

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**
(PCT Rule 43*bis*.1)

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2017/080811

International filing date (day/month/year)
29.11.2017

Priority date (day/month/year)
30.11.2016

International Patent Classification (IPC) or both national classification and IPC
INV. A21D2/26

Applicant
NOVOZYMES A/S

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

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Date of completion of this opinion

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - the international application in the language in which it was filed.
 - a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. forming part of the international application as filed:
 - in the form of an Annex C/ST.25 text file.
 - on paper or in the form of an image file.
 - b. furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. furnished subsequent to the international filing date for the purposes of international search only:
 - in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
 - on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
4. In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-15</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-15</u>
Industrial applicability (IA)	Yes: Claims	<u>1-15</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure.

- D1 US 2006/281080 A1 (ALBANG RICHARD [DE] ET AL) 14 December 2006 (2006-12-14)
- D2 US 2010/086640 A1 (BRUNSTEDT JANNE [DK] ET AL) 8 April 2010 (2010-04-08)
- D3 US 2015/017281 A1 (BORCH KIM [DK] ET AL) 15 January 2015 (2015-01-15)
- D4 US 2013/323359 A1 (BUDOLFSEN GITTE [DK] ET AL) 5 December 2013 (2013-12-05)
- D5 WO 2016/005315 A1 (NOVOZYMES AS [DK]) 14 January 2016 (2016-01-14)

1 Remarks to the interpretation and clarity of the claims

- 1.1 Claims 2 and 9 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined, since these claims lack technical features. The claims attempt to define the subject-matter solely in terms of the results to be achieved, which merely amounts to a statement of the underlying problem, without providing any technical features (e.g. method conditions and/or identity of the enzyme(s)) necessary for achieving these results.

2 Patentability

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-15 does not involve an inventive step in the sense of Article 33(3) PCT.

2.2 The present invention relates to the making of baked products, more particularly making of dough using a lipolytic enzyme for e.g. volume increase.

D1 represents the closest state of the art because D1 also relates to the making of baked products from dough and uses a lipolytic enzyme for volume increase.

D1 discloses a method for preparing a dough or a baked product prepared from the dough which method comprises incorporating into the dough a lipolytic enzyme (D1: [0019]-[0020] and example 4).

The lipolytic enzyme of D1 has an amino acid sequence which has 36.73 % identity (54.59 % similarity) over 196 positions in a common overlap (range (q:s): 60-248:24-219) with subject USPOP:AFO03853 (length: 262) from D1.

D1 further discloses a baking composition comprising said a lipolytic enzyme and one or more baking ingredients (see e.g. D1: [0207] or [0214]); as well as a baked product obtained by baking the dough according to claim 1 (passages see above, method).

According to the application the problem is to provide improved solutions to replace e.g., diacetyl tartaric acid esters of monoglycerides (DATEM) in the baking area.

As a solution to this problem the application proposes a method and products according to claims 1, 10 and 15 which are characterised in that the lipolytic enzyme has an amino acid sequence which has at least 50% sequence identity to amino acids 20 to 254 of SEQ ID NO: 1.

None of the available documents discloses a method involving such an enzyme, the method is thus novel (Article 33(2) PCT).

The above defined problem has however already been solved in D1 (D1: [0009]).

The problem underlying the present application in the light of D1 can thus be seen as being the provision of an alternative lipolytic enzyme for the known method and products.

The solution proposed in the independent claims of the present application cannot be considered as involving an inventive step for the following reasons: Since it is generally known to use lipolytic enzymes for the solution of the above defined problem (See D1, but also any one of D2-D5, c.f. below), arbitrarily choosing another lipolytic enzyme in order to provide an alternative is seen to be well within the routine practice of the skilled person.

Therefore, the subject matter of independent claims 1, 10 and 15 is seen to be not inventive in view of D1 (Article 33(3) PCT).

2.3 A comparable objection could be argued starting from any one of D2-D5, which all disclose the use of lipolytic enzymes in dough to e.g. increase the volume of the resulting products (D2: [0004], [0007], [0008], [0160], [0161], Example 11; D3: [0003]-[0009], [0056], [0086]-[0095], [0120], examples; D4: [0005]-[0007], [0061], example 3; D5: p.1, l.9-17, p.1, l.29-p.3, l.10, example 1).

2.4 Dependent claims 2-9 and 11-14 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step within the meaning of Article 33(3) PCT, the reasons being as follows:

Claims 2 and 9 do not contain any technical features and thus cannot support an inventive step (compare above, point 1).

The features of all other dependent claims have already been employed for the same purpose in comparable methods and products (see as mere example D3: [0093] for claim 3, [0095] for claim 4, [0112] for claim 5, [0120] for claims 6 and 7, [0103] for claim 8, [0088] for claim 11, [0092] for claim 12, [0087] for claims 13 and 14). Comparable disclosures can be found in all of D1, D2, D4 and D5 (passages see Search report).

The features selected are further seen to be within the routine praxis of a person skilled in the art.

It would therefore be obvious to the person skilled in the art, to apply these features with corresponding effect.

2.5 Having regard to the claimed methods and products and the prior art known (D1-D5), it is considered that the person skilled in the art would regard the methods and products of the present invention as an obvious alternative to those known, therefore the methods and products are regarded as being not inventive (Article 33(3)PCT).

Consequently, unless an unexpected effect over the prior art disclosure can be demonstrated for the present methods and products, like e.g. (a) further improved property/properties in the resulting baked products or doughs as opposed to products made by using other lipolytic enzymes like those known from D1-D5, e.g. by suitable comparative examples, this methods and products do not fulfill the requirements of Article 33(3)PCT.

Re Item VIII

Certain observations on the international application

The application does not meet the requirements of Article 6 PCT, because in claims 2 and 9 the matter for which protection is sought is not clearly defined, since these claims lack technical features. The claims attempt to define the subject-matter solely in terms of the results to be achieved, which merely amounts to a statement of the underlying problem, without providing any technical features (e.g. method conditions and/or identity of the enzyme(s)) necessary for achieving these results.