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[Continued on next page]

(54) Title: DELIVERY DEVICE AND RELATED METHODS

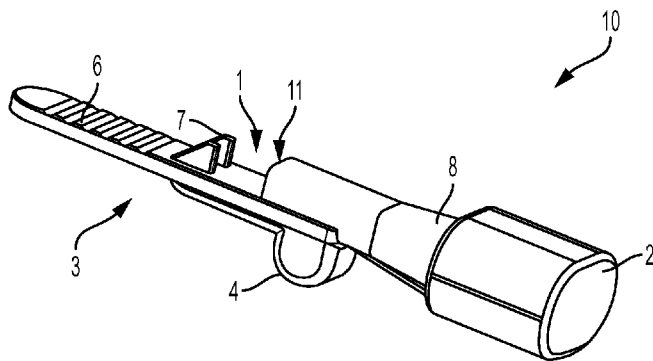


FIG. 1

(57) Abstract: Dose delivery device with partially or fully surrounding cover may be removed to open fluid communication with a dose chamber. The cover may allow an inhaler to be stored in sterile or otherwise in a controlled environment prior to use, and removal of the cover may automatically prepare the inhaler for use.



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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 15/28816

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(8) - A61M 15/00 (2015.01) CPC - A61M 15/0025 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC (8): A61M 15/00 (2015.01) CPC: A61M 15/0025 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched CPC: A61M 2202/064, A61M 15/0028, A61M 15/0021, A61M 15/003, A61M 15/0065; UC: 128/203.15 Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) PatBase, Google Patent, Google Scholar Search terms used: Dose delivery device inhaler seal blister single use mouthpiece cover clip dose* mouth* flow* fluid* seal* cap chambre		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/0190424 A1 (Lucking et al.) 14 August 2008 (14.08.2008), Entire document	1-2, 8-10, 12, 14-15, 17, 19-20
Y		4-5, 13, 16, 18
A		3, 6-7, 11
Y	US 2014/0102451 A1 (Jones et al.) 17 April 2014 (17.04.2014), para [0167]	4-5
A		6
Y	WO 2013/036881 A2 (Richardson) 14 March 2013 (14.03.2013), figs 7-8	13
Y	US 2013/0061851 A1 (Jones et al.) 14 March 2013 (14.03.2013), para [0008], [0009]	16, 18
A	US 2013/0312747 A1 (Eason et al.) 28 November 2013 (28.11.2013), Entire document	1-20
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>		
* 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 application or patent 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		
Date of the actual completion of the international search 28 September 2015 (28.09.2015)		Date of mailing of the international search report <b>23 OCT 2015</b>
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300		Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 15/28816

**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.:  
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:
  
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:  
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-20 directed to a dose delivery device including a cover.

Group II: Claim 21 directed to a dose delivery device including a hinge and an engagement portion.

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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 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.:  
1-20

**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/US 15/28816

Continuation of Box III: Observations where unity of invention is lacking

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

**SPECIAL TECHNICAL FEATURES**

The invention of Group I includes the special technical features of a cover that at least partially covers a portion of the body, not required by the claims of Group II.

The invention of Group II includes the special technical features of a hinge, wherein folding at the hinge positions the flow path over the dose chamber and engages and engagement portion of the body, not required by the claims of Group I.

**SHARED TECHNICAL FEATURES**

The inventions of Groups I-II share the common technical features of a dose delivery device, comprising: a body including a mouthpiece having an outlet, the body defining a flow path extending from an inlet to the outlet; a dose chamber containing a dose to be delivered to a subject via the mouthpiece; a seal that closes fluid communication between the flow path and the dose chamber. However, these shared technical features do not represent a contribution over prior art as being anticipated by US 2008/0190424 A1 to Lucking et al. (hereinafter Lucking). Lucking teaches a dose delivery device (abstract, fig 8-9), comprising: a body (111) including a mouthpiece having an outlet (107; para [0044]), the body defining a flow path extending from an inlet to the outlet (an airway is formed within the inhaler housing - para [0045]); a dose chamber containing a dose to be delivered to a subject via the mouthpiece (103; para [0044]); and a seal that closes fluid communication between the flow path and the dose chamber (105; para [0045]).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding technical feature.