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Datasheet for the decision of 5 May 2021

Case Number: T 0862/17 - 3.3.08

Application Number: 11156545.3

Publication Number: 2333056

IPC: C12N9/96, A23C19/032, C12N9/58, C12N9/64

Language of the proceedings: EN

Title of invention:
Liquid composition comprising an aspartic protease

Patent Proprietor:
DSM IP Assets B.V.

Opponents:
CSK food enrichment B.V.
Chr. Hansen A/S

Headword:
Acetate/DSM

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

Keyword:

Main request - added matter - (yes)
Auxiliary request 5B - added matter - (yes)
Auxiliary request 7B - inventive step - (no)
Auxiliary request 8B - inventive step - (yes))

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0862/17 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 5 May 2021

Appellant I: (Patent Proprietor)	DSM IP Assets B.V. Het Overloon 1 6411 TE Heerlen (NL)
Representative:	Duffy, James E. M. De Vroom, Erik DSM Intellectual Property P.O. Box 4 6100 AA Echt (NL)
Appellant II: (Opponent 2)	Chr. Hansen A/S Bøge Allé 10-12 2970 Hørsholm (DK)
Representative:	Renken, Joachim Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Party as of right: (Opponent 1)	CSK food enrichment B.V. Pallasweg 1 8938 AS Leeuwarden (NL)
Representative:	HGF 1 City Walk Leeds LS11 9DX (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 10 February 2017 concerning maintenance of the European Patent No. 2333056 in amended form.**

Composition of the Board:

Chair	B. Stolz
Members:	M. R. Vega Laso
	R. Winkelhofer

Summary of Facts and Submissions

I. European patent No. 2 333 056 with the title "Liquid composition comprising an aspartic protease" was granted from European application No. 11156545.3 which is a divisional application of the European patent application No. 07728023.8 filed under the Patent Cooperation Treaty and published as WO 2007/118838. References to the application as filed in this decision are to the original application documents.

II. Two oppositions based on the grounds for opposition of Article 100(a) in conjunction with Article 56, 100(b) and 100(c) EPC were filed against the patent.

III. In an interlocutory decision posted on 10 February 2017, an opposition division found that the amended claims according to the main request and the auxiliary request 1 offended against Article 123(2) EPC, but that, taking into account the amendments introduced into claims 1 and 2 according to the auxiliary request 2, the patent and the invention to which it relates met the requirements of the EPC.

IV. Each of the patent proprietor and the two opponents filed an appeal against the interlocutory decision.

V. Together with the statement of grounds of appeal, the patent proprietor (appellant I) filed 12 sets of claims as main request and 1st to 11th auxiliary requests.

VI. The claims of the main request are identical to those of the main request underlying the decision under appeal. Independent claims 1 and 15 read as follows:

"1. Liquid composition comprising:
(i) a *Rhizomucor miehei* aspartic protease; and
(ii) an inorganic salt; and
(iii) acetate
in which composition;
the sum concentration of sorbate, benzoate and alkyl esters of para-hydroxybenzoate is less than 0.010 mol/l;
the standard plate count ≤ 100 in 1 ml;
yeast count ≤ 10 in 1 ml; and
mould count ≤ 10 in 1 ml,
and wherein the pH is between 4.8 and 5.5; and
in which the concentration of acetate is at least 0.1 mol/l.

15. Process for preparing a liquid composition comprising a *Rhizomucor miehei* aspartic protease, said process comprising:
(a) providing a fermentation broth, said fermentation broth containing (i) micro-organisms that have produced the protease and
(ii) supernatant containing the protease;
(b) separating, by solid liquid separation, supernatant from the fermentation broth;
(c) purifying the separated supernatant, to obtain a purified solution;
(d) adding one or more additives to the purified solution, wherein at least one of said one or more additives is an inorganic salt and acetate, and
(e) filtering the purified solution containing said inorganic salt and acetate, and
wherein the concentration of acetate is at least 0.1 mol/l."

Dependent claims 2 to 13 are directed to various embodiments of the liquid composition of claim 1.

Claim 14 relates to a closed container comprising the claimed composition. Claims 16 and 17 are directed to variants of the process of claim 15. Claim 18 relates to the use of the claimed composition as a coagulant in the production of cheese, and claim 19 to a process for preparing cheese using the claimed composition.

