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(54) **Title:** METHOD TO PROVIDE FOR DRUG PRODUCT FILLING INTO BODY-WORN DRUG DELIVERY DEVICE

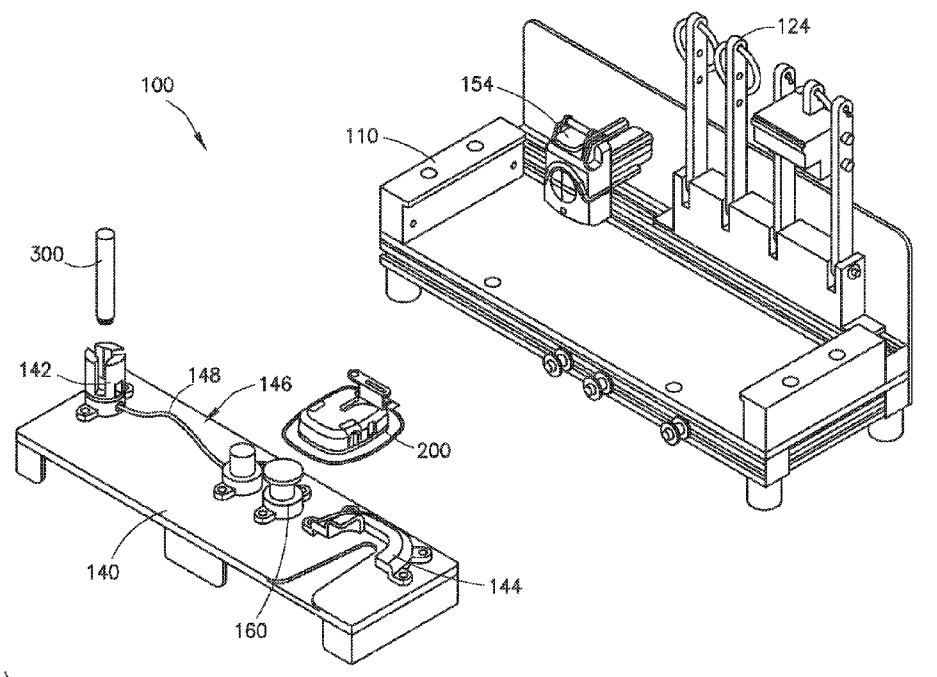


FIG. 4

(57) **Abstract:** A system for filling an on-body injector includes the on-body injector having a medicament reservoir, a fill cartridge having an internal chamber containing a medicament, and a filling station for receiving the on-body injector and the fill cartridge. The filling station includes an injector socket for receiving the on-body injector, a cartridge socket for receiving the fill cartridge, a fluid path section providing fluid communication between the injector socket and the cartridge socket and a pump operatively engaging the fluid path section to transfer the medicament from the internal chamber of the fill cartridge to the medicament reservoir of the on-body injector.



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- *with international search report (Art. 21(3))*
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02 May 2024 (02.05.2024)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 23/33445

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61M 5/14 (2023.01)

ADD.

CPC - INV. A61M 5/1413

ADD. A61M 2209/045

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)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/0008536 A1 (CEQUR SA); 14 January 2016 (14.01.2016); entire document, especially Fig. 17-18, para. [0079], [0098], [0106], [0123]-[0127].	1-3
X	US 2008/0119790 A1 (HAWKINS et al.); 22 May 2008 (22.05.2008); entire document, especially Abstract, Fig. 2, 4, 6; para. [0007], [0031]-[0033].	1, 4, 7, 10, 12
--		8-9, 11
Y		5-6, 13-14
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A	US 2015/0151041 A1 (ROCHE DIAGNOSTICS OPERATIONS, INC.); 4 June 2015 (04.06.2015); entire document, especially Abstract, Fig. 8a, para. [0077].	14
A	US 2020/0023123 A1 (INSULET CORPORATION); 23 January 2020 (23.01.2020); entire document.	1-14
A	US 2019/0151544 A1 (AMGEN INC.); 23 May 2019 (23.05.2019); entire document.	1-14

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"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

14 December 2023

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 23/33445

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 searched, the appropriate additional search fees must be paid.

Group I: Claims 1-14 directed to a system for filling an on-body injector, the on-body injector comprising a medicament reservoir.

Group II: Claims 15-23 directed to a filling station for filling an on-body injector, the filling station comprising a removable transfer tray.

-*-Continued in 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.:
1-14

- 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
Information on patent family members

International application No.

PCT/US 23/33445

-*-Box No. III - Lack of unity-*

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 system for filling [an on-body injector], the system comprising: [the on-body injector] having a medicament reservoir; [a fill cartridge] having an internal chamber containing a medicament, not required in Group II.

The invention of Group II includes the special technical features of [a filling station] for filling [an on-body injector], [the filling station] comprising a removable transfer tray, not required in Group I.

COMMON TECHNICAL FEATURES

The inventions of Groups I-II share the technical features of a filling station for receiving an on-body injector and a fill cartridge, the filling station comprising: an injector socket for receiving the on-body injector; a cartridge socket for receiving the fill cartridge; a fluid path section providing fluid communication between the injector socket and the cartridge socket; and a pump operatively engaging the fluid path section to transfer the medicament from the internal chamber of the fill cartridge to the medicament reservoir of the on-body injector. The common technical features are known in prior art as shown in US 2008/0119790 A1 to Hawkins et al. (hereinafter 'Hawkins'). Therefore, Groups I-II lack unity since the shared technical features do not represent a contribution over:

Hawkins teaches a filling station (service device 300, Fig. 4, para. [0032]) for receiving an on-body injector (detachably receiving infusion device 210, Fig. 4, para. [0032]) and a fill cartridge, (receive vial 132, Fig. 4, 6, para. [0033]), the filling station comprising:

an injector socket for receiving the on-body injector (portion of service device 300 receiving infusion device 210, Fig. 4; detachably receive infusion device 210, para. [0032]);

a cartridge socket for receiving the fill cartridge (cavity 332 for receiving vial 132, Fig. 4, para. [0033]);

a fluid path section providing fluid communication between the injector socket and the cartridge socket (conduit 336 serves to provide fluid communication between the vial 132 and the reservoir of the infusion device 210 to be filled, para. [0033]; see communication between cavity 332 and cavity receiving device 210, Fig. 4); and

a pump (pump 335, Fig. 4, para. [0033]) operatively engaging the fluid path section to transfer the medicament from the internal chamber of the fill cartridge to the medicament reservoir of the on-body injector (pump to pump air into the vial to displace liquid medicament from the vial and into the reservoir, para. [0007]).

As the common features were known in the art at the time of the invention, they 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 special technical feature.