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Datasheet for the decision of 12 February 2008

Case Number: T 0907/05 - 3.3.08

Application Number: 97610056.0

Publication Number: 0869167

IPC: C11B 3/00

Language of the proceedings: EN

Title of invention:
Reduction of phosphorus containing components in edible oils comprising a high amount of non-hydratable phosphorus by use of a phospholipase, a phospholipase from a filamentous fungus having phospholipase A and/or B activity

Patentee:
Novozymes A/S

Opponent:
DANISCO A/S
DSM IP Assets B.V.

Headword:
Phospholipase in baking/NOVOZYMES

Relevant legal provisions:
EPC Art. 54, 56, 83

Keyword:
"Admissibility of new experimental evidence (no)"
"Main request - novelty (yes)"
"Inventive step (yes)"
"Sufficiency of disclosure (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0907/05 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 12 February 2008

Appellant: (Patent Proprietor)	Novozymes A/S Krogshoejvej 36 DK-2880 Bagsvaerd (DK)
Representative:	Stevens, Ian Edward Potter Clarkson LLP Park View House 58 The Ropewalk Nottingham NG1 5DD (GB)
Respondent I: (Opponent O1)	DANISCO A/S Langebrogade 1 PO Box 17 DK-1001 Copenhagen K (DK)
Representative:	Williams, Aylsa D Young & Co 120 Holborn London EC1N 2DY (GB)
Respondent II: (Opponent O2)	DSM IP Assets B.V. Het Overloon 1 NL-6411 TE Heerlen (NL)
Representative:	Elkenbracht, Johan Christiaan DSM Intellectual Property Office Delft PP 600-0240 P.O. Box 1 NL-2600 MA Delft (NL)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted 20 June 2005 concerning maintenance of European patent No. 0869167 in amended form.**

Composition of the Board:

Chairman: L. Galligani
Members: P. Julià
C. Rennie-Smith

Summary of Facts and Submissions

I. European patent No. 0 869 167 with the title "Reduction of phosphorous containing components in edible oils comprising a high amount of non-hydratable phosphorus by use of a phospholipase, a phospholipase from a filamentous fungus having phospholipase A and/or B activity" and based on European patent application No. 97 610 056.0, was granted with 11 claims.

II. The patent was opposed by two opponents on the grounds as set forth in Articles 100(a),(b) and (c) EPC. The opposition division considered that the main request and the first auxiliary request did not satisfy the requirements of Article 56 EPC. An objection under Article 123(3) EPC was also raised against the main request. The patent was maintained in amended form based on a second auxiliary request filed on 1 March 2005.

III. The patentee and opponents 01 and 02 each filed a notice of appeal, paid the appeal fee and submitted statements setting out their grounds of appeal. The patentee filed also a new main request and fourteen auxiliary requests.

IV. In a letter dated 9 March 2006, the patentee replied to opponents' grounds of appeal and filed auxiliary requests 1A and 1B.

V. In a letter dated 15 March 2006, opponent 02 replied to the patentee's grounds of appeal.

VI. Opponent 01 withdrew its appeal by a letter dated 9 June 2006.

VII. With the summons to oral proceedings, the board sent a communication pursuant to Article 11(1) (now Article 15(1)) of the Rules of Procedure of the Boards of Appeal (RPBA) and informed the parties of its preliminary, non-binding opinion on substantive matters.

VIII. In their letters both dated 11 January 2008, the patentee and opponent 02 replied to the board's communication. The former filed a new main request and new auxiliary requests 1 to 13. The latter filed new experimental evidence.

IX. In a letter dated 25 January 2008, the patentee replied to the submissions of opponent 02 and requested the board to consider the issue of the admissibility of the new experimental evidence into the proceedings. The patentee also submitted several documents considered to be relevant for the assessment of the new experimental evidence.

X. In a fax dated 11 February 2008, opponent 02 withdrew its appeal and informed the board that it would not attend the oral proceedings.

XI. Oral proceedings took place on 12 February 2008, the patentee being the sole party represented at the oral proceedings and the sole appellant in the proceedings. During the oral proceedings, the appellant withdrew the main request and auxiliary request 1 to 6 then on file and filed a new main request (claims 1 to 3).