VII. Opponent 02 (appellant II) filed a statement of grounds of appeal including new documentary evidence.

VIII. Also opponent 01 filed a statement of grounds of appeal. However, by submission of 15 January 2020, opponent 01 withdrew the appeal. Hence, their present procedural status is that of a party as of right.

IX. Each of the parties filed a reply. Appellant I submitted new evidence. Additional submissions were made by appellant II at a later stage.

X. Pursuant to their respective requests, the parties were summoned to oral proceedings before the board.

XI. Subsequently, opponent 01, the party as of right, informed the board that they would not attend the scheduled oral proceedings.

XII. In a communication in preparation of the oral proceedings, the board commented on procedural and substantive issues relevant to the case, and expressed a provisional opinion on some of those issues.

XIII. Oral proceedings were held on 5 May 2021 in the absence of opponent 01. During the oral proceedings, appellant I submitted three sets of claims as new auxiliary requests 5B, 7B and 8B.

XIV. Independent claim 1 of auxiliary request 5B differs from the corresponding claim of the main request in that the concentration of acetate is at least 0.2 mol/l. Independent claim 14 of auxiliary request 5B reads as follows:

"14. Process for preparing a liquid composition comprising a *Rhizomucor miehei* aspartic protease, said process comprising:

(a) providing a fermentation broth, said fermentation broth containing (i) micro-organisms that have produced the protease and
(ii) supernatant containing the protease;
(b) separating, by solid liquid separation, supernatant from the fermentation broth;
(c) purifying the separated supernatant, to obtain a purified solution;
(d) adding to the purified solution, an inorganic salt and acetate; and
(e) filtering the purified solution containing one or more additives, and
wherein the concentration of acetate is at least 0.2 mol/l."

Dependent claims 2 to 12 and independent claim 13 are identical to, respectively, claims 3 to 13 and claim 14 of the main request. Except for the amended dependencies or references to previous claims, claims 15 to 18 are identical to claims 16 to 19 of the main request.

XV. Independent claim 1 of auxiliary request 7B differs from the corresponding claim 14 of auxiliary request 5B in that step (e) reads as follows:

"...

(e) filtering the purified solution containing an inorganic salt and acetate, and

wherein the concentration of acetate is at least 0.1 mol/l."

Dependent claims 2 and 3 are identical to claims 15 and 16 of auxiliary request 5B.

XVI. Independent claim 1 of auxiliary request 8B differs from the corresponding claim of auxiliary request 7B in that it includes the additional feature "..., wherein no compound selected from benzoate, sorbate or alkyl ester of para-hydroxybenzoate is added to the purified solution." Dependent claims 2 and 3 are identical to claims 15 and 16 of auxiliary request 5B.

XVII. Following documents are referred to in this decision:

(3): US Patent No. 3,763,010, published on 2 October 1973;

(7): H.-C. Wong and Y.-L. Chen, September 1988, Applied and Environmental Microbiology, Vol. 54, No. 9, pages 2179 to 2184;

(8): C. Daly *et al.*, 1972, J. Milk Food Technol., Vol. 35, No. 6, pages 349 to 357;

(10): K. Arima *et al.*, November 1968, Applied Microbiology, Vol. 16, No. 11, pages 1727 to 1733;

(12): http://en.wikipedia.org/wiki/Buffer_solution, printed on 4 February 2015;

(18): Hannilase® XL 205, CHR Hansen, Product Information, Version: 2PI-GLOB-EN 07-26-2013;

(20): M. Stratford and T. Eklund, Chapter 4 "Organic acids and Esters", in "Food Preservatives", ed. N.J. Russell *et al.*, pages 48 to 84;

(31b): Hannilase™ XL 730, CHR Hansen, Product Specification, dated May 2004; and

(34): Codex Alimentarius, General Standard for Food Additives, Codex Stan 192-1995.

