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Datasheet for the decision of 25 October 2007

Case Number:	T 0309/06 - 3.3.08
Application Number:	93304607.0
Publication Number:	0575133
IPC:	C12N 9/16

Language of the proceedings: EN

Title of invention:

Novel phospholipase A1, process for its preparation and the use thereof

Patentee:

Sankyo Lifetech Company Limited

Opponent:

DANISCO A/S

Headword:

Phospholipase A1/SANKYO

Relevant legal provisions:

EPC Art. 54, 56, 83

Keyword:

"Main request - novelty - yes" "Inventive step - yes" "Sufficiency of disclosure - yes"

Decisions cited: T 0019/90

Catchword:

-



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Boards of Appeal

Chambres de recours

Case Number: T 0309/06 - 3.3.08

DECISION of the Technical Board of Appeal 3.3.08 of 25 October 2007

Appellant: (Patent Proprietor)	Sankyo Lifetech Company Limited 4-23-14, Hongo Bunkyo-ku Tokyo 113-0033 (JP)	
Representative:	Lord, H.D. Marks & Clerk 90 Long Acre London WC2E 9RA (GB)	
Respondent: (Opponent)	DANISCO A/S Langebrogade 1 DK-1411 Copenhagen K (DK)	
Representative:	Williams, Aylsa D Young & Co 120 Holborn London EC1N 2DY (GB)	
Decision under appeal:	Decision of the Opposition Division of the European Patent Office posted 28 December 2005 revoking European patent No. 0575133 pursuant to Article 102(1) EPC.	

Composition of the Board:

Chairman:	L.	Galligani
Members:	F.	Davison-Brunel
	с.	Rennie-Smith

Summary of Facts and Submissions

I. European patent EP-A-0 575 133 with the title "Novel phospholipase A1, process for its preparation and the use thereof" was granted on the basis of the European patent application No. 93 304 607.0 with 31 claims. Claims 1 and 6 read as follows:

> "1. Phospholipase A1 obtainable from fungus selected from <u>Aspergillus</u> <u>niger</u> and <u>Aspergillus</u> <u>oryzae</u> **characterised in that** said Phospholipase A1:

(a) hydrolyses phospholipid between about pH 2.5and about pH 6.0;

(b) has a molecular weight of between about 30,000 and about 40,000 daltons, as determined by sodium dodecyl sulphate polyacrylamide gel electrophoresis;

(c) has a stability to temperature with an upper limit of between about 45 and about 90°C;

(d) has a pI under isoelectric pointelectrophoresis at about pH 2.8 to about pH 4.5;and

(e) has an optimum temperature for activity of from about 30 to about 65°C.

6. Phospholipase Al according to Claim 1 which has an optimum pH for activity of about from pH 3.2 to about pH 5.5."

Claims 2 to 5 and 7 related to further features of the phospholipase A1 of claim 1. Claims 8 to 13 were directed to phospholipase A1 isolated from specific deposited organisms. Claims 14 to 25 related to various uses of the phospholipase A1 of claims 1 to 13. Claim 26 to 31 were directed to various methods for the preparation of the phospholipase of claims 1 to 13.

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- II. An opposition was filed under Article 100(a) to (c) EPC for the reasons of lack of novelty and inventive step, insufficiency of disclosure, added subject-matter. The opposition division revoked the patent on the basis that there was no sufficient disclosure in relation to the subject-matter of claim 1 of the request then on file (granted claim 1 having incorporated granted claim 6; request filed on 2 December 2003).
- III. The appellant (patentee) filed an appeal, paid the appeal fee and submitted a statement of grounds of appeal which was accompanied by the request refused by the opposition division as main request and by an auxiliary request.
- IV. The respondent (opponent) answered the appellant's statement of grounds of appeal.
- V. The board sent a communication pursuant to Article 11(1) of the Rules of Procedure of the Boards of Appeal, indicating its preliminary, non binding-opinion.
- VI. Both parties filed submissions in answer to this communication. The appellant's submissions were accompanied by three auxiliary requests to replace the auxiliary request filed with the grounds of appeal. The

main request remained the request refused by the opposition division. Claims 1, 13 and 25 of this request read as follows:

"1. Phospholipase A1 obtainable from fungus selected from <u>Aspergillus</u> <u>niger</u> and <u>Aspergillus</u> <u>oryzae</u> **characterised in that** said Phospholipase A1:

(a) hydrolyses phospholipid between about pH 2.5and about pH 6.0;

(b) has a molecular weight of between about 30,000 and about 40,000 daltons, as determined by sodium dodecyl sulphate polyacrylamide gel electrophoresis;

(c) has a stability to temperature with an upper limit of between about 45 and about 90°C;

(d) has a pI under isoelectric pointelectrophoresis at about pH 2.8 to about pH 4.5;

(e) has an optimum temperature for activity offrom about 30 to about 65°C; and

(f) has an optimum pH for activity of about from pH 3.2 to about pH 5.5.

13. The use of Phospholipase A1 as defined in any one of claims 1 to 12 in the preparation of a lysophospholipid from a phospholipid substrate.

25. A method for the preparation of a Phospholipase Al according to any one of Claims 1 to 12 which comprises

(a) culturing a Phospholipase A1 producing strain of <u>Aspergillus</u> <u>niger</u> or <u>Aspergillus</u> <u>oryzae</u> at temperatures of between 10 and 40°C and for a period of between 3 and 20 days;

(b) at the end of the culture period, diluting the culture with water or an appropriate buffer solution;

(c) filtering the resulting solution under pressure to remove any insoluble matter; and if desired:

(d) purifying the enzyme."

Claims 2 to 5, 6 to 12, 14 to 24, 26 to 30 corresponded to granted claims 2 to 5, 7 to 13, 15 to 25, 27 to 31 being re-numbered to take into account that the subject-matter of granted claim 6 was incorporated in claim 1.

- VII. The documents which are mentioned in this decision are the following:
 - (1) : Bulkacz, J. et al., Biochimica et BiophysicaActa, Vol. 664, pages 148 to 155, 1981;
 - (2) : Ghanghro, A.B. and Dahot, M.U., Sci.Int.(Lahore), Vol.4, No.2, pages 169 to 172, 1992;
 - (3) : Blain, J.A. et al., FEMS Microbiology Letters, Vol. 3, pages 85 to 87, 1978;

- (8) : EP-A- 0 513 709 published on 19 November 1992;
- (10) : English translation of certified copy of the Japanese patent application No. JP 15626492 dated 16 June 1992 (first priority document of the patent in suit).
- (12) : US- 3 260 606.
- VIII. The appellant's arguments in writing and during oral proceedings insofar as relevant to the present decision may be summarised as follows:

Main request, claims 1, 13 and 25 Article 54 EPC; novelty

- Document (12) was not novelty destroying for the subject-matter of claim 25 - and, a fortiori, for that of claims 1 and 13 - because it did not mention that the starting strains for carrying out the method therein described were phospholipase A1 producers. In fact, there was no mention at all of this enzyme in the document which only referred to phospholipases in general (column 2, lines 34 to 37).

- In document (3), Table 1 taught that <u>Asp. niger</u> or <u>oryzae</u> contained phospholipase B as the predominant phospholipase. It also suggested that phospholipases A1 were of common occurrence amongst filamentous fungi but provided no evidence that the claimed specific phospholipase A1 would be present in the strains which had been investigated. It was not relevant to novelty. - The phospholipase A described in document (2) differed from the presently claimed phospholipase A1, in particular, in its optimum pH (6.0) which fell outside of the claimed range. And besides, it was a mixture of phospholipases which was disclosed whereas claim 1 related to a purified enzyme, as evidenced by the fact that the claimed properties could not have been ascertained without prior purification.

Article 56 EPC; inventive step

- The catalysis of phospholipids into lysophospholipids was a very important reaction in industry. Yet, at the filing date of the application, only one enzyme, pancreatin, had been used to carry it out. This enzyme had unwanted properties such as, for example, its extreme resistance to heat. A number of solutions had been proposed to eliminate the enzyme from the reaction when necessary, which all had drawbacks. The phospholipase A1 of the present invention was a most advantageous alternative to pancreatin because on the one hand, it was more efficient (cf. patent in suit, Table 1) and, on the other hand, it could be denatured at temperatures so "low" as not to affect the end product of the reaction. The advantageous properties of the enzyme were fully unexpected and justified acknowledging inventive step.

- If one was to choose a document as closest prior art, it could be document (3) which taught that phospholipase A1 may be present in fungi. Yet, this research article provided no incentive to isolate the enzyme, in particular, it did not in any way suggest that it may have advantageous properties as an alternative to pancreatin.