XII. Claim 1 of the **main request** read as follows:

"1. Use of a polypeptide exhibiting phospholipase A activity selected from the group consisting of:

a) a polypeptide encoded by the phospholipase A-encoding part of the DNA sequence cloned into plasmid pYES 2.0 present in Escherichia coli DSM 11299;

b) a polypeptide having an amino acid sequence as shown in positions 31-346 of SEQ ID NO 2;

c) a polypeptide having an amino acid sequence as shown in position 31-303 of SEQ ID NO 2; and

d) a polypeptide which is at least 80% homologous with said polypeptide defined in (b) or (c)

in a process for reducing the content of phospholipid in an edible oil having a phosphorus content from 50-250 ppm, comprising treating the oil with the polypeptide so as to hydrolyze a major part of the phospholipid, and separating an aqueous phase containing the hydrolyzed phospholipid from the oil."

Claim 2 was directed to the use of a polypeptide exhibiting phospholipase A activity selected from the group as defined in claim 1 in a process for making a baked product, comprising adding the polypeptide to a dough, and baking the dough to make the baked product. Claim 3 was dependent on claims 1 or 2 and defined the polypeptide as a phospholipase A1.

XIII. The following documents are referred to in the present decision:

D1: EP-B-0 130 064 (publication date: 31 August 1988);

D3: WO-A-95/09909 (publication date: 13 April 1995);

D6: T. Hoshino et al., Biosci. Biotech. Biochem., 1992, Vol. 56(4), pages 660 to 664;

D7: T. Nagao et al., J. Biochem., 1994, Vol. 116, pages 536 to 540;

D19: WO-A-96/13579 (publication date: 9 May 1996);

D30: WO-A-94/04035 (publication date: 3 March 1994);

D62: Declaration of Mrs. L. Erlandsen dated 21 October 2005 with experimental evidence;

D76: Experimental evidence filed by opponent 02 with letter dated 11 January 2008.

XIV. The arguments of the appellant relevant to the present decision may be summarised as follows:

Admissibility of the new experimental evidence

The new experimental evidence was filed in response to the declaration of Mrs. Erlandsen (document D62) which had been filed with the appellant's grounds of appeal and had thus been available from the very beginning of the appeal proceedings. No reasonable explanation had been given as to why this experimental evidence was

filed shortly before the oral proceedings, rather than in the two years since document D62 was filed. It was established case law that the filing of new experimental data before oral proceedings, without good reasons for the delay, was contrary to fair procedure since the patentee was thereby denied sufficient time to consider the data, perform its own tests and file evidence in reply.

Main request
Article 54 EPC

Document D3 disclosed the modification of enzymes of many different types, of which lipase was only one class. This document described a wide range of different applications for the modified enzymes, such as the preparation of detergents, paper processing and animal feed. Document D3 also disclosed a long list of possible sources of lipases. However, there was no disclosure of a polypeptide exhibiting the phospholipase activity of the patent in suit nor a disclosure of the use in baking of any phospholipase, let alone one from *Fusarium oxysporum*.

Article 56 EPC

As regards claim 1, it was surprising that the enzyme of the patent in suit not only had effective phospholipase activity to be used for reducing the content of phospholipids in edible oils but also that this use was not prevented by its lipase activity. It was reasonable to expect that the glycerides that made up the major part of an edible oil could be deleteriously affected by the lipase activity. The

alleged deficiencies of Example 14 of the patent in suit were based on differences that did not affect the conclusions of the example, which together with Examples 16 and 17 showed the advantages of the phospholipase of the patent in terms of its rate of degumming of vegetable oil.

As regards claim 2, document D1 was not the closest prior art since it related to lipases for use in detergents and not to phospholipases for use in baking. Both activities were different and the two technical fields unrelated. Those skilled in the art of baking would never had taken as a starting point a document disclosing only detergents. When the "problem-solution" approach was adopted correctly, the closest prior art was represented by a document in the field of baking, such as document D30. However, starting from this document, it was not obvious to look to document D1, which related only to detergents, for a solution to any problem based on document D30.

