

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
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ETATS-UNIS D'AMERIQUE

INVITATION TO PAY ADDITIONAL FEES
AND, WHERE APPLICABLE, PROTEST FEE
(PCT Article 17(3)(a) and Rule 40.1 and 40.2(e))

	Date of mailing (day/month/year) 9 October 2018 (09-10-2018)
Applicant's or agent's file reference 1846265-0017-172	PAYMENT DUE within ONE MONTH from the above date of mailing
International application No. PCT/US2018/040079	International filing date (day/month/year) 28 June 2018 (28-06-2018)
Applicant ABIOMED, INC.	

1. This International Searching Authority

(i) considers that there are 2 (number of) inventions claimed in the international application covered by the claims indicated on an extra sheet:

(ii) therefore considers that **the international application does not comply with the requirements of unity of invention** (Rules 13.1, 13.2 and 13.3) for the reasons indicated on an extra sheet:

(iii) has carried out a partial international search (see Annex) will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:
see extra sheet

(iv) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid.


2. Consequently, the applicant is hereby **invited to pay**, within the time limit indicated above, the amount indicated below:

<u>EUR 1.775,00</u>	x	<u>1</u>	=	<u>EUR 1.775,00</u>
Fee per additional invention		number of additional inventions		currency/total amount of additional fees

3. The applicant is informed that, according to Rule 40.2(c), **the payment of any additional fee may be made under protest**, i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive, where applicable, subject to the payment of a protest fee.
Where the applicant pays additional fees under protest, the applicant is hereby invited, within the time limit indicated above, to pay a protest fee (Rule 40.2(e)) in the amount of EUR 875,00 (currency/amount)

Where the applicant has not, within the time limit indicated above, paid the required protest fee, the protest will be considered not to have been made and the International Searching Authority will so declare.

4. Claim(s) Nos. see extra sheet have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

Name and mailing address of the International Searching Authority  European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040 Fax: (+31-70) 340-3016	Authorized officer DUPKE, Debora Tel: +49 (0)30 25901-211
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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 206

Continuation of Box 4.

Claim(s) completely searchable:
1-24

Claim(s) not searched:
25-30

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).

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. 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.

2. 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 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 than 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.

The Search Authority consequently invites the applicant to pay one (1) extra search fee before all the inventions can be searched.

**Annex to Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS
OF THE PARTIAL INTERNATIONAL SEARCH**

International Application No
PCT/US2018/040079

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
- see 'Invitation to pay additional fees'
2. This communication is not the international search report which will be established according to Article 18 and Rule 43.
3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2017/031243 A1 (ABIOMED INC [US]) 23 February 2017 (2017-02-23) the whole document	1-16
X	WO 2007/044907 A2 (FLOWMEDICA INC [US]; ELKINS JEFFREY M [US]; GOODSON HARRY B [US]; BALL) 19 April 2007 (2007-04-19) the whole document	1-16
X	US 2008/015625 A1 (VENTURA CHRISTINE P [US] ET AL) 17 January 2008 (2008-01-17) the whole document	1-16
X	WO 2011/109307 A1 (TYCO HEALTHCARE [US]; HANLON JAMES GEORGE [US]; MCCRAE ROBERT GORDON [US]) 9 September 2011 (2011-09-09) the whole document	1-16

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Patent Family Annex

Information on patent family members

International Application No PCT/US2018/040079
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2017031243 A1	23-02-2017	AU 2016308193 A1	08-03-2018
		CA 2995707 A1	23-02-2017
		EP 3337530 A1	27-06-2018
		JP 2018523541 A	23-08-2018
		KR 20180078226 A	09-07-2018
		US 2017049947 A1	23-02-2017
		WO 2017031243 A1	23-02-2017

WO 2007044907 A2	19-04-2007	EP 1933920 A2	25-06-2008
		JP 2009511199 A	19-03-2009
		US 2007167913 A1	19-07-2007
		WO 2007044907 A2	19-04-2007

US 2008015625 A1	17-01-2008	US 2008015625 A1	17-01-2008
		US 2011257592 A1	20-10-2011

WO 2011109307 A1	09-09-2011	EP 2542294 A1	09-01-2013
		US 2011264133 A1	27-10-2011
		US 2014379012 A1	25-12-2014
		WO 2011109307 A1	09-09-2011

Application no:
Demande n°: PCT/US2018/040079
Anmelde-Nr:

DISCLAIMER

The attached provisional opinion on the patentability of the first invention searched serves only as information.
A reply addressing the points raised in the opinion is **not** required and will **not** be taken into account when issuing the final search report and opinion on patentability.

AVERTISSEMENT

L'avis provisoire ci-joint sur la brevetabilité de la première invention recherchée ne sert qu'à titre d'information.
Une réponse abordant les points soulevés dans l'avis n'est **pas** nécessaire et ne sera **pas** prise en compte lors de l'établissement du rapport final de la recherche et de l'avis sur la brevetabilité.

DISCLAIMER

Die beigefügte vorläufige Stellungnahme zur Patentierbarkeit der ersten geprüften Erfindung dient lediglich zur Information.
Eine Antwort auf die erhobenen Punkte in der Stellungnahme ist **nicht** erforderlich und bleibt bei der Erstellung des endgültigen Recherchenberichts und der Stellungnahme zur Patentierbarkeit **unberücksichtigt**.

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 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 than 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)

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*" are 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. Nevertheless, 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]). In conclusion, 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, raising the doubt about what is the "*first lumen*" of the defined claim 1.

This objection is so extensive 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 for a guidewire.

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 claim 1 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).