PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

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

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2018/040079	28.06.2018	28.06.2017

International Patent Classification (IPC) or both national classification and IPC
INV. A61M25/06 A61M25/09 A61B17/00 A61B90/00

Applicant
ABIOMED, INC.

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 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 notifed 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:	Date of completion of this opinion	Authorized Officer
European Patent Office Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	see form PCT/ISA/210	Amaro, Henrique Telephone No. +49 30 25901-0

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:

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. 25-30

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 the whole application or for said claims Nos. 25-30

☐ 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 13*ter*.1(a) or (b).

☒ See Supplemental Box for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☒ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-24

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	17-24
	No:	Claims	1-16
Inventive step (IS)	Yes:	Claims	17-24
	No:	Claims	1-16
Industrial applicability (IA)	Yes:	Claims	1-24
	No:	Claims	

2. Citations and explanations

   see separate sheet

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 III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Independent claim 25 intends to define a method of attaching an access sheath to a medical device; one of the defined steps includes positioning the access sheath within the vasculature, which contradicts Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy. Therefore claims 25-30 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) PCT and consequently, no opinion will be formulated with respect to novelty, inventive step and industrial applicability (Article 34(4)(a)(i) PCT).

Re Item IV

Lack of unity of invention

2. This Authority considers that the application does not meet the requirements of unity of invention and that there are two (2) inventions covered by the claims indicated as follows:

Claims 1-16: A vascular access sleeve comprising:

> a tubular sleeve body extending along a longitudinal axis of the access sleeve, the sleeve body having first and second open ends; a first lumen extending along the longitudinal axis between the first and second open ends of the sleeve body; and a lateral opening in the sleeve body connecting the first lumen to an outer surface of the sleeve body, wherein the lateral opening of the access sleeve is configured to be selectively expanded to attach the access sleeve to a medical device.

Claims 17-24: An access system comprising:

> a medical device configured for insertion into an arteriotomy of a patient, the medical device having a first end and a second end; and an access sleeve having a a tubular sleeve body extending along a longitudinal axis, the sleeve body having first and second open ends: a first lumen extending along the longitudinal axis between the first and second open ends of the sleeve body; and a lateral opening in the sleeve body connecting the first lumen to an outer

surface of the sleeve body, the lateral opening comprising a slit that extends along the length of the sleeve body wherein the access sleeve is configured to be selectively expanded to attach the access sleeve to the medical device such that the medical device is positioned in the first lumen and the first lumen allows for the passage of at least the medical device.

The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

The reason for the objection of lack of unity resides in the definition of the access sleeve in both groups of claims i.e. although they have both a lateral opening and are configured to be selectively expanded, lack of further definitions render the scope of both defined sleeves such that they might not be the same: While the sleeve of the first group of claims is provided with a slit that extends along the length of the sleeve body that apparently, enables the sleeve to be selectively expanded, the selectively expansion of the sleeve defined in the second group of claims can be obtained other then a slit as defined in the sleeve of the first group of claims, rendering the defined sleeves different from each other, and therefore subject to an objection under Rule 13.1 PCT.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: WO 2017/031243 A1 (ABIOMED INC [US]) 23 February 2017 (2017-02-23)

D2: WO 2007/044907 A2 (FLOWMEDICA INC [US]; ELKINS JEFFREY M [US]; GOODSON HARRY B [US]; BALL) 19 April 2007 (2007-04-19)

D3: US 2008/015625 A1 (VENTURA CHRISTINE P [US] ET AL) 17 January 2008 (2008-01-17)

D4: WO 2011/109307 A1 (TYCO HEALTHCARE [US]; HANLON JAMES GEORGE [US]; MCCRAE ROBERT GORDON [) 9 September 2011 (2011-09-09)

FIRST INVENTION

3. The application does not meet the requirements of Article 6 PCT, because claim 1 is not clear. The reasons are the following:

Independent claim 1 defines a "*first lumen extending along the longitudinal axis between the first and second open ends of the sleeve body*"; from the description, "*first and second open ends of the sleeve body*" refer to two open ends: Open end (225) from distal end (230) and open end (235) from proximal end (230) of lumen (215) (see [0030]). Furthermore, claim 1 defines a "*lateral opening in the sleeve body connecting the first lumen to an outer surface of the sleeve body*", which according to the above interpretation, should then define a sleeve body (210) having a lumen (215) provided with a lateral opening connecting the lumen (215) to an outer surface of the sleeve body. However, the description defines a lateral opening (217) that is where a second or peripheral lumen (216) terminates (this lumen is for the purpose of the passage of a guidewire) (see [0030]). Therefore, as the description nowhere defines a first or what seems to be the main lumen suitable for the passage of a medical device with a lateral opening as defined in claim 1, it is not clear which feature in the description corresponds to the defined "*first lumen*" of claim 1.

This objection is so extense that it is not feasible to perform a detailed search until the applicant has the opportunity to file a clear and concise set of claims. Therefore, the documents D1-D4 cited in the search report merely represent access sleeves provided with a (lateral) opening suitable for a guidewire lumen e.g. opening (107) in D1 and exit port (236) in D2.

SECOND INVENTION

4. The argumentation above raised under point "3" sustaining the opinion on lack of clarity (Article 6 PCT) of claim 1 applies, mutatis mutandis, to the subject matter of claim 17, which therefore also does not meet the requirements of the PCT with respect to clarity i.e. according to the description, lateral opening (217) is where the periphery or second lumen terminates; therefore, it is neither connects the first lumen to an outer surface of the body nor it is provided with a slit. Slit (260) is, as defined in [0036], "fabricated as an opening in the sleeve body 210 and runs longitudinally along the length of the access sleeve 200".

5. It is to be noted that, if claim 17 would had defined a tubular sleeve body having a first lumen allowing for passage of the medical device, the tubular sleeve body terminating at a distal tip, a slit running down the entire length of the sleeve and a peripheral lumen terminating in the tip at a lateral opening, than, in the light of the documents found in the search, the defined subject matter would have been new, inventive and be industrially applicable according to Article 33 (1) PCT.The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim [...] is not new in the sense of Article 33(2) PCT.

Re Item VII

Certain defects in the international application

4. The following formal deficiencies were noted.

- A document reflecting the prior art described on paragraphs [0002] to [0004] should have been identified in the description (Rule 5.1(a)(ii) PCT).
- Independent claims 1,17 should have been drafted in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art acknowledged by the applicant being placed in the preamble (Rule 6.3(b)(i) PCT) and the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- The features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).