

From the INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing <i>(day/month/year)</i> 20 July 2017	
Applicant's or agent's file reference PCA-66144/20187	FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/EP2017/059873	International filing date <i>(day/month/year)</i> 26 April 2017
Priority date <i>(day/month/year)</i> 26 April 2016	
International Patent Classification (IPC) or both national classification and IPC A61K 47/34(2017.01)i; C09D 1/04(2006.01)i; A23P 20/10(2016.01)i	
Applicant FRAUNHOFER-GESELLSCHAFT ZUR FÖRDERUNG DER	

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 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.

Name and mailing address of the ISA/	Date of completion of this opinion	Authorized officer

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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 43*bis*.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 13*ter*.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 13*ter*.1(a)).
 - on paper or in the form of an image file (Rule 13*ter*.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 and industrial applicability;
citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>11</u>	YES
	Claims	<u>1-10, 12-19</u>	NO
Inventive step (IS)	Claims	<u></u>	YES
	Claims	<u>1-19</u>	NO
Industrial applicability (IA)	Claims	<u>1-19</u>	YES
	Claims	<u></u>	NO

2. Citations and explanations :

See Supplemental Box

**WRITTEN OPINION OF THE
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PCT/EP2017/059873**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 Supplemental Box

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PCT/EP2017/059873**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 Supplemental Box

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V**Reasoned statement with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement****1. Reference**

Reference is made to the following documents:

D1	EP 0 802 218 A2 (FRAUNHOFER GES FORSCHUNG [DE]) 22 October 1997 (1997-10-22)
D2	US 2007/141104 A1 (HAUENSTEIN DALE [US]) 21 June 2007 (2007-06-21)
D3	PINGGUI LIU ET AL: "Microstructure and thermal properties of silyl-terminated polycaprolactone-polysiloxane modified epoxy resin composites", JOURNAL OF APPLIED POLYMER SCIENCE, Vol. 109, No. 2, 1 January 2008 (2008-01-01), pages 1105-1113, XP55387949, US ISSN: 0021-8995, DOI: 10.1002/app.28292 cited in the application

2. Novelty

The present application fails to comply with the requirements of PCT Article 33(2) because the subject matter of claims 1-10 and 12-19 is not novel.

2.1 It is noted that the subject matter of claims 5 and 6 is defined in terms of the result to be achieved, but in so doing merely states the problem to be solved, without indicating the technical features necessary for achieving this result. In the present case, said features relate to the precise structure of the coating. Claims 5 and 6 will therefore be interpreted as broadly as possible for the purpose of assessing novelty over the prior art.

2.2 Document D1 discloses:

- composite system, consisting of a flavor or odor barrier layer and a carrier material, characterized in that the carrier material comprises organic materials, and in that the flavor or odor barrier layer is an organically modified silicic acid polycondensate or an organically modified silicic acid hetero-polycondensate. Method for production. (claim 1; examples 1-4).
- use on foodstuffs or pharmaceutical products (page 15, lines 53-55).
- incorporation of epoxy groups / heteroatoms / functional groups / chains (page 4, line 15 to page 11, line 50).

The subject matter of claims 1-10 and 12-19 is therefore not novel.

2.3 Document D2 discloses:

- coatings containing a medicament and a silicic acid (hetero-)polycondensate that has been modified with organic groups (claims 1-50; examples 1-4). Polycaprolactone or cellulose as polymers for the organic group (paragraph 85). Pharmaceutical preparations (paragraphs 87-89).

The subject matter of claims 1-6, 8-10 and 12-19 is therefore not novel over D2.

3. Inventive step

The present application fails to comply with the requirements of PCT Article 33(3) because the subject matter of claims 1-19 does not involve an inventive step.

Supplemental Box

3.1 Due to the lack of novelty, claims 1-10 and 12-19 are not inventive.

3.2 Claim 11 differs from document D1 in that the organic groups are selected from the group consisting of polycaprolactone triol, chitosan, cellulose, cellulose derivatives and cellulose building blocks.

It is not possible to identify any unexpected effect arising from this difference. The examples of the application disclose only polycaprolactone triol (PCL-T) as the organic group.

The problem addressed by claim 11 is therefore that of using, as a coating for a medicament, a composition which contains silicic acid (hetero-)polycondensate that has been modified by alternative organic groups.

The solution proposed in claim 11 of the present application cannot be considered inventive (PCT Article 33(3)), for the following reasons: The alternative groups such as chitosan or cellulose are generally known to a person skilled in the art. For instance, document D2 also discloses said polymers as alternative organic groups (D2: paragraph 85).

4. The invention

The examples of the application disclose exclusively silicic acid (hetero-)polycondensate with PCL-T (polycaprolactone triol) as the organic group. The application plausibly demonstrates that these condensates, as a coating, have advantageous properties such as an advantageous appearance, adhesion, biodegradability and barrier properties.

A claim that has only polycaprolactone triol as the organic group would therefore be inventive.

Box VII**Certain defects in the international application**

Contrary to the requirements of PCT Rule 5.1(a)(ii), the description does not cite documents D1-D2 or indicate the relevant prior art disclosed therein.

Box VIII**Certain observations on the international application**

The application does not meet the requirements of PCT Article 6 because claims 2 and 11 are unclear. The term "derivatives" in claims 2 and 11 makes the scope of said claims unclear because a person skilled in the art cannot know what structures are supposed to be covered by the term.

Terms such as analogs/derivatives encompass compounds obtained by chemical reaction from a different compound (including compounds with a structure very different from the starting material), functional derivatives (such as compounds in which heteroatoms are replaced by alternative atoms), compounds having numerous different types of side groups, etc. However, only some of the claimed compounds, namely those explicitly mentioned, such as for example cellulose itself or PCL-T, are supported by the description (PCT Article 6).