Firstly, there was no reference in document D30 to *Fusarium* and, in the absence of any indication, the skilled person faced a wide choice of fungal lipases. The selection of a lipase from *Fusarium*, such as those from documents D1, D6 or D19, was far removed from a "one-way-street" situation and not evident. Secondly, none of these documents referred to phospholipases nor to any use in baking. Prior art on file disclosing the use of phospholipases in baking required this activity to be substantially free from any lipase. Contrary thereto, the patent demonstrated that the presence of both activities was advantageous. These advantages were shown in Examples 20 and 21 of the patent and supported

by further evidence on file. They were indicative of a purposive selection, not of an arbitrary one.

There was no conclusive evidence on file to support an allegation that the same advantages were not also evident for enzymes which were more than 80% homologous with the specific sequence of the patent. On the contrary, the patent in suit disclosed two phospholipases from *Fusarium* (*F. oxysporum* and *F. culmorum*) having these advantages, which were also present in two other lipases (*F. venenatum* and *F. sulphureum*) with the appropriate degree of homology. These advantages were thus shared by enzymes with this degree of homology.

Article 83 EPC

The patent in suit disclosed several phospholipases and described how the invention could be put into effect. The sequence of the phospholipase from *F. oxysporum* was disclosed in the patent and the skilled person was thereby enabled to produce variants by routine techniques in genetic engineering. There was no conclusive evidence on file showing that the invention could not be worked throughout the scope of the claims. On the contrary, the evidence on file showed that the teachings of the patent were fulfilled.

XV. The arguments in writing of the opponents 01 and 02 (respondents I and II) relevant to the present decision may be summarised as follows:

Admissibility of the new experimental evidence

The new experimental evidence was not available sooner, it could not be filed earlier since the experimental data were a response to document D62.

Main request
Article 54 EPC

Document D3 disclosed the use in baking of a lipase from *Fusarium oxysporum*. Since there was only one lipase gene in *F. oxysporum* and the encoded lipase inherently had phospholipase (side)activity, even though the claims referred to phospholipase, they related to the same polypeptide.

Article 56 EPC

As regards claim 1, neither Example 14 nor Figure 2 of the patent in suit provided information as to whether the results obtained were statistically significant. Moreover, the conditions for each of the three experiments were not comparable since the substrates (oils) were not the same and, therefore, the differences between the three experiments were not necessarily attributable to the enzymes used. Example 14 could not be used to show any advantages, the less so for enzymes defined only in terms of homology.

As regards claim 2, it did not involve an inventive step with respect to document D1 in combination with any document of the prior art disclosing the use of lipases or phospholipases in baking, such as document

D30. This prior art related to lipases in general and its teachings were automatically applicable to the lipase of document D1. This document disclosed a lipase from *Fusarium oxysporum* DSM 2672 as suitable for use in detergents and, since the prior art disclosed the use of the same lipases both in detergents as well as in baking, the person skilled in the art would have combined the teachings of document D1 with any document of this prior art with a reasonable expectation of success.

If document D30 was taken as closest prior art, the advantages of using a fungal lipase in baking were already disclosed therein. The technical problem was thus to provide an alternative fungal lipase. Document D19 disclosed a lipase from *F. culmorum* that was more than 80% homologous to the sequences disclosed in the patent in suit. The skilled person had a reasonable expectation of success when using the lipase from *F. culmorum* in baking, and thereby would have achieved, without any inventive effort, the claimed subject-matter and the associated advantages, merely as a bonus effect. The alleged importance of both lipase and phospholipase activities was not acknowledged in the patent as underlying those alleged advantages. Moreover, a mere structural limitation could not reflect the alleged advantageous functional requirements. The less so since the ratio of phospholipase and lipase activities had to be defined with a specific measurement method, which was however not indicated in the claims.

Example 20 of the patent showed that even the use of the disclosed enzyme did not provide the alleged

advantages across the breadth of the claim. The results shown in Table 20 indicated that, particularly at high concentrations of phospholipase, the specific volume index in panned bread or in rolls did not differ significantly from the control without phospholipase. If inventive step was based on a given technical effect, this effect had to be achieved over the whole area claimed. This was not the case since the claims were not limited to any dosage of enzyme. Furthermore, the claims failed to refer to the technical effect allegedly achieved when using the phospholipase in baking.

Article 83 EPC

The skilled person was not given the means to work the invention over the whole range as claimed. For a 80% homology range, variation was possible for 54 individual amino acids on 272 positions of the protein. This amounted to a huge number of possible phospholipases having a homology range between 80 and 100% homology. There was no indication of the measures to be taken or which part of the sequence could be manipulated without having any consequence for the activity of the enzyme.

XVI. The appellant (patentee) requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request filed during the oral proceedings on 12 February 2008.

XVII. No requests were made by respondents I and II (opponent 01 and 02) after they withdrew their appeals.

Reasons for the Decision

Admissibility of the new experimental evidence

1. The new experimental evidence (cf. document D76) was filed by respondent II on the final date given by the board for receipt of any written submissions of the parties in response to the board's communication pursuant to Article 11(1) (now Article 15(1)) of the Rules of Procedure of the Boards of Appeal (RPBA). The new evidence was said not to be available earlier and to be filed in response to document D62 (cf. Section XV *supra*).

2. According to the RPBA, the statement of grounds of appeal and the reply thereto must contain a party's complete case, specifying all the facts, arguments and evidence relied on. Any amendment to a party's case may only be admitted at the board's discretion and, as criteria for exercising this discretion, consideration may be given *inter alia* to the complexity of the new subject-matter submitted and the current state of the proceedings.

3. Document D62 was filed with appellant's grounds of appeal and compares the performance in baking of the lipases from *Fusarium culmorum* and *Humicola lanuginosa*, which are disclosed, respectively, in documents D19 and D30, filed by the respondents with their grounds of opposition. The relevance of these lipases, the former being more than 80% homologous to the sequences disclosed in the patent in suit, was thus evident at the beginning of the opposition proceedings. The

results shown in document D62 were not unexpected, as they only confirmed the appellant's assertions and the expectations of the patent in suit. Moreover, the respondents did not face an unforeseeable amendment of the claims, since the subject-matter of the request under consideration essentially corresponds to that of claims 10 and 11 as granted, which have been in all requests filed by the appellant.

4. The new evidence, which - as already stated - was not filed with the reply to the appellant's grounds of appeal but only shortly before oral proceedings, reports experimental tests with the lipases from *Fusarium oxysporum* and *Humicola lanuginosa* and a lipase of unidentified source (DSM lipase). Several possible deficiencies have been identified by the appellant in these experiments. To repeat them, in order to give the appellant a fair chance to provide its own experimental evidence in reply, would have required the cloning, purification and isolation of this new lipase. Without entering into the substantive merit of these experiments, the board considers that the reasons for the late filing are not convincing and that the advanced stage of the proceedings and the nature and complexity of the evidence prevented their admission into the proceedings. Thus, document D76 is disregarded.

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

5. The claimed subject-matter corresponds to that of claims 10 and 11 as granted, except for the degree of homology that has been further increased to "at least 80%" instead of "at least 70%". Formal support is found

in the application as published, in particular, claims 65 and 67 as filed and page 20, line 45 to page 22, line 5 disclose the claimed uses for the phospholipases. The main request thus fulfils the requirements of Articles 123(2),(3) and 84 EPC.

Article 54 EPC

6. Document D3 discloses the derivatisation of several enzymes, namely lipases, amylases, oxidoreductases, pectinases and/or hemicellulases, in a way that masks their negatively charged side groups. This modification may lead to unexpected high increase in enzyme activity and/or in substrate availability. Suitable sources for these enzymes are, in particular, microbial lipases selected from yeast, bacterial or fungal, wherein *Fusarium oxysporum* is merely one out of more than 25 fungi cited as possible sources of lipases (cf. page 5, lines 11 to 31). Document D3 further discloses possible uses for the modified enzymes, wherein baking is only one out of seven other possible uses, including the preparation of detergent and dishwashing compositions, pulp and paper applications, beer brewing, animal feed, etc. (cf. page 19, line 9 to page 31, line 7). The teachings of this document are mainly exemplified with a lipase from *Humicola lanuginosa*.

