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(54) Title: ANTI-TAMPERING APPARATUS AND METHOD FOR DRUG DELIVERY DEVICES

(57) Abstract: An anti-tampering apparatus and method for drug delivery devices provides for the capture of caps in a manner that restricts repositioning of a captured cap onto a corresponding drug delivery device. The anti-tampering apparatus includes one or more retention members to define a capture region for restrainably capturing a cap. The anti-tampering apparatus further locates an obstruction surface thereof to engage a surface of a drug delivery device and thereby restrict recapping of the device by the captured cap. As such, tampering of a drug delivery device is indicated by the absence of a cap captured within the anti-tampering apparatus.
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INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 5/00, 5/32; B65D 83/10 (2012.01)
USPC - 604/1 10, 604/1 92, 604/1 98; 206/364
According to International Patent Classification (IPC) or to both national classification and IPC

II. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
IPC: A61M 5/00, 5/32; B65D 83/10 (2012.01)
USPC: 604/1 10, 192, 198; 206/364

Documents searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC: A61M 5/00, 5/32; B65D 83/10 (2012.01)
USPC: 604/1 10, 111, 192, 198; 206/364, 365, 570, 571; 215/200, 201, 202, 209, 228, 250, 251, 273, 274, 400, 901

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category* Citation of document, with indication, where appropriate, of the relevant passages  

X  
Y  
A  

Relevant to claim No.

Date of the actual completion of the international search  

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Name and mailing address of the ISA/US  

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Form PCT/ISA/2 10 (second sheet) (July 2009)
Box No. 11 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. 111 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 extra 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 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. 1-21

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.
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 1-21; directed to an anti-tampering apparatus comprising a frame member.
Group II: Claims 22-51; directed to a method and system comprising a liquid medication.

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:

The special technical feature of Group I is a frame, which is not present in Groups II. The special technical feature of Group II is liquid medication, which is not present in Group I.

The only elements of commonality between groups I and II are those of:
A) a drug delivery device having a cap disposed on a port, which is known in the prior art (ref. US 6,068,614 A to Kimber et al.; Abstract: "A plastic pre-filled syringe which includes an open ended barrel sealed at one end by a moveable stopper"); col 5, in 55-57; "The barrel 2... is sealed at the other end by a closure 4"; Fig. 1), and
B) non-removable capture of said cap by said anti-tampering apparatus, which is known in the prior art (ref. US 6,068,614 A to Kimber et al.; col 5, in 19-22; "after the filling of the barrel separately injection moulding an overcap which includes closure retention means and fitting said overcap over the closure, and connecting it to the closure end of the barrel"); col 5, in 55-67; "The barrel 2... is sealed at the other end by a closure 4... An overcap 6 is positioned over the top of the closure 4 and is attached to the needle fitting end 5 of the syringe. The overcap 6 includes a frangibly connected ring 6a which inhibits downward movement of the overcap 6. Ring 6a is connected to the outer wall of overcap 6 by frangible bridges 6b and abuts against the end of the needle fitting end 5 of the syringe. The overcap 6 also includes a hollow channel 7. The overcap end 6 is connected to the end of the syringe by spot welding"); col 6, in 25-38; "In use, overcap 6 is rotated so to break its connection with the end of needle fitting end 5. It is then pushed in the direction of arrow 21 so that ring 6a is, separated from overcap 6 and so that closure 4 is pushed into and retained within channel 7. The closure 4 is held tightly within the closure as channel 7 is of gradually reducing diameter; tapering inwardly at an angle of about 1.5 degrees from opening 20. Once closure 4 has been retained with overcap 6, the overcap is pulled outwardly in the direction of arrow 22 bringing the closure with it as shown in FIG. 4. The closure breaks away from conical portion 8 of needle filling end 5 by rupture of the minimum cross-sectional portion of bridging portion 10").

Accordingly, unity of invention is lacking under PCT Rule 13.1.