

# 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/EP2018/073217

International filing date (day/month/year)  
29.08.2018

Priority date (day/month/year)  
29.08.2017

International Patent Classification (IPC) or both national classification and IPC  
INV. A61K9/48

Applicant  
CHR. HANSEN AS

**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.

Name and mailing address of the ISA:



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Date of completion of this opinion

see form PCT/ISA/210

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**Box No. I Basis of the opinion**

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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:

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**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**

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1. Statement

Novelty (N)	Yes: Claims	<u>10-12</u>
	No: Claims	<u>1-9, 13-15</u>
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

**Re Item V**

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

**1 DOCUMENTS**

Reference is made to the following documents:

- D1 WO 2016/065279
- D2 US 2012/039998
- D3 GB 1 190 386
- D4 US 5 310 555
- D5 US 2017/189363

**2 NOVELTY (Art. 33(2) PCT)**

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-7 and 13-15 is not new in the sense of Article 33(2) PCT.
- 2.2 The capsules mentioned in claim 1 are not further defined, apart from being hard capsules. However, according to the wording of this claim the term seems to apply to the outer shell of the whole composition, so that the following document is considered relevant for novelty:
- 2.3 D1 discloses fecal bacteria which are encapsulated by extrusion (microcapsules). The wall contains sodium alginate and glycerol (example 1). The capsules are suspended with a hydrogenated oil and are filled into HPMC capsules, which are considered "hard capsules". The oil prevents contact of the microcapsules with the inner surface of the capsule shell (example 1). Consequently, the subject-matter of claims 1-7 and 13-15 is not novel in view of D1.

**3 INVENTIVE STEP (Art. 33(3) PCT)**

- 3.1 Being not novel, the subject-matter of claims 1-7 and 13-15 does not involve an inventive step in the sense of Article 33(3) PCT.
- 3.2 Documents D1-D4 are relevant for the evaluation of inventive step and disclose the following:
- 3.3 D2 discloses a softgel capsule which contains microencapsulated probiotic bacteria (example 1). The bacteria are encapsulated with lecithin, soy oil and bees wax. The capsules are dried and encapsulated with soy oil monoglyceryl monostearate and lecithin and encapsulated in a soft gel capsule (example 1 and 2). D2 does not disclose a hard capsule.
- 3.4 D3 discloses a composition comprising lactic acid bacteria and starch which is used encapsulated into enteric coated gelatin capsule (example). There is no inner and outer capsule.
- 3.5 D4 discloses a capsule comprising an inner capsule and an outer capsule. The inner capsule contains bacteria and the outer capsules contain a nutritional supplement (see claim 1). The capsules are made out of gelatin (claim 7). D4 does not disclose the presence of a hydrophobic liquid.
- 3.6 Dependent claims 8-12 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, as they only refer to minor modifications which are already known from the prior art.

**4 INDUSTRIAL APPLICABILITY (Art. 33(4) PCT)**

The subject-matter of claims 1-15 is industrial applicable according to Art. 33(4) PCT.