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Datasheet for the decision of 7 December 2010

Case Number:	T 0778/08 - 3.3.09			
Application Number:	00910566.9			
Publication Number:	1162889			
IPC:	A23C 19/04			
Language of the proceedings:	EN			
Title of invention: Process for producing cheese				
Patentee: Novozymes A/S				
Opponent: DANISCO A/S				
Headword: -				
Relevant legal provisions: EPC Art. 54, 56, 83, 123				
Relevant legal provisions (EPC 1973): -				
Keyword: "Added subject-matter - no" "Sufficiency - yes" "Novelty - yes" "Inventive step - yes"				
Decisions cited: T 1329/04				
Catchword:				

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Boards of Appeal

Chambres de recours

European 101(2)

Case Number: T 0778/08 - 3.3.09

DECISION of the Technical Board of Appeal 3.3.09 of 7 December 2010

Appellant: (Opponent)	DANISCO A/S Langebrogade 1 PO Box 17 DK-1001 Copenhagen K (DK)
Representative:	Williams, Aylsa D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Respondent: (Patent Proprietor)	Novozymes A/S Krogshøjvej 36 DK-2880 Bagsvaerd (DK)
Representative:	Stevens, Ian Edward Potter Clarkson LLP Park View House 58 The Ropewalk Nottingham NG1 5DD (GB)
Decision under appeal:	Decision of the Opposition Division of the European Patent Office announced orally on 22 January 2008 and posted on 3 March 2008 rejecting the opposition filed against Euro patent No. 1162889 pursuant to Article 101(EPC.

Composition of the Board:

Chairman:	W.	Sieber	
Members:	J.	Jardón	Álvarez
	F.	Blumer	

Summary of Facts and Submissions

I. European patent No. 1 162 889 was granted in respect of European patent application No. 00910566.9, which was filed in the name of Novozymes A/S on 14 March 2000 as International application PCT/DK2000/000109 (WO 2000/054601). The mention of grant was published on 23 February 2005 in Bulletin 2005/08. The patent was granted with 23 claims, Claim 1 reading as follows:

"1. A process for producing cheese, which comprises the steps of:

a) treating cheese milk or a fraction of cheese
milk with a phospholipase selected among
phospholipase A₁, phospholipase A₂, phospholipase B,
and combinations thereof; and
b) producing cheese from the cheese milk or the
fraction of cheese milk,

wherein step (a) is conducted before and/or during step (b)."

Claims 2 to 23 were dependent claims.

II. A notice of opposition was filed against the patent by Danisco A/S on 23 November 2005. The opponent requested revocation of the patent in its entirety, reference being made to Article 100(a) EPC as regards novelty and inventive step and to Articles 100(b) and (c) EPC.

During the opposition proceedings *inter alia* the following documents were cited:

- D1: Molochnaya Promyshlennost 1980, No 11, 21-25, 47 Abstract from Food Sci & Tech Abs.;
- D1A: English translation of whole document D1;
- D2: E. Fernandez-Garcia et al., "The Use of Lipolytic and Proteolytic Enzymes in the Manufacture of Manchego Type Cheese from Ovine and Bovine Milk"; J. Dairy Sci. 77, pages 2139-2149, 1994;
- D6: US 3 973 042 A;
- D8: C. Koçak et al., "Effect of added fungal lipase on the ripening of Kasar cheese"; Milchwissenschaft 51(1), pages 13 -17, 1996;
- D13: L.M. Rich et al., "The effects of phospholipases on Mozzarella cheese"; 2001 IFT Annual Meeting -New Orleans, Louisiana, (one page);
- D15: "AMANO ENZYMES. Lipase for Industrial Use" News Letter, Issue No. 6, Nov 1998 (4 pages); and
- D18: E. Høier et al., "Enhancing cheese yield by phospholipase treatment of cheese milk", The Australian Journal of Dairy Technology, Vol. 61(2), pages 179-182, 2006.
- III. By its decision announced orally on 22 January 2008 and issued in writing on 3 March 2008, the opposition division rejected the opposition.

The opposition division acknowledged novelty of the claimed subject-matter essentially because there was no

indisputable evidence that the lipases used in the cited prior art documents had also phospholipase activity. In particular with regard to D8, the opponent had neither convincingly demonstrated that the lipase used in this document, namely Palatase M 200L, had phospholipase A_1 , A_2 or B activity nor that Palatase M 200L was identical to Palatase 20000L, which had been used by the opponent in its further experiments. The opposition division also acknowledged an inventive step because there was no teaching in the prior art that the problem of reducing oiling-off and/or increasing the yield in cheese could be solved by treating cheese milk with phospholipases.

Finally, the opposition division found that the invention in the patent in suit was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art and that the subject-matter of the claims did not extend beyond the content of the application as filed.

- IV. On 17 April 2008 the opponent (appellant) filed an appeal against the decision of the opposition division and paid the prescribed fee on 21 April 2008. With the statement setting out the grounds of appeal filed on 2 July 2008, the appellant requested that the decision to maintain the patent be set aside and that the patent be revoked in its entirety. The appellant also filed seven new documents in support of its arguments.
- V. The patent proprietor (respondent) filed its reply by letter dated 13 January 2009, together with Auxiliary Requests 1 to 16 and three new documents. It requested that the appeal be dismissed or, in the alternative,

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that the patent be maintained on the basis of one of the auxiliary requests.

- VI. Further submissions were filed by the appellant on 19 June 2009 and 15 July 2009 (including 10 new documents) and by the respondent on 6 November 2009 and 14 January 2010 (including 3 new documents).
- VII. On 6 July 2010 the board dispatched a summons to attend oral proceedings on 7 December 2010. In a communication dated 9 August 2010 the board expressed its preliminary view that the requirements of Articles 100(b) and (c) EPC appeared to be met and drew the parties' attention to the points to be discussed during the oral proceedings.
- VIII. With letter dated 26 October 2010 the appellant filed further submissions and three new documents.
- IX. With letters dated 5 November 2010 and 2 December 2010 the respondent also filed four new documents and further arguments.
- X. Out of the 30 fresh documents cited during the appeal proceedings the following documents are relevant to the present decision:
 - D30: M.V. Arbige *et al.*, "Novel Lipase for Cheddar Cheese Flavor Development" Food Technology, pages 91-98, 1986; and
 - D46: Declaration of John J. Jaeggi, dated 9 December 2009, 5 pages.

XI. On 7 December 2010 oral proceedings were held before the Board. In the course of the oral proceedings, the respondent withdrew all the requests on file except for its previous fifteenth auxiliary request which was refiled at the oral proceedings as "Second Auxiliary Request" and ultimately became the respondent's sole request. Claim 1 reads as follows:

"1. A process for producing cheese, which comprises the steps of:

a) treating cheese milk or a fraction of cheese milk with a phospholipase selected among phospholipase A_1 , phospholipase A_2 , phospholipase B and combinations thereof; and

b) producing cheese from the cheese milk or the fraction of cheese milk,wherein step a) is conducted before and/or during stepb), and said phospholipase is an enzyme havingessentially only phospholipase activity."

- XII. The arguments presented by the appellant in its written submissions and at the oral proceedings insofar as they are relevant for the present decision may be summarized as follows:
 - The appellant maintained that the wording "and combinations thereof" in Claim 1 was not supported by the application as originally filed. Further, the expression "said phospholipase is an enzyme having essentially only phospholipase activity" was disclosed in the application as filed only together with the statement "and wherein the phospholipase enzyme activity is not a side activity". The

appellant concluded that amended Claim 1 extended beyond the content of the application as filed.

- The application as filed did not provide data enabling the invention to be carried out. The problem of increasing the yield in cheese production was not solved by the enzyme Lecitase[™], the only enzyme exemplified in the patent, and the oiling-off effect was only demonstrated for one specific type of phospholipase A₁ and one specific phospholipase A₂.
- The subject-matter of the claims as granted lacked novelty having regard to several prior art documents using a lipase in cheese production, e.g. D8.
 Palatase M 200 L used in D8 had phospholipase A₁, A₂ or B activity as shown by several declarations filed during the proceedings. With regard to the second auxiliary request filed at the oral proceedings, the appellant had no further comments.
- Concerning inventive step, the appellant stated that the invention did not solve a technical problem. It disputed that the examples in the patent showed any improvement either in increasing the yield of cheese or in decreasing the oiling-off effect. Moreover, the evidence filed later by the respondent related in part to phospholipase enzymes that were not available at the priority date of the patent. In the absence of any improvement over the prior art, the disclosure of D1/D1A, in which the effect on quality of Kostroma cheese of bacterial starter cultures having phospholipase activity was investigated, could be regarded as the closest prior art document. In its opinion the replacement of the bacterial

starter culture by the endogenous enzyme was routine work for the skilled person and lacked inventive step.

- XIII. The arguments of the respondent may be summarised as follows:
 - The wording "and combinations thereof" in Claim 1 was implicitly disclosed in the application as filed. The feature of granted Claim 23 now introduced into Claim 1 was explicitly disclosed on page 12, line 12 of the application as filed.
 - The respondent maintained that the skilled person knew from the disclosure in the specification and from background general knowledge how to apply the teaching of the invention throughout the entire scope of the claims.
 - The respondent stated that the claimed subjectmatter was novel because there was no disclosure in any of the documents of a process for producing cheese in which cheese milk or a fraction of cheese milk was treated with a phospholipase having essentially only phospholipase activity.
 - Concerning inventive step, the respondent maintained that the claimed invention solved the technical problem of increasing the yield of the cheese and the further problem of increasing the fat stability of cheese, as shown in the working examples of the patent and in the evidence filed during the proceedings. The solution according to the patent in suit, namely the treatment of cheese milk with a

phospholipase, was not obvious to a person skilled in the art, essentially because there was no disclosure in any of the cited documents that a phospholipase could be useful in cheese production.

XIV. The appellant requested that the decision under appeal be set aside and that the European patent No. 1 162 889 be revoked.

> The respondent requested that the patent be maintained on the basis of the second auxiliary request as filed during the oral proceedings before the Board.

Reasons for the Decision

1. The appeal is admissible.

THE RESPONDENT'S SOLE REQUEST

- 2. Amendments (Article 100(c) EPC/Article 123 EPC)
- 2.1 Claim 1 is a combination of granted Claims 1 and 23 ("... and said phospholipase is an enzyme having essentially only phospholipase activity"). The remaining claims correspond to granted Claims 2 to 22.
- 2.2 The appellant has questioned whether there is a basis in the application as filed for specifying in granted Claim 1 and amended Claim 1, respectively, the use of the combination of the three phospholipases A₁, A₂ and B.

However, the wording "and combinations thereof" in granted Claim 1 and amended Claim 1, respectively, is

supported by the application as originally filed (cf. page 10, line 15 to page 12, line 15) for the following reasons.

2.2.1 The paragraph on page 10, lines 15 to 22 states:

"The enzyme[s] used in the process of the present invention include a phospholipase, such as, phospholipase A₁, phospholipase A₂ and phospholipase B. In the process of the invention the phospholipase treatment may be provided by one or more phospholipase, such as two or more phospholipases, e.g. two phospholipases, including, without limitation, treatment with both type A and B; both type A₁ and A₂; both type A₁ and B; both type A₂ and B; or treatment with two different phospholipase of the same type. Included is also treatment with one type of phospholipase, such as A₁, A₂ or B."

- 2.2.2 It is not disputed that this paragraph provides support for the use of phospholipase A_1 , phospholipase A_2 and phospholipase B and for the use of two of these phospholipases in combination (A_1 and A_2 ; A_1 and B; A_2 and B). The objection of the appellant is directed only to the combination of the three phospholipases (A_1 , A_2 and B) which is not explicitly disclosed in the above paragraph.
- 2.2.3 However, this combination is indeed implicitly disclosed in the application as filed. The phospholipases to be used in the invention are those having the ability to hydrolyze one and/or both fatty acyl groups in a phospholipid (page 11, lines 1-2), that is to say, phospholipase A₁ that cleaves the acyl

chain in the sn-1 position, phospholipase A_2 that cleaves the acyl chain in the sn-2 position, and phospholipase B that cleaves both acyl chains. This means that the invention is only concerned with phospholipases A_1 , A_2 and B that hydrolyse fatty acyl groups in a phospholipid, but not with phospholipases C and D, which do not act in this way and do not liberate free fatty acids.