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- As for document (12), it taught a process for producing a <u>mixture</u> of enzymes to be used in hydrolysing eggs, and this teaching did not amount to teaching a process for isolating a phospholipase A1. Furthermore, although document (12) taught that the enzyme mixture could be inactivated by heat, this did not mean that phospholipase A1 was the relevant enzyme in the mixture which was inactivated by heat, if only because, as already mentioned, there was no disclosure of phospholipase A1 being present in the preparation.

- Document (8) taught a process for removing phosphates from edible vegetable or animal oil and cited phospholipases A1, A2 and B as potentially useful enzymes. The sole teaching relative to phospholipase A1 was that it was obtainable from <u>Rhizopus</u>. This could not affect inventive step on its own. Furthermore, the skilled person would have had no reason to combine document (8) with document (12) published some 27 years before, disclosing that a mixture of enzymes would be useful for hydrolysing eggs. In any case, even if this combination was ever made, it would not affect inventive step.

Article 83 EPC; sufficiency of disclosure

- The appellant had disclosed a novel group of phospholipases A1 characterised by useful properties and had provided five deposited strains which all produced such enzymes. Under these circumstances, it would not be fair to restrict the scope of the claims to the specific phospholipases A1 purified from the deposited strains. Indeed, once the existence of the claimed phospholipase A1 was known from the patent in suit, it was only too easy to look for some equivalent enzymes in other species.

- The isolation of the enzyme from other species, whichever they may be, could be achieved using standard purification procedures and the fact that the enzyme must have the property of hydrolysing phospholipids at a pH of between 2.5 and 6.0 (feature (a)) was a first limiting factor which facilitated the search. Thus, even if, as it happened, some strains did not produce the claimed phospholipase A1, it was nonetheless no undue burden to identify those which potentially produced it.

- The argument that not all enzymes with characteristics falling within the claimed ranges would also be advantageous - and therefore inventive - was a mere assumption which had not been backed by any experimental data and, therefore, was of no value.

- Finally, the arguments as regard claim 1 failing to give information on the conditions in which to test the enzyme properties or giving inconsistent information as regards the properties of the enzymes which had been isolated were, de facto, arguments under Article 84 EPC which could not be considered because non-compliance with the requirements of Article 84 EPC, if any, was not a ground of opposition. In any case, and in accordance with the case law, claims should be read in light of the description which gave detailed information on how to measure the claimed parameters,

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which were classical ones. And besides, there was nothing inconsistent in the way the specific enzymes isolated had been described: it was perfectly possible for an enzyme to have its optimum activity at the same temperature that may affect its stability.

The requirements of Article 83 EPC were, therefore, fulfilled.

IX. The respondent's arguments in writing and during oral proceedings insofar as relevant to the present decision may be summarised as follows:

> Main request, claims 1, 13 and 25 Article 54 EPC; novelty

- Document (12) described a method for the preparation of an enzyme mixture from <u>Asp. oryzae</u> which included the same steps as the method of claim 25. The inherent result of carrying out the teaching of document (12) would be a preparation containing phospholipase A1 as now claimed in claim 1. Thus, the subject-matter of claim 25 lacked novelty as well as that of claim 1 which did not exclude phospholipase A1 being part of an enzyme mixture. Claim 13 to the use of phospholipase A1 for preparing a lysophospholipid from a phospholipid also lacked novelty over the teachings of document (12) of using the enzyme mixture to treat egg yolk.

- Document (3) taught a strain of <u>Asp</u>. <u>niger</u> in which phospholipase A1 could be detected. It was novelty destroying for the subject-matter of claim 1 which related to the enzyme without mentioning that it had to be purified. - Document (2) disclosed an enzyme having the same properties (a),(c),(e) and (f) as the claimed enzyme. It did not give any information as to molecular weight (feature (b)) or pI (feature (d)). Yet, these two features would have no influence on the relevant properties of the enzyme. Therefore document (2) was novelty destroying for the subject-matter of claim 1.

Article 56 EPC; inventive step

- Document (3) could be taken as closest prior art as it taught the presence of phospholipase A1 enzymes in <u>Asp. niger or Asp. oryzae</u>. The only problem to be solved over the teachings of document (3) was the isolation of the enzyme. This could be achieved by standard techniques. Indeed it was common in the art to purify a phospholipase from fungi as shown in document (8)- which although published between the first priority date and the filing date of the patent in suit could be taken into account since the first priority document was not valid.

- In the same manner, document (12) could be regarded as the closest prior art as it provided evidence for the use of phospholipases in industry and taught a process for obtaining them. The objective problem to be solved could be defined as improving that process. This had been achieved by using a conventional non-inventive method, namely diluting the culture prior to filtration. There again the teaching of document (8) provided additional evidence that at the priority date, the skilled person would regard the isolation of phospholipases as being an obvious task. - Inventive step had been argued by the appellant on the basis of the property of the claimed enzyme to be sensitive to heat, ie. on the basis of it being advantageous over pancreatin then in use for hydrolysing phospholipids. However, document (12) itself provided evidence that phospholipases could be eliminated by heat (column 4, lines 10 and 11). Therefore, this feature of the claimed enzyme would be fully expected and could not impart inventive step.

Article 83 EPC; sufficiency of disclosure

The patent in suit failed to fulfil the requirements of sufficiency of disclosure for the following reasons:

- Claim 1 covered thousands of phospholipases A1. In contrast, the appellant had only provided examples of at most three enzymes coming from two different <u>Aspergillus</u> species. The scope of protection was, thus, not commensurate with the technical achievement.

- The skilled person was left without guidance as to how to choose further relevant starting strains for the isolation of phospholipase Al enzymes likely to possess all of the claimed characteristics. Furthermore, the appellant himself had admitted that not all strains of <u>Asp</u>. <u>niger</u> or <u>oryzae</u> produced the enzyme. Undue burden was, thus, associated with identifying the relevant starting strains.

- The parameters used to characterise the enzyme were so broadly defined that it was not credible that all enzymes having properties falling within the claimed ranges would necessarily also exhibit the properties which were argued to impart inventive step.

- The description failed to give adequate information on the conditions in which to measure the parameters chosen to characterise the enzyme and it disclosed on page 5, eg. that the optimum pH activity or the stability of the enzyme would be dependent on the experimental conditions. The skilled person, thus, could not ascertain whether or not an enzyme he/she would have isolated fell within the scope of the claim. In addition, the description was inconsistent as regards the properties of the specific enzymes which were isolated. For example, it was taught in paragraph [0061] that the phospholipase may be de-activated by eg. heating the reaction mixture to between 45°C and 90°C whereas these values overlapped with those claimed as being optimal temperatures for activity.

X. The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request filed with its letter of 2 December 2003 or one of the auxiliary requests 1 to 3 filed on 25 September 2007.

The respondent requested that the appeal be dismissed.

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Reasons for the decision

Main request Articles 123(2)(3) and 84 EPC; formal requirements

1. The main request now on file corresponds to the granted claim request with the amendment that the subjectmatter of granted claim 6 was introduced into claim 1. The respondent did not raise any objection to this request under Article 123(2) EPC nor did it argue that the amendment resulted in a widening of the scope of the claim and/or in a lack of clarity. The board is of the opinion that the requirements of Articles 123(2)(3) EPC and 84 EPC are fulfilled.

Article 54 EPC, novelty

2. Three documents were argued to be novelty destroying. Document (12) teaches a method for hydrolysing eggs which makes use of a mixture of enzymes comprising "protease, lipase, phospholipase, nucleic acid decomposing enzyme, and other known and unknown enzymes", originating from fungi or molds such as Aspergillus oryzae or Rhizopus cinencis. The method steps involved are said to be well known in the art and indeed they comprise cultivation (not restricted to any particular method), filtration of a culture extract and purification (in any suitable manner) (see column 2). It is not mentioned anywhere in the document that the starting strains for this method produce phospholipase A1. Insofar as Aspergillus is concerned, it is accepted by both parties that not all strains produce the now claimed phospholipase A1. In the board's judgment, the disclosure in document (12) does not amount to a clear

and unambiguous disclosure of the method of claim 25. For the same reason, document (12) is not regarded as teaching a phospholipase A1 (claim 1) - even as one enzyme in a mixture of enzymes. A fortiori, it does not teach the use of a phospholipase A1 such as claimed (claim 13).

- 3. Document (3) (Table 1) teaches that mycelia of <u>Asp</u>. <u>niger</u>, <u>niger</u>(B) or <u>oryzae</u> essentially produce phospholipase B and suggests that the mycelia may also exhibit phospholipase A1 activities (page 87, passage bridging the columns). It is also mentioned on page 87 that "the results of this survey would suggest that phospholipase A1 and lyphospholipase are of common occurrence amongst filamentous fungi...". However, there is no mention of a phospholipase A1 with the now claimed properties. Like document (12), document (3) does not amount to a clear and unambiguous disclosure of the enzyme of claim 1.
- 4. Document (2) (passage bridging pages 170 and 171) teaches that the <u>Melia azadirachta</u> phospholipase A has activity at pH 6.0, which, in accordance with Figure 4, is the optimum pH of the enzyme. This optimum pH is outside the range of optimum pH characterising the phospholipase of claim 1. Furthermore, neither the pI nor the molecular weight of the enzyme is mentioned in document (2). It is also observed that the authors suggest that the phospholipase A activity is most likely attributable to phospholipase A2 (page 171, first full paragraph). The document is not relevant to novelty.

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5. The claimed subject-matter fulfils the requirements of Article 54 EPC.

Article 56 EPC; inventive step

- 6. At the filing date of the patent in suit, the skilled person experienced difficulties when attempting to convert phosphoslipids into lysophospholipids using pancreatin (patent in suit, pages 2 and 3). For this reason, he/she may have turned to prior art relating to further enzymes carrying out that reaction, in particular phospholipases, as guidance towards substituting another enzyme for pancreatin. As shown in the prior art on file, this approach leads to the identification of prior art documents (3) or (12), respectively published some 15 and 27 years before the priority date.
- 7. Document (3) presents a study of which lypolytic enzymes are present in filamentous fungi, mentioning the occurrence of phospholipase A1. Document (12) is a patent document relating to the use of a mixture of all possible enzymes present in a starting fungal strain amongst them phospholipases - to hydrolyse eggs, which does not provide any evidence as to which enzymes in the mixture are responsible for the observed effect. For the board, this scant and diffuse teaching cannot not be used as the closest prior art in relation to solving problems due to pancreatin.
- 8. Document (3) is the closest prior art for the sole reason that, as above mentioned, it discloses the occurrence of phospholipase A1 in fungi. Its "review character" does not in any way suggest any need for the

purification of the enzyme itself, let alone any potential use. The weakness of this document as closest prior art, in addition to its age, are taken as secondary indicia that the claimed subject-matter could be inventive.

- 9. Starting from document (3), the problem to be solved may be defined as providing an enzyme with phospholipase A1 activity.
- 10. The solution provided is the claimed phospholipase Al with a range of specific properties which was isolated from <u>Aspergillus niger</u> or <u>oryzae</u>. This enzyme turns out to be more efficient at catalysing the hydrolysis of phospholipids into lysophospholipids than the enzyme pancreatin, until then considered as the most suitable for this purpose (patent in suit, Table 1). Furthermore, it can be inactivated by heating it to such an extent which does not damage the end products of the reaction whereas pancreatin was strongly heat resistant. It would have been impossible to envisage the existence of such a phospholipase Al on the basis of the teachings of document (3) which, thus, does not on its own affect inventive step.
- 11. In order to deny inventive step, an attempt was also made at combining the teachings of document (3) with those of document (8). This last document has the publication date of 19 November 1992, that is between the first priority date (16 June 1992) and the filing date (14 June 1993) of the patent in suit. Yet, it may be used as prior art for the assessment of inventive step as priority may not be validly claimed from the first priority document - represented by document (10)

on file, a certified translation from the Japanese language - which admittedly does not disclose the claimed phospholipase A1.

- 12. Document (8) teaches a method for removing phosphorus from edible vegetable or animal oil. Phospholipases A1, A2 or B are mentioned as potentially useful. The only further relevant information regarding phospholipase A1 is that it may be obtained from <u>Rhizopus arrhizus</u>. All examples are carried out with phospholipase A2. It is not obvious to the board that the skilled person would ever think of combining the teachings of documents (3) and (8), nor which purpose would be achieved by combining them. It may be that document (8) was mentioned because it provides an example of a mould producing phospholipase A1. This, however, has no bearing on the claimed enzyme.
- 13. The board, thus, concludes that none of the documents on file alone or in combination are damaging to the inventive step of the claimed subject-matter.

Article 83 EPC; sufficiency of disclosure

14. All through the oral proceedings, the respondent repeatedly emphasized that claim 1 had a very wide scope which was not commensurate with the technical contribution provided. It is undoubtedly true that the breadth of the claim is very large. However, such case law as T 19/90 (OJ EPO 1990, 476) must be remembered at this point. In this earlier case, transgenic non-human mammals were claimed on the basis of having produced transgenic mice. The then competent board decided (point 3.3 of the decision) that the mere fact that a claim is broad was not in itself a ground for considering the application as not fulfilling the requirements of sufficient disclosure under Article 83 EPC. What is of importance is whether or not the skilled person could reproduce the invention without undue burden.