7. There is no reference in document D3 to any phospholipase and certainly not to a specific phospholipase from *F. oxysporum*. The respondents' arguments rely on the fact that in their view, when using the lipase from *F. oxysporum*, which inherently exhibits a phospholipase activity, document D3 implicitly contemplates the use of a phospholipase (cf.

Section XV *supra*). The board does not need to enter in detail into this argument since, in the specific context of baking, reference is only made, in very general terms, to all the enzymes cited in the document, alone or in combination, with or without the modification as described in document D3. In the board's opinion, the particular combination of the very specific lipase from *F. oxysporum* with the specific use in baking is not directly and unambiguously disclosed in document D3 and this combination can only be derived with hindsight.

Article 56 EPC
Claim 1 (use of disclosed lipases for vegetable oil degumming)

8. The relevant prior art on file refers to lipases from several *Fusarium*, in particular document D6 discloses a lipase from *F. oxysporum* and refers to the use of lipases in food technology, including the treatment of fish oil (cf. page 660, left-hand column, first and last paragraph). However, there is no reference to a phospholipase activity in this prior art and, therefore, the use of these lipases in a process for reducing the content of phospholipid in an edible oil with a particular phosphorus content is not derivable from any of this prior art in an obvious manner. Since it is not obviously derivable from this prior art, no unexpected or advantageous effect is needed for acknowledging inventive step. Nevertheless, an advantageous effect is shown at least in Examples 16 and 17 of the patent in suit.

Claim 2 (use of disclosed lipases for making a baked product)

9. Although document D1 discloses a lipase preparation derived from *F. oxysporum* DSM 2672, the same source as the patent in suit, the document is only concerned with detergents, detergent additives and washing methods. There is no hint of any other application in document D1 and, in the absence of any indication, there is no motivation to look for these alternatives in the prior art nor to choose baking among all those other possible applications. The selection of document D1 as closest prior art for the claimed use can only be made with the knowldege of the patent, i.e. with hindsight. The more so in the light of the unexpected advantages obtained when using this specific lipase in baking (cf. *infra*).

10. The closest prior art is considered to be document D30 which discloses the use of lipases in baking. Document D30 refers to the advantages obtained by adding lipases in the industrial production of dough and baked products, such as an increased volume and improved softness of the baked product and anti-staling effect, etc. (cf. *inter alia* page 4, lines 20 to 31). Although lipases of any origin are mentioned, microbial lipases are preferred and fungal lipases of several strains are explicitly cited, such as lipases from *Humicola lanuginosa*, *Rhizomucor miehi* and *Pseudomonas cepacia*, which exemplify the teachings of the document (cf. page 6, line 20 to page 7, line 3 and page 14, line 31 to page 15, line 37). There is no mention, however, to use any phospholipase in baking nor any reference to a lipase, let alone to a phospholipase, from *Fusarium*.

11. Starting from this closest prior art, the technical problem to be solved may be seen in the provision of an alternative lipase. The lipase from *F. oxysporum* DSM 2672, which inherently exhibits a phospholipase activity, as well as phospholipases that are at least 80% homologous with the sequence of the *F. oxysporum* DSM 2672 phospholipase, are the proposed solution to this technical problem.

12. It has been argued by the respondents that a solution is not provided over the whole breadth of the claim, the argument being made in relation not only to the homologous variants but to the specific phospholipase from *F. oxysporum* DSM 2672 (cf. section XV *supra*).

13. The arguments put forward are mainly based on the absence from the claims of features such as the concentration of phospholipase, the conditions of phospholipase assay, activity measurement and/or baking results, etc. Evidence is, however, on file showing that the dosage effect of lipase concentration in baking was known in the art and that standard optimization of enzyme concentration - for optimal activity and baking results - was routine in the field (cf. *inter alia* the examples of document D30). Although the claims do not refer to any effect, the results in baking are disclosed in the patent (Examples 20 and 21) and achieved in a straightforward manner when using the phospholipase as defined in the claim. The same results are to be expected by the skilled person with knowledge of the patent in suit, the concentration of phospholipase being selected in accordance with these expectations and the type of baked product prepared. Post-published documents and experimental evidence on

file show that these effects are provided by the phospholipase from *F. oxysporum*. In view of all this information and in line with the case law, which establishes that the claims are addressed to a skilled person with a mind willing to understand (cf. "Case Law of the Boards of Appeal of the EPO", 5th edition 2006, II.B.5.1, page 205), the board concludes that the technical problem is solved by the specific phospholipase from *F. oxysporum*.