- 2.2.4 Thus, the disclosure in the application as filed of "two or more phospholipases" at page 10, line 18 must be a disclosure of all three, ie A₁, A₂ and B. Logically, in the context of the originally filed application, it cannot mean anything else. Therefore, the disclosure of using a combination of all of the phospholipases A₁, A₂ and B is clear and unambiguous.
- 2.3 The appellant has also questioned whether the wording "... and said phospholipase is an enzyme having essentially only phospholipase activity" introduced into Claim 1 as granted has a proper basis in the application as filed, because the corresponding passage at page 12, lines 10 to 13 states "In other embodiments of the invention the phospholipase enzyme activity is provided by an enzyme having essentially only phospholipase activity and wherein the phospholipase enzyme activity is not a side activity" (emphasis added by the board). Concerning the omission of the expression "and wherein the phospholipase enzyme activity is not a side activity", the board notes that this expression is redundant in view of the immediately preceding text. In other words, the expression "and wherein the phospholipase enzyme activity is not a side activity" provides no further limitation to the

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expression incorporated into Claim 1, namely that the "phospholipase is an enzyme having essentially only phospholipase activity". Hence, this amendment of Claim 1 also meets the requirements of Article 123(2) EPC.

- 2.4 The amendment made to Claim 1 undisputedly limits its scope. The requirements of Article 123(3) are also satisfied.
- 3. Sufficiency of disclosure (Article 100(b) EPC)
- 3.1 Claim 1 is directed to a process for producing cheese comprising:
 a) treating cheese milk or a fraction of cheese milk with a phospholipase having essentially only phospholipase activity; and
 b) producing cheese from the cheese milk or the fraction of cheese milk.
- 3.2 The requirements of sufficiency are met if:
 - at least one way is clearly indicated in the patent specification enabling the skilled person to carry out the invention, and
 - the disclosure allows the invention to be performed in the whole area claimed without undue burden, applying common general knowledge.
- 3.3 Having regard to the disclosure of the patent, which includes several working examples, the first requirement is met. Moreover, there is no experimental evidence showing that the invention cannot be performed in the whole area claimed without undue burden.

3.4 The objections raised by the appellant concerning sufficiency are mainly that the problem of increasing the yield in cheese production is not solved by the enzyme Lecitase[™] and so the claims are not enabled (see statement of grounds of appeal, page 4, third paragraph) and that some phospholipases do not decrease the oiling-off effect (see statement of grounds of appeal, page 6, last paragraph).

> However, the increasing of cheese yield or the oilingoff effect are issues relating to the technical problem solved by the invention and therefore to be considered later when assessing inventive step. Thus, they are not relevant for sufficiency of disclosure, as the claimed process only requires the production of cheese without defining any increase of yield or any other improvement.

3.5 In view of the above, the requirement of sufficiency of disclosure is met.

4. Novelty

4.1 The novelty of the subject-matter of the granted claims was contested by the appellant having regard to the disclosures of documents D2, D6, D8, D15 and D30, which disclose processes for producing cheese using lipases. In the appellant's view the lipases used therein show phospholipase side-activity and are therefore novelty destroying for those embodiments covered by the granted claims in which the "phospholipase activity may e.g. be from a lipase with phospholipase side activity" (cf. paragraph [0045] of the patent specification).

- 4.2 The subject-matter of Claim 1 of the respondent's sole request has been limited to the use of phospholipases having "essentially only phospholipase activity" and thus excludes those lipases of the prior art having phospholipase side activity. The objections of the appellant therefore do not apply to the subject-matter of the claims of this request.
- 4.3 None of the documents on file discloses a process for producing cheese in which cheese milk or a fraction of cheese milk is treated with a phospholipase having essentially only phospholipase activity.
- 4.4 The subject-matter of Claim 1 is therefore novel.