XVIII. The submissions made by appellant I, as far as relevant to the present decision, were essentially as follows:

Main request – Article 123(2) EPC

The opposition division erred in finding that claim 1 contained subject-matter that extended beyond the content of the application as filed. Claim 1 did not include a combination of elements taken from different lists. The sole feature selected from a list was the concentration of acetate of at least 0.1 mol/l. A liquid composition comprising inorganic salt was disclosed on page 6, lines 3 and 4 of the application as filed, as a specific embodiment of the invention. Contrary to the opposition division's view, the pH range specified in claim 1 was not an arbitrary selection from a list of possible pH ranges disclosed on page 7, lines 20 to 23 of the application as filed. Notwithstanding the use of the term "for instance" in this passage, it was clear that a pH between 4.8 and 5.5 was the most preferred range because it was the most specific and smallest pH range disclosed. It was immediately evident to the skilled person that this was

the pH range which was optimally used in the composition. In Examples 2 to 4, the liquid composition comprised acetate and had a pH of, respectively, 5.0, 5.3 and 4.8, all pH values being within the range specified in claim 1. Hence, Article 123(2) EPC was not contravened.

Auxiliary request 5B
Admittance and consideration in the appeal proceedings

Auxiliary request 5B differed from auxiliary request 5 filed together with the statement of grounds of appeal in that claim 2 was omitted because the feature specified in this claim had been included in the amended claim 1. The request was filed in response to the board's adverse findings on Article 123(2) EPC with respect to the main request, and represented a fair attempt to solve the problem of added matter. Hence, the request should be admitted and considered by the board.

Article 123(2) EPC

Contrary to the opposition division's view, the 0.2 mol/l limit for the acetate concentration was not an arbitrary selection from the list on page 3, lines 26 to 30, but the most preferred limit. The elements of the list were ordered in terms of gradually becoming narrower in terms of scope. Since 0.2 mol/l was the last mentioned limit, the skilled person would regard it as the most preferred. Hence, the sole feature selected from a list was the pH range. The combination of both features did not offend against Article 123(2) EPC.

Auxiliary request 7B
Admittance and consideration in the appeal proceedings

The request was filed in response to the board's findings on auxiliary request 5B. The specific amendment introduced into claim 1 had been already on file.

Articles 123(2), 123(3) and 84 EPC

The scope of claim 1 was narrower than the scope of protection conferred by the claims of the patent as granted because the additives had been restricted to an inorganic salt and acetate. It was clear that the acetate concentration was that in the final composition. Thus, the claims were clear, as required by Article 84 EPC.

Article 56 EPC

The purpose of the invention was to get rid of sorbate, and benzoate while maintaining the microbial stability of the enzyme composition. The problem was solved over the whole scope of the claims.

Auxiliary request 8B
Admittance and consideration in the appeal proceedings

The subject-matter of claim 1 was identical to that of claim 2 of the previous request. No new issues arose from the amendment.

Article 56 EPC

The opposition division was correct in acknowledging an inventive step. Starting from document (3) as the

closest state of the art and seeking to provide an alternative process, it was not obvious to a person skilled in the art to add acetate to a liquid composition comprising aspartic protease. There was no evidence on file of a need to replace benzoate or sorbate. The skilled person had various possibilities to achieve microbial stability and the prior art documents did not provide a clear hint to acetate.

XIX. The submissions made by appellant II, as far as relevant to the present decision, were essentially as follows:

Main request – Article 123(2) EPC

The subject-matter of claim 1 extended beyond the content of the application as filed. Claim 1 was directed to a liquid composition comprising a specific combination of features from two different "aspects" of the invention, a first aspect in which the liquid composition comprised an aspartic protease and an inorganic salt and/or a polyalcohol, as disclosed in the passage starting on page 2, line 8, and a second aspect in which an organic acid was added to the aspartic protease, as disclosed in the passage starting on page 3, line 7. There was no pointer in the application as filed to this specific combination. Moreover, each the acetate concentration and the pH range recited in claim 1 were selected from separate lists, but there was no clear indication that those were the most preferred ranges.

Auxiliary request 5B
Admittance and consideration in the appeal proceedings

Auxiliary request 5B should not be admitted in the proceedings because it could have been presented in opposition proceedings. Moreover, the request was clearly unallowable.

Articles 123(2) and 84 EPC

The objections raised in connection with claim 1 of the main request applied also to the auxiliary request 5B. Moreover, the amendment in step (e) of claim 14 to recite that the solution contained one or more additives was unclear.

Auxiliary request 7B
Admittance and consideration in the appeal proceedings

Since the request could and should have been filed in opposition proceedings, it should not be admitted in the appeal proceedings.

