

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

CAHILL John J.
Choate, Hall & Stewart LLP, Two International Place
Boston, Massachusetts 02110
United States of America

Date of mailing (<i>day/month/year</i>) 10 June 2015 (10.06.2015)		
Applicant's or agent's file reference 2002458-0777		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/US 2015/019163	International filing date (<i>day/month/year</i>) 06 March 2015 (06.03.2015)	Priority date (<i>day/month/year</i>) 07 March 2014 (07.03.2014)
International Patent Classification (IPC) or both national classification and IPC A23L 3/3526 (2006.01) A01N 3/00 (2006.01) C07K 14/425 (2006.01) C07K 14/435 (2006.01) C07K 14/78 (2006.01)		
Applicant TUFTS UNIVERSITY		

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/RU: Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	Date of completion of this opinion 25 May 2015 (25.05.2015)	Authorized officer S.Ilchenko Telephone No. 495 531 65 15
---	---	--

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 2015/019163

Box No. I Basis of this 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 filed or furnished:
 - 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 in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 2015/019163

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 6-34, 38-54

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international search (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 6-34, 38-54

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).

☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US 2015/019163

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	2-5, 36-37	YES
	Claims	1, 35	NO
Inventive step (IS)	Claims		YES
	Claims	2-5, 36-37	NO
Industrial applicability (IA)	Claims	1-5, 35-37	YES
	Claims		NO

2. Citations and explanations:

D1: KU KUOUNG-JU et al. «Preparation of a Silk Fibroin Film Containing Catechin and Its Application», Food Science and Biotechnology, 2008, Vol.17, no 6, pp.1203-1206

D2: WO 1997/023137 A1 (MCARDLE BLAISE) 03.07.1997

D3: CAO ZHENGBING et al. «The preparation of regenerated silk fibroin microspheres», Soft Matter, 2007, Vol.3, pp.910 – 915

D4: WANG YI et al. «Nanoscale Characterization of Zein Self-Assembly», Langmuir, 2012, Vol. 28, pp.2429 - 2435

D1 (abstract) discloses a product comprising a perishable item and a coating comprising a polypeptide - silk fibroin. At that it is obvious to the persons skilled in the art that the product disclosed in D1 comprises fibroin with all its properties and characteristics of the native structure, which have been described, for example, in D2 (p. 913 right column of the last paragraph) which discloses that the native silk fibroin is an amphipathic polypeptide, as it comprises hydrophobic and hydrophilic amino acid residues. Moreover, 73% of amino acid residues are hydrophobic fibroin.

In light of the foregoing, it is clear that discloses D1 a product coated with a film consisting of amphiphilic polypeptide - silk fibroin possessing hydrophobicity of more than 73%, i.e. wherein 73% of the amino acid residues are hydrophobic ones.

Therefore, the invention of claim 1 does not meet the criterion of novelty.

D3 (claims) discloses a product containing perishable component and a coating comprising a hydrophobic polypeptide - zein. Despite the fact that D3 does not mention zeinamphiphilicity and the number of hydrophobic amino-acid residues in its structure, it is obvious to a person skilled in the art that D3 discloses the use of zein with all its natural properties and structural features. Native zein characteristics are known from the prior art. For example, D4 (p.2429 left column, par. 1) discloses that zein is an amfiflnym protein containing 50% of hydrophobic amino acid residues, and includes a coil secondary structures and beta-plate secondary structure.

In this view, the invention of claim 1 does not meet the criterion of novelty.

Supplemental Box

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

The features of claims 2-5 characterize the well-known properties of native fibroin or zein proteins are known from D2 which discloses that fibroin consists of amorphous and crystalline areas. The crystalline fraction corresponds to beta-plate structure of the protein and amorphous – to a random helical structure of the protein (p.914 left column 1-2 par.) and D4(p.2429 left column, par. 1), correspondingly.

In view of the foregoing, the invention of claims 2-5 does not meet the criterion of inventive step.

D1 (abstract, p.1204 par. 7, left column) discloses a method for preserving a product by covering it with a layer comprising silk fibroin. Thus, the product is retained and its shelf life is increases as compared to uncoated product.

It is known from the prior art (D2) that fibroin is amphiphilic peptide comprising hydrophobic amino acid residues and including beta-plate secondary structure. It will be appreciated by a person skilled in the art that the method disclosed in D1 comprises fibroin with all its native properties and structural features.

Thus, the invention of claim 35 does not meet the criterion of novelty.

Also D3 (claims) discloses a method of preserving a perishable product, comprising adding a coating to a product comprising water insoluble zein (an amfiflnym biopolymer), i.e. which is hydrophobic and amphiphilic by nature. D3 (examples 5-8) discloses that the product treated by a coating comprising zein, retains its organoleptic properties, in contrast to the product without said coating.

Thus, the invention of claim 35 does not meet the criterion of novelty.

The features according to claims 36 characterize the known native properties of fibroin and zein are known from D2 and D4, correspondingly.

The features according to claims 36-37 characterize the known native properties of fibroin are known from D2.

In view of the foregoing, the invention of claims 36-37 does not meet the criterion of inventive step.

The inventions according to claims 1-5, 35-37 meet the criterion of industrial applicability