

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

To:

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Date of mailing (<i>day/month/year</i>) 06 September 2018 (06.09.2018)		FOR FURTHER ACTION See paragraph 2 below	
Applicant's or agent's file reference P14552-02			
International application No. PCT/US 2018/030624	International filing date (<i>day/month/year</i>) 02 May 2018 (02.05.2018)	Priority date (<i>day/month/year</i>) 02 May 2017 (02.05.2017)	
International Patent Classification (IPC) or both national classification and IPC A61L 27/14 (2006.01) A61F 2/06 (2006.01) B82Y 5/00 (2011.01)			
Applicant THE JOHNS HOPKINS 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 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 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/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 14 August 2018 (14.08.2018)	Authorized officer E. Rozhkova Telephone No. (495) 531-64-81
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 2018/030624

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 2018/030624

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	1-18	YES
	Claims		NO
Inventive step (IS)	Claims	18	YES
	Claims	1-17	NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims		NO

2. Citations and explanations:

D1: US 2014/0309726 A1

D2: US 2015/0118747 A1

D3: US 2007/0269481 A1

D1 a non-cellularized vascular graft comprising: a tubular scaffold comprising a hollow core with inner diameter less 6 mm and layer attached to the tubular scaffold (abstract, [0007]-[0008], [0011]-[0013], [0028], [0033], [0036]-[0039], [0062], claims 1-6, 8-11, 13, 15, 17-19, 21-25)

The invention of claim 1 differs from the one known from D1 in that the hollow core is surrounded by one or more sheets comprising dehydrated or hydrated hydrogel nanofibers having internally aligned polymer chains.

The invention of claim 6 differs from the one known from D1 in that vascular graft is a cellularized vascular graft and that the hollow core is surrounded by one or more sheets comprising hydrated hydrogel nanofibers with internal polymer alignment.

Therefore the inventions of claims 1, 6 and dependent claims 2-5, 7-12 meet the criterion of novelty.

D2 (abstract, [0012]-[0014], [0018], [0023], [0040], [0050]-[0051], claims 1-2) discloses a cellular vascular graft comprising hydrated hydrogel nanofibers having internally aligned polymer chains.

D3 ([0005], [0010]) discloses a tubular scaffold comprising sheets.

Therefore the inventions of claims 1, 6 do not meet the criterion of inventive step.

The features of claims 2, 7, concerning aligned hydrated hydrogel nanofibers, are known from D2 (abstract, [0013], [0022]-[0023], [0050], claim 1). The features of claims 3, 8, concerning aligned hydrated hydrogel nanofibers, are known from D2 ([0013]-[0014]). The features, concerning comprising the sheets, are known from D3 ([0005], [0010], [0111]).

The features of claims 4, 9, concerning the diameter of the core, are known from D1 ([0046]).

The features of claims 5, 10, 11, concerning thicknesses of the sheets and layers, are known from D3 ([0005], [0010], [0111]).

The features of claim 12, concerning aligning endothelial colony forming cells, are known from D2 (abstract, [0012]-[0014], [0018], [0023], [0040], [0050]-[0051], claims 1-2).

Supplemental Box

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

The inventions of claims 2-5, 7-12 do not meet the criterion of inventive step.

D3 (abstract, [0196], [0214]-[0215]) discloses a method of using a vascular graft to treat vascular damage comprising the steps of: administering a vascular graft to a subject with vascular damage; treating the vascular damage of the subject.

The invention of claim 13 differs from the one known from D3 in that the method uses a graft according to claims 1-12.

Therefore the invention of claim 13 and claims 14-17 meets the criterion of novelty.

As mentioned above D1-D3 discloses a graft according to claims 1-12.

Therefore the invention of claim 13 does not meet the criterion of inventive step.

The features of claims 14-17, concerning administering the vascular graft by vascular bypass surgery and diseases to be treated, are known from D3 (abstract, [0196], [0214]-[0215]).

Therefore, the invention of claims 14-17 does not meet the criterion of inventive step.

D3 ([0005], [0010]) also discloses a structure comprises sheets having internally aligned polymer chains.

The invention of claim 18 differs from the one known from D3 in that the structure is a mesh, the sheets comprises dehydrated or hydrated hydrogel nanofibers wherein each sheet has a controlled nanofiber orientation that is longitudinal, perpendicular, or otherwise angled.

Therefore the invention of claim 18 meets the criterion of novelty.

D2 discloses hydrated hydrogel nanofibers.

The distinctive features of claim 18, concerning that the structure is mesh and that the each sheet of the mesh has a controlled nanofiber orientation that is longitudinal, perpendicular, or otherwise angled, are not known from the prior art and the invention of claim 18 is not obvious for the person skilled in the art to provide improving the mechanical properties of the vascular graft.

Therefore the invention of claim 18 meets the criterion of inventive step.

The inventions of claims 1-18 meet the criterion of industrial applicability.