Article 123(2) EPC

Claim 1 had been amended to specify features selected from two different lists in combination. Since the application did not provide a clear pointer to such a combination, the amendment added matter.

Article 84 EPC

Neither claim 1 nor the specification gave an indication whether the acetate concentration had to be 0.1 mol/l before or after it was added to the purified solution, i.e. whether it 0.1 mol/l was the concentration in the final solution or in the stock solution. Thus, the amendments resulted in the scope of claim 1 becoming unclear.

Article 56 EPC

Starting from document (3) as the closest state of the art, the problem to be solved was to provide an alternative process for preparing an aspartic protease composition. The problem was not plausibly solved because claim 1 did not exclude the addition of sorbate or benzoate.

Auxiliary request 8B
Admittance and consideration in the appeal proceedings

The request had been filed late and should not be admitted and considered in appeal proceedings.

Article 56 EPC

Contrary to the opposition division's finding, the claimed subject-matter did not involve an inventive step. Starting from document (3) and seeking to provide an alternative process, it was obvious to the skilled person to add acetic acid, which was known as a food preservative from documents (20) and (34), also to a food additive, as the aspartic protease composition. Since documents (10) and (12) showed that acetic acid had antimicrobial properties, the skilled person had a reasonable expectation of success.

XX. The submissions of opponent 01 in writing were essentially the same as those of appellant II.

XXI. Appellant I requests that the decision under appeal be set aside and the patent be maintained based on the set of claims of the main request or any of the auxiliary

requests in the following order: 5B, 7B, 8B and 1 to 11.

XXII. Appellant II requests that the decision under appeal be set aside and the patent be revoked.

XXIII. Opponent 01 as the party as of right requests in writing that the decision under appeal be set aside and the patent be revoked. Further, they request that documents (30) to (34) filed in opposition proceedings be admitted and considered in the appeal proceedings.

Reasons for the Decision

Main request - Article 123(2) EPC

1. In the decision under appeal, the opposition division found that, since two of the features characterizing the liquid composition of claim 1 were arbitrary selections from a list of different possibilities, and the application as filed did not contain a clear pointer to the specific combination of those two features, the subject-matter of claim 1 extended beyond the content of the application as filed.

2. This finding is correct. A liquid composition characterized by the specific combination of an acetate concentration of at least 0.1 mol/l and a pH between 4.8 and 5.5 is not directly and unambiguously derivable from the application as filed. As appellant I admitted, on page 3, lines 26 to 28 of the application an acetate concentration of at least 0.1 mol/l is disclosed only as one of several equally suitable acetate concentrations ("Preferably, the composition comprises at least 0.02 mol/l of acetate, for instance at least 0.05 mol/l, for instance at least 0.1 mol/l,

for instance at least 0.2 mol/l of acetate"). A skilled person does not derive from the wording of this passage that the particular acetate concentration specified in claim 1 is the most preferred.

3. Nor does the skilled person derive directly and unambiguously from the application as filed which of the various pH ranges disclosed therein is particularly preferred, or the most preferred. It is disclosed in the application that, according to one aspect of the invention, the liquid composition has a pH between 4 and 7 (see page 4, lines 13 to 15). Further, on page 7, lines 20 to 23 the application discloses: "In a preferred embodiment, the composition has a pH of less than 7, preferably less than 6. Preferably, the pH is at least at least[sic] 3, preferably at least 4, preferably at least 5. The pH may for instance be between 4.8 and 5.5."

4. There is no clear pointer in the application as filed to any specific combination of elements of those two lists, and in particular to the combination specified in claim 1. Appellant I's argument that Examples 2 to 4 of the application provide such a pointer is not persuasive. As apparent from Table 1, the acetate concentration in the protease formulations is 30 g/l, which amounts to a molar concentration of 0.37 mol/l. Since this acetate concentration is within each of the open ranges disclosed on page 3, lines 26 to 28 of the application, it does not provide a pointer to the specific range specified in claim 1. Table 1 lists several protease formulations having different pH values which vary from pH 4.2 in Example 5 to pH 5.3 in Example 3. These pH values are within several pH ranges disclosed in the application, e.g., in the range between 4 and 7 disclosed on page 4, or in the range of

"less than 6" disclosed on page 7. Moreover, there is no indication whatsoever in the application that the formulation of Example 5, which has a pH value outside of the range specified in claim 1, is not a composition according to the invention and is tested only for comparison.

5. For these reasons, the specific combination of an acetate concentration of 0.1 mol/l and a pH between 4.8 and 5.5 which characterizes the liquid composition of claim 1 represents new information which a person skilled in the art cannot derive directly and unambiguously from the application as filed. Hence the subject-matter of claim 1 extends beyond the content of the application as filed and offends against Article 123(2) EPC.

Auxiliary request 5B

Admittance and consideration in the appeal proceedings – Article 12(4) RPBA 2007

6. The auxiliary request 5B was filed at the oral proceedings as a reaction to the adverse board's findings on the main request. Claim 1 is identical to the corresponding claim of both the auxiliary request 1 underlying the decision under appeal, and the auxiliary request 5 filed together with the statement of grounds of appeal. Thus, the request does not give rise to any new issues which could not be dealt with by the other party or the board without procedural delay. For these reasons, the request was to be admitted and considered.

Article 123(2) EPC

7. The opposition division correctly found – in connection with the auxiliary request 1 then on file – that, for essentially the same reasons as claim 1 of the main request, claim 1 of the auxiliary request 5B contained subject-matter that extended beyond the content of the application as filed. In fact, a liquid composition characterized by the specific combination of an acetate concentration of 0.2 mol/l selected from the list of acetate concentrations on page 3, lines 26 to 28 of the application as filed, and a pH between 4.8 and 5.5, which is selected from the list of possible pH ranges disclosed on page 7, lines 20 to 23, cannot be derived directly and unambiguously from the application as filed, and in particular not from the examples. Thus, also the auxiliary request 5B contravenes Article 123(2) EPC.

Auxiliary request 7B

Admittance and consideration in the proceedings – Article 12(4) RPBA 2007

8. Auxiliary request 7B, which is based on the auxiliary request 7 filed together with the statement of grounds of appeal, was presented at the oral proceedings in reaction to the adverse findings on Article 123(2) EPC concerning the main request and the auxiliary request 5B, and as an attempt to overcome an objection of lack of clarity (Article 84 EPC) raised by appellant II against claim 14 of the latter request. While step (d) of the process of claim 1 of auxiliary request 7B differs in wording from the corresponding step in claim 15 of the main request, the subject-matter of both claims is essentially the same. Thus, neither the other party nor the board were presented

with a fresh case. Under these circumstances, the request was to be admitted and considered.

Articles 123(2) and (3) EPC

9. Claim 1 is derived from claim 21 of the application as filed, in which two amendments have been introduced: (i) step (d) has been restricted to the addition of an inorganic salt and acetate; and (ii) the concentration of acetate in the liquid composition is at least 0.1 mol/l.

10. Contrary to appellant II's view, the amendment (i) does not involve a double selection of inorganic salt and acetate from a list of possible additives in claim 21 of the original application, because it is apparent from page 3, line 26 of the application as filed that a preferred embodiment of the liquid composition comprises acetate. Moreover, the application discloses compositions comprising an inorganic salt as a preferred embodiment (see page 6, lines 3 and 4). Since each of the formulations of the protease from Rhizomucor miehei in Examples 1 to 11 of the application contains acetate in combination with an inorganic salt (sodium chloride), a clear pointer to the combination specified in step (d) is derivable from the application as filed.

11. As regards amendment (ii), a concentration of acetate of at least 0.1 mol/l is disclosed on page 3, lines 26 to 28 as an element of a single list of different possible acetate concentrations in the liquid composition according to the invention. Appellant II argued that a concentration of acetate of at least 0.1 mol/l is not disclosed in the application as filed in connection with the process, but only in connection

with the liquid composition. However, it is apparent from the passage on page 9, lines 27 to 29 of the application as filed ("The composition according to the invention can be prepared using a process for preparing a liquid composition comprising an aspartic protease, said process comprising ...") that the process described in the application is intended, and also suitable for preparing a liquid composition with the features disclosed in the application, in particular a liquid composition with a concentration of acetate of at least 0.1 mol/l.

12. In sum, claim 1 does not contain added matter which extends beyond the content of the application as filed.

Article 84 EPC - clarity

13. Appellant II alleged that the wording "the concentration of acetate is at least 0.1 mol/l" in claim 1 was ambiguous because it could be interpreted as indicating the acetate concentration before or after it is added to the purified solution. However, such an artificial interpretation is not supported either by the wording itself or the disclosure on page 3, lines 26 to 28 of the application ("... the composition comprises [...] at least 0.1 mol/l [...] of acetate").