14. These post-published documents and additional experimental evidence not only demonstrate that the phospholipase from *F. oxysporum* solves the technical problem but that the results achieved when using this enzyme in baking are unexpectedly advantageous. These advantages are an indication that the selection of this enzyme among a large number of possible microbial and, more particularly, fungal lipases (cf. *inter alia* paragraph bridging pages 6 and 7 of document D30 and page 5, first full paragraph of document D3), is not an arbitrary selection but a purposive one. The more so since not all fungal lipases may inherently exhibit a phospholipase activity. Hence, the combination of documents D30 with D1, or alternatively, with documents D6 or D19 (both disclosing *Fusarium* lipases with more than 80% homology with the sequences of the patent in suit), is not arbitrary. Thus, inventive step is acknowledged for claim 2 in relation to the embodiments (a),(b) and (c), which are directed to the use of the phospholipase from *F. oxysporum* in a process for making a baked product (cf. Section XII *supra*).

15. It remains to be assessed whether the appellant's intention to obtain a fair protection by extending the

scope of the invention to homologous variants of the specific phospholipase from *F. oxysporum*, i.e. claim 2 (d), is also inventive and thereby justified. The use of an homology feature for defining a group of generic variants of a specific sequence is normal in the field of genetic engineering as shown by prior art on file. This feature, however, is a structural feature, which in itself does not impose any functional limitation to the so defined variants. Nevertheless, the homologous variants as defined in claim 2(d) are still required to exhibit a phospholipase activity. Furthermore, there is evidence on file showing that several phospholipases with the defined degree of homology still provide, when used in baking, the advantages disclosed in the patent. Among those cited, there is the lipase from *F. culmorum* of document D19, which exhibits phospholipase activity as well. In the light of this evidence, the presence of these advantages in baking is also acknowledged for those homologous variants and thereby inventive step is acknowledged as well.

Article 83 EPC

16. The objections raised by the respondents mainly concern the homologous variants defined in claim 2(d) and, more particularly, their production by genetic engineering methods (cf. Section XV *supra*). In the board's opinion, these objections are however not relevant.

17. Firstly, genetic engineering methods are not the sole methods available to the skilled person for obtaining the homologous variants. The patent in suit discloses the advantages in baking for the phospholipases from *F. oxysporum* and *F. culmorum*. Although only the amino

acid sequence of the former phospholipase is disclosed, no particular effort is required to determine the sequence of the latter. Phospholipases from closely related *Fusarium* strains were also available to the skilled person (cf. document D6) and evidence is on file showing that these enzymes, such as those from *F. venenatum* and *F. sulphureum*, have the required degree of homology and achieve the expected results when used in baking.

18. Secondly, although the patent in suit does not provide any detailed guidance as to how to obtain homologous variants by genetic engineering, the disclosed phospholipases are not to be considered in isolation but in the context of the general information in the art related to lipases and phospholipases. In fact, the patent in suit already acknowledges some of this prior art in the "Background of the invention" (cf. pages 3 to 4) and it further refers to a sequence homology comparison, in particular with the lipase from *F. heterosporum* of document D7 (cf. pages 3 to 4 and page 6, paragraphs [0050] to [0054] of the patent in suit). Figure 4 of document D7 identifies putative residues having structural (Cys residues forming disulfide bonds) as well as functional (catalytic triad and oxyanion hole, helical lid) relevance. This information might allow the skilled person (with a mind willing to understand, cf. point 13 *supra*) to modify (e.g. by performing conservative substitutions of residues in non-essential positions) available phospholipase sequences within the range of homology defined in claim 2(d) (at least 80%).

19. It follows from the above, that the requirements of Article 83 EPC are fulfilled.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of the main request filed during the oral proceedings and a description and figures to be adapted thereto.

The Registrar: The Chairman:

A. Wolinski L. Galligani