6 are dependent on claim 8 only. The combination of an alkaline serine protease and a protease from *Bacillus* is thus not suggested by D6.

12. Similar considerations apply to D5 as the starting point, this document teaching even lower degrees of hydrolysation than D6 of between 35 and 55% (see page 1, lines 22 to 31).

13. For these reasons, the opposition division's assessment of inventive step is correct, and the ground for opposition pursuant to Articles 100(a) and 56 EPC does not prejudice the maintenance of the patent.

Conclusion

14. Since none of the objections of the appellant prejudices the maintenance of the patent, the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

L. Stridde A. Haderlein

Decision electronically authenticated