14. Also the argument that there was a contradiction between the stipulation in claims 1 and 2 fails. The alleged contradiction does not arise from the amendments introduced into current claim 1, but also exists between claims 16 and 17 of the patent as granted. Neither the current claim 1 nor claim 16 of the patent as granted exclude the addition of benzoate,

sorbate or alkyl ester of para-hydroxybenzoate at some stage of the process.

15. Hence, the clarity requirement of Article 84 EPC is fulfilled.

Article 83 EPC – sufficiency of disclosure

16. The sufficiency of the disclosure of the claimed invention was disputed by appellant II relying on essentially the same argument put forward to substantiate the objection of lack of clarity (see paragraph 13 above). For the reason given above, also the objection under Article 83 EPC fails.

Article 56 EPC – inventive step

17. In the decision under appeal, document (3) was regarded as the closest state of the art because, in the opposition division's view, this document dealt with the same problem of improving microbial stability of Rhizomucor miehei aspartic protease. However, document (3) is rather concerned with the preparation of a dry stabilized preparation of microbial aspartic protease (rennet) which is easy to handle "... from the standpoint from both dedusting and solubility in aqueous solution ..." (see column 2, lines 1 to 4). Stabilization of the dry composition is achieved by admixing the solid enzyme product recovered from the fermentation broth with 2-3% of fatty acid monoesters of polyoxyethylene sorbitan ("Tween®") (see column 1, lines 55 to 60). The admixture "... is storage stable, dust free and readily soluble in aqueous solution. As such, its ease of handling is substantially superior to that of the original powder." (see column 3, lines 30 to 33). It is stated in document (3) that the

stabilized enzyme preparation can contain, additionally, minor amounts of conventional rennet additives like, for example, salts such as sodium chloride, mould inhibitors and preservatives such as sorbic acid, potassium sorbate, or sodium benzoate, and other such non-toxic, rennet-compatible substances (see column 2, lines 43 to 50).

18. It is described in Example 1 of document (3) that, in order to obtain a liquid enzyme preparation, the dust free solid admixture "... is readily dissolved in an aqueous solution containing 17.5 percent sodium chloride and 2.5 percent propylene glycol. [...] Potassium sorbate (1 percent) and sodium benzoate (1/8 of 1 percent) are added as preservatives" (see column 3, lines 33 to 38). For the manufacture of cheese, the liquid preparation is added to milk.

19. Undisputedly, document (3) describes a process for preparing a liquid aspartic protease composition comprising the steps (a) to (c) specified in current claim 1. The process of claim 1 differs from the prior art not only in the filtration step (e), but also in that acetate are added to the purified solution (step (e)) to obtain a liquid enzyme composition having an acetate concentration of at least 0.1 mol/l.

20. It is undisputed that, starting from document (3), the problem to be solved is to provide an alternative method for producing a liquid aspartic protease composition with a comparable stability. It is also undisputed that this problem is solved by the process of claim 1.

21. However, as stated above in connection with Article 84 EPC, claim 1 does not exclude the addition of benzoate,

sorbate or other additives at some stage of the claimed process. It is not at all surprising that, if any of those preservatives is added to the enzyme solution after the purification step, a liquid enzyme composition obtained by performing the claimed process has a high enzymatic stability. Hence, it is not apparent which technical effect the addition of acetate to an enzyme solution containing other preservatives may have.

22. As appellant II asserted, the technical effect attributable to the filtration step (e) is the removal of undesirable insoluble contaminants, e.g. bacteria. Since this is a measure well-known in the art, an inventive step cannot be acknowledged for the subject-matter of claim 1.

Auxiliary request 8B

Admittance and consideration in the appeal proceedings – Article 12(4) RPBA 2007

23. Claim 1 of the auxiliary request 8B includes the feature "..., wherein no compound selected from benzoate, sorbate or alkyl ester of para-hydroxybenzoate is added to the purified solution" which characterized the process of claim 2 of the previous request. The same feature was included in claim 1 of the auxiliary request 2 underlying the decision under appeal, on the basis of which the opposition division intended to maintain the patent. Hence, the auxiliary request 8B, which was filed as a reaction to the board's findings on Article 56 EPC regarding the auxiliary request 7B, does not give raise to any new issues. For these reasons, the request was to be admitted and considered.