5. Inventive step

The patent in suit relates to a process for producing cheese from enzyme-treated cheese milk. The patent aims in particular to improve the yield of the cheese and to increase the fat stability of cheese, that is to say, to reduce the oiling-off properties of the cheese (see paragraphs [0009] and [0011] of the patent in suit).

5.1 Closest prior art

5.1.1 None of the documents cited by the appellant is directed to achieving the technical effects of improving the yield in cheese production and increasing the fat stability. As a consequence, a process for the preparation of cheese and having the most structural elements in common with the claimed subject-matter should be regarded as the closest prior art document. Documents for the production of cheese and using a lipolytic enzyme, albeit a lipase, for instance the process for making Kasar cheese described in D8 (see page 13 paragraph 2.2), and/or the method for making Manchego cheese described in D2 (see abstract), can be seen as representing the closest prior art.

- 5.1.2 Independently of which document is chosen as closest prior art, the distinguishing feature of the claimed process lies in the treating of the cheese milk with a specific phospholipase, namely phospholipase A₁, phospholipase A₂, phospholipase B or combinations thereof and having essentially only phospholipase activity.
- 5.2 Problem to be solved and its solution
- 5.2.1 Taking account of the fact that the use of a phospholipase is said to have two effects in the cheese production, the patent in suit aims to solve two technical problems, namely
 - the problem of increasing the yield of the cheese production, and
 - the problem of increasing the fat stability of the cheese.
- 5.2.2 The solution to these problems proposed by the patent in suit is the method according to Claim 1, which is characterized by the use of a specific phospholipase as enzymatic aid.
- 5.2.3 The board is satisfied that these problems are solved by the method of Claim 1 for the following reasons:

5.2.4 As set out in paragraph [0062] of the patent specification an increase in cheese fat yield and/or cheese protein yield is evidence for an increase of the

yield of cheese.

An increase in cheese yield is evident from the data in Table 2 in the patent specification which show an increase in the fat and protein content in the cheese when using Lecitase[®], a phospholipase, in Trial 1 as compared with the Trial 1-control without Lecitase[®]. Thus, the protein in cheese increases from 18.1% to 18.8% and the fat in cheese from 36.8% to 38.1%.

These results in the patent specification are confirmed by the further evidence submitted by the respondent during the proceedings. Thus D46 (see conclusion on page 5) states that "The addition of phospholipase significantly increased the retention of milk fat resulting in a higher cheese yield". In fact, D46 confirms that the results demonstrated in the patent in suit can also be attained on a large scale using the same enzyme.

Further confirmation of the effect of a phospholipase on cheese yield is provided by D18. D18 shows that the addition of the phospholipase A_1 enzyme YieldMAXTM PL to the cheese milk gives a significant increase in cheese yield in production of Mozzarella cheeses (see abstract, page 179, right column).

5.2.5 Similar considerations apply to the problem of increasing the stability of the fat in the cheese. This effect is seen in Examples 1 and 3 in the patent specification wherein the oily diameter formed on a

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filter paper by the cheese on heating is significantly less in the cheese made using Lecitase[®] than in the control cheese (cf. Table 1 wherein the diameter in centimetres is reduced from 6.6 without phospholipase to 5.8 with Lecitase[®] or from 6.8 to 5.4 and in Table 2 wherein the oily area in percent of the cheese area is reduced from 176% to 57% (Trial 1-control versus Trial 1)).

Again this effect is confirmed by further evidence filed by the respondent during the proceedings. For example, D13 (see last paragraph) confirms the finding of the patent and concludes that "oiling-off can be decreased in Mozzarella cheese without affecting meltability or cheese composition using phospholipases".

