

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
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 Software Park., Xiamen, Fujian

**XIAMEN SHICHENG ASSOCIATES
 INTELLECTUAL PROPERTY AGENCY**

PCT

WRITTEN OPINION OF THE
 INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing <i>(day/month/year)</i> 06 July 2020	
Applicant's or agent's file reference xmsc2020004	FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/CN2020/082258	International filing date <i>(day/month/year)</i> 31 March 2020
Priority date <i>(day/month/year)</i> 01 April 2019	
International Patent Classification (IPC) or both national classification and IPC A61M 25/10(2013.01)i; A61M 25/01(2006.01)i; A61M 31/00(2006.01)i; A61L 29/08(2006.01)i; A61L 29/16(2006.01)i	
Applicant VASCUROS MEDICAL (SHANGHAI) CO., LTD	

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/ National Intellectual Property Administration, PRC China 6, Xitucheng Rd., Jimen Bridge, Haidian District, Beijing 100088	Date of completion of this opinion 30 June 2020	Authorized officer DOU,Bojian
Facsimile No. (86—10) 62019451	Telephone No. 62411125	

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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 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. 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. 1-4

because:

the said international application, or the said claims Nos. 1-4 relate to the following subject matter which does not require an international search (*specify*):

[1] The subject matter of claims 1-4, which encompasses a method of treatment of the human/animal body, is not required to be searched by this Authority. Regardless, the search has been carried out and a written opinion has established based on use of the balloon aspiration catheter and the drug coated balloon catheter for the manufacture of a medicament for the therapeutic application.

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. _____

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.

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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>1-4</u>	YES
	Claims	<u>None</u>	NO
Inventive step (IS)	Claims	<u>None</u>	YES
	Claims	<u>1-4</u>	NO
Industrial applicability (IA)	Claims	<u>1-4</u>	YES
	Claims	<u>None</u>	NO

2. Citations and explanations :

[1] Reference:

[2] D1: WO2019009809A1,10.01.2019

[3] D2: WO2018093329A1,24.05.2018

[4] D3: WO2019024726A1,07.02.2019

[5] The subject matter of claims 1-4, which encompasses a method of treatment of the human/animal body, is not required to be searched by this Authority. Regardless, the search has been carried out and a written opinion has established based on use of the balloon aspiration catheter and the drug coated balloon catheter for the manufacture of a medicament for the therapeutic application.

[6] 1. Novelty:

[7] D1 discloses a rapid exchange drug delivery catheter balloon device, which comprises a balloon catheter shaft having an inflation lumen both having a proximal end and a distal end; a balloon having a proximal end, a distal end and a working portion therebetween, where the proximal end of the balloon is coupled to and in fluid communication with the distal end of the inflation lumen; an exit port for a guidewire lumen in the balloon catheter shaft spaced apart in the proximal direction from the proximal end of the balloon; a guidewire lumen, where the guidewire lumen runs co-axially through the inflation lumen from a proximal end that extends through the exit port to a distal end that extends through the distal end of the balloon; a sheath having a proximal end and a distal end; and a therapeutic agent coating on a surface of the balloon facing the sheath(see claims 1-6, description page 4 lines 10-25).

[8] D2 discloses a drug delivery device for treating narrowing or obstruction of body lumen, which comprises balloon catheter shaft with inflation lumen having proximal and distal end, and balloon having proximal end, distal end and working portion, and a therapeutic agent coating on a surface of the balloon facing the first sheath(see claims 1-3, description page 3 lines 27-37, abstract).

[9] D3 discloses a drug coated balloon catheter, which has balloon provided with drug coating and sheath, wherein the sheath is moved with respect to pushing catheter such that balloon with drug coating is housed in sheath or exposed at outside of sheath. The catheter prevents blood flow from eroding the drug coating during a delivery process, thus effectively reducing a drug loss rate during the delivery process(see claims 1-2, description page 1 lines 21-29, page 3 lines 14-21, abstract).

[10] The subject matter of claims 1-4 is not disclosed by D1-D3, therefore, the subject matter of these claims is novel in the sense of PCT Article 33 (2).

[11] Inventive step:

[12] The subject matter of claim 1 differ from D1 is that the balloon aspiration catheter. The problem to be solved by the present subject-matter is considered to provide an additional catheter for removing free floating non-therapeutic drug particles. However, the use of the manufacture of a medicament for the therapeutic application is directly correlated to the drug coated balloon catheter and is not correlated to the balloon aspiration catheter, because the drug is only present on the coated catheter and the release of the drug is only carried out by the coated catheter. And, there is no unexpected effect about the drug available by the distinguishing feature. Therefore, claim 1 does not involve an inventive step in the sense of PCT Article 33 (3).

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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**

- [13] For the same reasons, claim 1 do not involve an inventive step with respect to D2 or D3 in the sense of PCT Article 33 (3).
- [14] For the same reasons as for the subject matter of claim 1, the subject matter of claims 2-4 do not involve an inventive step in the sense of PCT Article 33 (3).
- [15] 3. Industrial Applicability:
- [16] The subject-matter of claims 1-4 is considered industrially applicable in the sense of Art 33 (4) PCT.