Articles 123(2), 123(3), 84, 83 EPC

24. The findings on the auxiliary request 7B above apply, mutatis mutandis, also to the auxiliary request 8B.

Article 56 EPC – inventive step

25. In claim 1 of this request, the addition of benzoate, sorbate or alky ester of para-hydroxybenzoate to the purified aspartic protease solution is excluded. Hence, the claimed process differs from the process described in document (3) not only in that it includes a filtration step, but also in that acetate is added instead of the known preservatives described in column 2, lines 47 and 48 of document (3).

26. Starting from document (3), the objective technical problem is the provision of an alternative process for preparing a liquid aspartic protease composition. In view of the experimental data in the examples of the application as filed, this problem is solved by the method of claim 1.

27. Thus, the sole question remaining for decision is whether it was obvious to a person skilled in the art to replace the preservatives described in document (3) by acetate at a concentration of 0.1 mol/l.

28. Appellant II argued that, since the liquid composition described in document (3) is a food additive, a skilled person seeking for an alternative to the addition of the known preservatives, would have looked for safe and non-toxic compounds which have antimicrobial properties. Document (20) described that acetic acid has an inhibitory effect on the growth of

microorganisms like yeast. Also document (34), which had been admitted in the appeal proceedings after hearing the parties, described acetic acid and its salts as a food preservative. Hence, it was obvious to replace the undesired toxic preservatives described in document (3) by acetate.

29. This line of argument is not persuasive. There is nothing in document (3) that may motivate the skilled person to replace the conventional preservatives mentioned therein by acetate. As a matter of fact, it is suggested by the statement "... and other such non-toxic, rennet-compatible substances" (see column 2, lines 43 to 49) that minor amounts of preservatives such as sorbic acid, potassium sorbate or sodium benzoate are not toxic.

30. Nor does document (20) or document (34) provide any motivation to use acetate at a concentration of 0.1 mol/l as a preservative in a liquid aspartic protease composition. It is stated in document (20) that some organic acids "... such as citric acid, acetic acid, and lactic acid, at used at high concentration (per cent levels) and are often regarded as acidulants rather than antimicrobial agents. Others, such as sorbic and benzoic acids, are known primarily as food preservatives." (see page 49, second full paragraph, second and third sentence). As apparent from Table 4.1 of document (20), high concentrations of acetic acid are required for preserving food stuffs. Lower concentrations of acetic acid may have an antimicrobial effect on some microorganisms under certain conditions (see documents (7) and (8)), but there is no evidence on file that this effect could be extended to any microorganism.

31. Documents (10) and (12) were also cited by appellant II. These documents describe the use of acetate as a buffer, in particular for eluting or dialyzing a microbial protease enzyme (see Abstract of document (10)). Appellant II contended that acetate buffers are common in compositions containing aspartic protease. In these compositions, acetate buffer is not used as a preservative, but is added to keep the pH of the composition stable.

32. Summarising the above: none of the cited documents teaches or even suggests that acetate at a concentration of 0.1 mol/l may be used as a preservative for a liquid aspartic protease composition.

33. Appellant II and opponent 01 as the party as of right substantiated the objection of lack of inventive step starting also from documents (18) and (31b) as the closest state of the art. These documents describe Hannilase®, a commercial aspartic protease composition which contains sodium benzoate as a preservative. However, they do not describe any process for preparing the composition. Moreover, a person skilled in the art does not find in these documents any motivation to replace sodium benzoate by a different preservative. As stated above in the assessment of inventive step starting from document (3) as the closest state of the art, there is no teaching or suggestion in the cited documents to use acetate at a concentration of 0.1 mol/l as a preservative for a liquid aspartic protease composition. Hence, also this line of argument fails.

34. For these reasons, an inventive step is acknowledged for the subject-matter of auxiliary request 8B.

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 claims 1 and 2 of auxiliary request 8B as filed during the oral proceedings before the board, and a description to be adapted.

The Registrar: On behalf of the Chair (according to Art.8(3) RPBA 2020):

L. Malécot-Grob R. Winkelhofer

Decision electronically authenticated