PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

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

Date of mailing
(day/month/year) see form PCT/ISA/220 (second sheet)

FOR FURTHER ACTION
See paragraph 2 below

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

International application No.
PCT/ES2011/070118
International filing date (day/month/year) 24.02.2011
Priority date (day/month/year) 26.02.2010

International Patent Classification (IPC) or both national classification and IPC
INV. A23L1.00 A61K9/64

Applicant
INSTITUTO CIENTÍFICO Y TECNOLÓGICO DE NAVARRA...

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 43bis.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 66.1bis(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.

3. For further details, see notes to 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/220

Authorized Officer
Delorenzi, Sibilla
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Form PCT/ISA/237 (Cover Sheet) (July 2009)
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 filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

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 in 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

1. Statement

   **Novelty (N)**
   
   Yes: Claims 5-7, 14-21, 25-31
   
   No: Claims 1-4, 8-13, 22-24

   **Inventive step (IS)**
   
   Yes: Claims
   
   No: Claims 1-31

   **Industrial applicability (IA)**
   
   Yes: Claims 1-31
   
   No: Claims

2. Citations and explanations

   see separate sheet

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Box No. VII  Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet
Re Item V

1 Reference is made to the following documents:


2 NOVELTY (ARTICLE 33(2) PCT)

The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of claims 1-3, 8-13 and 22-24 is not new in the sense of Article 33(2) PCT.

2.1 Product claims 22 and 23 are admissible only if the products as such fulfill the requirements for patentability (in terms of technical features of the product itself). A product is not rendered novel merely by the fact that it is produced by means of a new process. Claims defining a product in terms of a process are to be construed as claims to the product as such (see Guidelines Chapter V, 5.26).

2.2 Document D1 discloses nano-sized (cf. claim 13) casein micelles for controlled release applications and a method for the preparation comprising the steps of (cf. claim 21):
   i) preparing an aqueous solution comprising a source of casein (casein comprises implicitly a basic amino acid);
   ii) adding a co-solvent solution comprising at least one type of hydrophobic biologically active compound (e.g. vitamins A, D, E or K, phospholipids, cf. page 11, lines 3-10 and claims 3) to the casein solution;
   iii) adding a source of citrate ions, a source of phosphate ions and a source of calcium ions to the mixture of step (b) to form a nano-sized micelle dispersion;
iv) adjusting the pH of the dispersion to stabilize the nano-sized micelles.

The source of casein can be sodium caseinate (cf. page 8, line 3).

The subject-matter of claims 1-4, 8-13, and 22-24 can therefore, in view of D1, not be considered as new (Article 33(2) PCT).

2.3 Document D2 discloses nano-sized (cf. page 30, left-hand column, line 15) casein micelles for controlled release application, comprising calcium (present in casein micelles per definition, cf. page 30, left-hand column, line 5) and lysine (cf. page 30, left-hand column, line 22), said micelle having a diameter of 100 nm (cf. abstract).

The subject-matter of claims 1-3 can therefore, in view of D2, not be considered as new (Article 33(2) PCT).

3 INVENTIVE STEP (ARTICLE 33(3) PCT)

4 The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of claims claims 5-7, 14-21 and 25-31 does not involve an inventive step in the sense of Article 33(3) PCT.

4.1 Dependent claims 5-7, 14-21 and 25-31 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 (Art. 33(3) PCT), because in these claims a change is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen.

Re Item VII

5 Claim 8 comprises all the features of claim 9 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT).
6 Claim 21 comprises all the features of claim 22 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT).