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— with international search report (Art. 21(3))

[Continued on next page]

(54) Title: BIOLOGICAL FLUID COLLECTION DEVICE

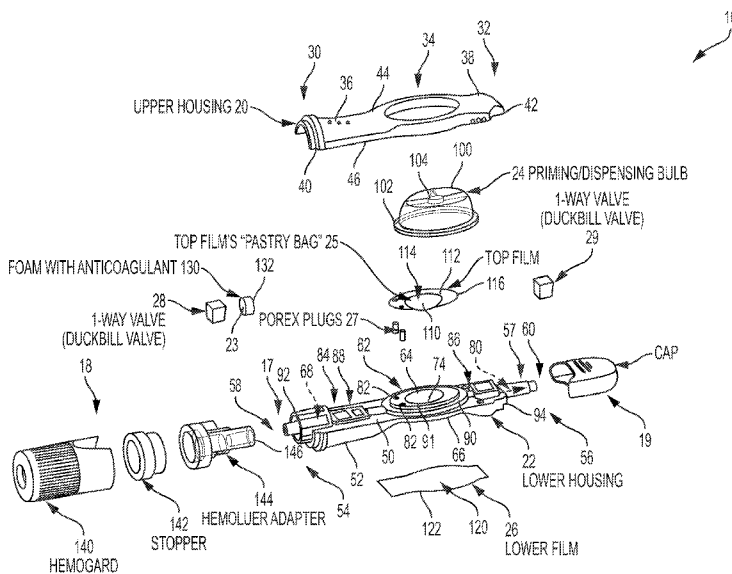
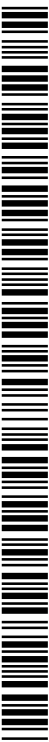


FIG. 6

(57) Abstract: A biological fluid collection device (10), comprising: a housing (10) having a superior surface (14) and an inferior surface (16), wherein a portion of the superior surface defines a cavity having a cavity superior surface; a film engageable with the housing, the film having a film inferior surface and a film superior surface, the film transitionable between an initial position in which the film inferior surface is in contact with the cavity superior surface and a fill position in which the film inferior surface is spaced from the cavity superior surface forming a chamber between the film and the housing; and an actuator (24) disposed at least partially within the housing and in communication with the film and the housing, the actuator transitionable between an original position and a depressed position, wherein after actuation of the actuator to the depressed position, as the actuator returns to the original position, the actuator applies a vacuum to the film superior surface.



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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

**(88) Date of publication of the international search report:**  
2 February 2017

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2016/038324

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.: 5-16, 29-32  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:  
see FURTHER INFORMATION sheet PCT/ISA/210
  
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
  
2.  As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
  
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:  
1-16, 29-32

### Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2016/038324

A. CLASSIFICATION OF SUBJECT MATTER  
INV. A61B5/15 A61B5/153  
ADD.  
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED  
Minimum documentation searched (classification system followed by classification symbols)  
A61B  
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2011/172508 A1 (CHICKERING III DONALD E [US] ET AL) 14 July 2011 (2011-07-14) abstract paragraph [0224]; figure 13C -----	1-4
A	US 5 636 640 A (STAEHLIN JOHN H [US]) 10 June 1997 (1997-06-10) abstract -----	1-4
A	WO 03/099123 A1 (SPECTRX INC [US]; FAUPEL MARK [US]; LINCOLN DANNY [US]) 4 December 2003 (2003-12-04) abstract -----	1-4
A	WO 00/78212 A1 (UNIV VIRGINIA [US]; SKALAK THOMAS C [US]; COTTLER PATRICK S [US]) 28 December 2000 (2000-12-28) abstract -----	1-4
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Further documents are listed in the continuation of Box C.

See patent family annex.

\* Special categories of cited documents :

<p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"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</p> <p>"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</p> <p>"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</p> <p>"&amp;" document member of the same patent family</p>
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Date of the actual completion of the international search  10 October 2016	Date of mailing of the international search report  05/12/2016
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer  Nielsen, Michael
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## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2016/038324

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 92/02175 A1 (SWIERCZEK REMI [US]) 20 February 1992 (1992-02-20) abstract	1-4
A	----- WO 01/43643 A1 (ALZA CORP [US]) 21 June 2001 (2001-06-21) abstract -----	1-4

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No  
PCT/US2016/038324

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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			EP 2523603 A2
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			JP 2013517061 A
			US 2011172508 A1
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US 5636640	A	10-06-1997	NONE
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WO 03099123	A1	04-12-2003	AU 2003231824 A1
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			US 2002077584 A1
			WO 0143643 A1
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**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

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

1. claims: 1-16, 29-32

Claims 1 to 16 and 29 to 32 defining biological fluid collection devices which are capable of drawing blood by means of a vacuum produced by a film (membrane).

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2. claims: 17-28

Claims 17 to 28 defining a biological fluid collection device capable of drawing blood by means of combination of channels and venting plugs.

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**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

Continuation of Box II.2

Claims Nos.: 5-16, 29-32

Although claims 1, 5, 29 and 31 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, claims 1, 5, 29 and 31 do not meet the requirements of Article 6 PCT. Consequently only claims 1 to 4 are being searched.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.