- 15. It is readily apparent from the documents on file that numerous species were known to produce enzymes with phospholipase activity, for example document (3) (Table 1) cites six organisms as having phospholipase Al activity as the predominant phospholipase. Further teaching of sources for phospholipase A1 is found in document (8) or (1). It is, thus, not convincing that the skilled person wanting to reproduce the claimed invention would not know where to start as presence of activity can easily be tested. The board admits that there exists no prior art on file teaching the isolation of phospholipase A1 from other mammals than swine. Neither is there a disclosure, for example, that insects were ever investigated for the presence of phospholipase, whereas at least in theory, phospholipases from such origins are comprised within the claim, just like transgenic elephants were comprised within the generic claim considered in case T 19/90 (supra). As in that earlier case, however, the board decides that such kinds of potentially unachievable embodiments do not jeopardize sufficiency of disclosure inasmuch as the skilled person was aware of other sources for the enzyme.
- 16. Of course, it is not enough to obtain a phospholipase which, in accordance with feature (a) of claim 1, hydrolyses phoppholipids at a pH of about 2.5 to about

6.0. It must also be that the phospholipase has the other claimed properties. In this framework, it was argued that such properties were dependent on the experimental conditions used to measure them, which conditions were not mentioned in the claim. This argument is prima facie one of lack of clarity of the claim wording and Article 84 EPC is not a ground of opposition. Yet, it nonetheless reflects the situation often encountered in the case law where there exists a definite relationship between Articles 83 and 84 EPC (cf. Case Law of the Boards of Appeal of the EPO, Edition 2006, Chapter II.A.6), the relevant question being: is it possible to reproduce a claimed product without undue burden on the basis of its properties when one is not certain of how they were originally established ?

17. In such circumstances, it is generally admitted that it is sufficient to define the claimed product by parameters if these parameters can be clearly and reliably determined by objective procedures known in the art. Here the parameters used to characterise the claimed enzyme are classical ones: pH, pI, temperature, molecular weight. Furthermore, the description teaches in detail the experimental conditions which were used to establish these parameters for the isolated enzymes: see paragraphs [0031] to [0033] for determining optimal pH and temperature as well as stability ranges; in paragraphs [0028] and [0029], isoelectric point and molecular weight are said to be measured by the conventional techniques of isoelectric point and SDS gel electrophoresis. In the board's judgement, this information is enough for the skilled person to be able to test in a meaningful manner the properties of phospholipase A1.

- 18. In this context, a further point which must be given due consideration is the fact that the appellant himself agreed that not all strains of <u>Aspergillus</u> <u>oryzae</u> would produce the claimed phospholipase A1. Asis common ground, the purification of the enzyme is a matter of applying standard procedure. Furthermore, as just shown, testing the enzyme's properties is a matter of following well-described instructions. Thus, while it is not denied that the overall isolation and characterisation process may require much work involving "trial and error", it is concluded that while occasional failures to find the enzyme can be expected, that does not amount to lack of sufficient disclosure.
- 19. Doubts were also raised that the properties which were acknowledged to impart inventive step (enhanced activity, suitable temperature sensitivity) could be attributed to all enzymes falling within the scope of the claim, each parameter used to characterise the enzyme being defined by an extremely broad range. This may well be true but no evidence was provided that an enzyme falling within the scope of the claim would not at the same time exhibit the above mentioned properties. And, thus, the argument remains an assumption which is not sufficient to challenge the reproducibility of "the inventive character" of the claimed enzyme.

20. As regards the isolated specific enzymes, it was further objected that their characterisation was inconsistent insofar as the ranges described for optimal activity overlapped with those where thermal instability was said to occur. To this, the appellant answered that such a phenomenon was a common occurrence with hydrolytic enzymes. In the absence of any evidence to the contrary from the respondent, who bears the burden of proving its case, the board accepts this counter-argument.

- 21. In summary, the patent in suit provides a novel enzyme with advantageous properties as well as describing ways of obtaining it. Isolating such an enzyme may require much work but no undue burden insofar as no information is missing which would be essential for its isolation. In the board's judgement, it is a fair reward for such a contribution in the art that the appellant be allowed to claim "more" than the specific enzymes which have been isolated.
- 22. For these reasons, patentability is acknowledged.

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 on 2 December 2003 and the description and drawings as granted.

The Registrar

The Chairman

A. Wolinski

L. Galligani