- 5.2.6 The appellant contested that the above mentioned problems were solved by the use of a phospholipase and argued essentially that:
 - (a) The patent application as filed did not provide data which showed that the technical problems had been solved. In particular the data concerning the improvement of yield in the examples of the patent were contradictory and not at all conclusive of any improvement.
 - (b) The later filed evidence could not correct this deficiency. The post-published documents were the first disclosure going beyond mere speculation and should not be taken into consideration. In this context reference was made to T 1329/04 of 28 June 2005 (not published in the OJ EPO).

- (c) In any case this evidence merely showed that specific phospholipases could solve the above problems. However, it was not plausible that all phospholipase A₁, A₂ or B enzymes covered by Claim 1 would solve the technical problems.
- 5.2.7 The board cannot accept these arguments of the appellant for the following reasons:
 - Concerning (a) it is noted that the results in the patent in relation to the "oiling off" have not been questioned by the appellant. Rather, its objection related only to the increase of the yield. However, the appellant's criticism in this respect is not justified. First of all, Trial 1 in Table 2 undoubtedly provides evidence for an increase in cheese yield due to the use of a phospholipase (see point 5.2.4 above). While it is true that the comparison between Trial 2 and Trial 2-control in Table 2 actually shows a slight decrease in cheese yield, this example cannot be taken into account because it is obviously wrong. The sum of the components of Trial 2-control is not 100% but 101%, making this example meaningless. Consequently, no conclusion can be obtained from the comparison of Trial 2 with Trial 2-control. As to the data of Table 1, these experiments, as pointed out by the respondent, have been carried out on a small scale and are therefore less informative. In any case, D46 provides evidence that the alleged effect is more evident on a large scale production.
 - Contrary to the position of the appellant, the postpublished documents D46, D18 and D13 can be taken

into account in the present case because they simply provide a confirmation that the general concept of the method of the invention, namely the use of a phospholipase to improve the yield of cheese and the stability of fat, is sound. In reaching this conclusion, the board does not deviate from T 1329/04, cited above. In this decision, it is stated that post-published documents which were the first disclosure going beyond speculation should not be taken into consideration for the assessment of inventive step (see point 12 of the reasons). Since, in the present case, the experimental data provided in the application as filed render the alleged effect and its solution plausible, documents D46, D18 and D13 cannot be regarded as the first disclosure going beyond speculation, but rather additionally confirm that the general concept of the claimed invention works. Consequently, these documents can be taken into consideration.

Finally, in the absence of any experimental evidence to the contrary, the appellant's argument that not every phospholipase covered by Claim 1 would increase the yield of cheese is not convincing. In fact, what is important is the function of the phospholipase, not its type and/or origin (see paragraph [0046] of the patent specification). Thus, it is reasonable to expect that phospholipases other than those exemplified would perform in the same way and achieve the same results.

5.3 Obviousness

- 5.3.1 It remains to be decided whether, in view of the available prior art documents, it would have been obvious for the skilled person to solve these technical problems by the means claimed, namely by the treatment of cheese milk with a specific phospholipase.
- 5.3.2 There is no hint to this solution in any of the documents cited by the appellant. In fact, there is no disclosure in the cited prior art that a phospholipase could be useful in cheese production in order to improve the yield of cheese and the fat stability.

Also D1/D1A does not provide a hint in this direction. D1A analyses the effect on the quality of Kostroma cheese of 53 strains of *Streptococcus lactis* as starter microorganisms, all having phospholipase activity. However, there is nothing in D1/D1A which would suggest that an enzyme having essentially only phospholipase activity, in particular phospholipase A₁, phospholipase A₂ or phospholipase B, might have an effect on the yield and/or fat stability. In fact, D1/D1A teaches away from the claimed subject-matter, because the use of bacterial starters with high phospholipase activity leads to deterioration of cheese quality (see page 8, second paragraph).

6. For these reasons the subject-matter of Claim 1 of the second auxiliary request and, by the same token, the subject-matter of dependent Claims 2 to 22, involve an inventive step.

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 Second Auxiliary Request (Claims 1-22) as filed during the oral proceedings before the Board and after any necessary consequential amendment of the description.

The Registrar

The Chairman

G. Röhn

W. Sieber