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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	10-1188-US-CON3
First Named Inventor	Robert Frederick Veasey
Title	Pen-Type Injector
Express Mail Label No.	

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☐ **Fee Transmittal Form** (PTO/SB/17 or equivalent)
2. ☐ **Applicant asserts small entity status.** See 37 CFR 1.27
3. ☐ **Applicant certifies micro entity status.** See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
4. ☑ **Specification** [*Total Pages* 18] Both the claims and abstract must start on a new page. *(See MPEP § 608.01(a) for information on the preferred arrangement)*
5. ☑ **Drawing(s)** (35 U.S.C. 113) [*Total Sheets* 7]
6. **Inventor's Oath or Declaration** [*Total Pages* 4] *(including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))*
   a. ☑ Newly executed (original or copy)
   b. ☐ A copy from a prior application (37 CFR 1.63(d))
7. ☐ **Application Data Sheet** ** See note below.* See 37 CFR 1.76 (PTO/AIA/14 or equivalent)
8. **CD-ROM or CD-R** in duplicate, large table, or Computer Program (*Appendix*)
   ☐ Landscape Table on CD
9. **Nucleotide and/or Amino Acid Sequence Submission** (*if applicable, items a. – c. are required*)
   a. ☐ Computer Readable Form (CRF)
   b. ☐ Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ Paper
   c. ☐ Statements verifying identity of above copies

ADDRESS TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

ACCOMPANYING APPLICATION PAPERS

10. ☐ **Assignment Papers** (cover sheet & document(s)) Name of Assignee _____
11. ☐ **37 CFR 3.73(c) Statement** (*when there is an assignee*) ☐ **Power of Attorney**
12. ☐ **English Translation Document** (*if applicable*)
13. ☑ **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    ☑ Copies of citations attached
14. ☑ **Preliminary Amendment**
15. ☐ **Return Receipt Postcard** (*MPEP § 503*) (*Should be specifically itemized*)
16. ☐ **Certified Copy of Priority Document(s)** (*if foreign priority is claimed*)
17. ☐ **Nonpublication Request** Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
18. ☑ **Other:** Certification and Request for Prioritized Examination Form (Track1)
    General Authorization

Note*: (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must be included in an Application Data Sheet (ADS).
(2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS

☑ The address associated with Customer Number: 20306 **OR** ☐ Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	

Signature	/Thomas E. Wettermann/	Date	June 4, 2013
Name (Print/Type)	Thomas E. Wettermann	Registration No. (Attorney/Agent)	41,523

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON3
	Application Number	
Title of Invention	Pen-Type Injector	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Robert	Frederick	Veasey	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	Warwickshire	Country of Residence i	GB

Mailing Address of Inventor:

Address 1	31 Lonsdale Road		
Address 2	Leamington Spa		
City	Warwickshire	**State/Province**	
Postal Code	CV32 7EP	**Country** i	GB

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Robert		Perkins	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	Oxfordshire	Country of Residence i	GB

Mailing Address of Inventor:

Address 1	6 Printers Court Abingdon		
Address 2			
City	Oxfordshire	**State/Province**	
Postal Code	OX14 SBZ	**Country** i	GB

Inventor 3 Remove

Legal Name

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON3
	Application Number	
Title of Invention	Pen-Type Injector	

Prefix	Given Name	Middle Name	Family Name	Suffix
	David	Aubrey	Plumptre	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	Worcestershire	Country of Residence i	GB

Mailing Address of Inventor:

Address 1	36 Shire Way		
Address 2	Droitwich		
City	Worcestershire	**State/Province**	
Postal Code	WR97	**Country** i	GB

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	20306		
Email Address	docketing@mbhb.com	Add Email	Remove Email

Application Information:

Title of the Invention	Pen-Type Injector		
Attorney Docket Number	10-1188-US-CON3	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	7	**Suggested Figure for Publication (if any)**	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON3
	Application Number	
Title of Invention	Pen-Type Injector	

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

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Customer Number	20306		

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This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	12/944544	2010-11-11

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
12/944544	Continuation of	11/483546	2006-07-11	7918833	2011-04-05

Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
11/483546	Continuation of	10790225	2004-03-02

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This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) [i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country [i]	Filing Date (YYYY-MM-DD)	Access Code [i] (if applicable)
0304822.0	GB	2003-03-03	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON3
	Application Number	
Title of Invention	Pen-Type Injector	

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

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☒ Authorization to Permit Access to the Instant Application by the Participating Offices

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Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

◯ Assignee	◯ Legal Representative under 35 U.S.C. 117	◯ Joint Inventor
◯ Person to whom the inventor is obligated to assign.	◯ Person who shows sufficient proprietary interest	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON3
	Application Number	
Title of Invention	Pen-Type Injector	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information:

Address 1			
Address 2			
City		**State/Province**	
Country [i]		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Non-Applicant Assignee Information:

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Assignee 1

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Remove

If the Assignee is an Organization check here. ☒

Organization Name	DCA Design International LTD

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON3
	Application Number	
Title of Invention	Pen-Type Injector	

Mailing Address Information:			
Address 1	19 Church Street		
Address 2			
City	Warwick	**State/Province**	
Country i	GB	Postal Code	CV34 4AB
Phone Number		Fax Number	
Email Address			

Additional Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications					
Signature	/Thomas E. Wettermann/			Date (YYYY-MM-DD)	2013-06-04
First Name	Thomas E.	Last Name	Wettermann	Registration Number	41523

Additional Signature may be generated within this form by selecting the Add button. Add

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PEN-TYPE INJECTOR

CROSS REFERENCE TO RELATED APPLICATIONS

The present application is a continuation application of U.S. Patent Application No. 12/944,544, filed November 11, 2010, entitled "Pen-Type Injector", which is a continuation application of U.S. Patent Application No. 11/483,546, filed July 11, 2006, now U.S. Patent No. 7,918,833, which is a continuation application of U.S. Patent Application No. 10/790,225, filed March 2, 2004, abandoned, and claims priority to GB Patent Application No. 0304822.0, filed March 3, 2003, the entire contents of each of which are incorporated herein by reference.

BACKGROUND

Improvements in and relating to a pen-type injector

The present invention relates to pen-type injectors, that is to injectors of the kind that provide for administration by injection of medicinal products from a multidose cartridge. In particular, the present invention relates to such injectors where a user may set the dose.

Such injectors have application where regular injection by persons without formal medical training occurs. This is increasingly common amongst those having diabetes where self-treatment enables such persons to conduct effective management of their diabetes.

These circumstances set a number of requirements for pen-type injectors of this kind. The injector must be robust in construction, yet easy to use both in terms of the

manipulation of the parts and understanding by a user of its operation. In the case of those with diabetes, many users will be physically infirm and may also have impaired vision. Where the injector is to be disposable rather than reusable, the injector should be cheap to manufacture and easy to dispose of (preferably being suitable for recycling).

OVERVIEW

It is an advantage of the present invention that an improved pen-type injector is provided.

According to a first aspect of the present invention, a pen-type injector comprises a housing;
a piston rod adapted to operate through the housing;
a dose dial sleeve located between the housing and the piston rod, the dose dial sleeve having a helical thread of first lead;
a drive sleeve located between the dose dial sleeve and the piston rod, the drive sleeve having a helical groove of second lead;
characterized in that the first lead of the helical thread and the second lead of the helical groove are the same.

Preferably, the piston rod has a first threaded portion at a first end and a second threaded portion at a second end;
an insert or radially inwardly extending flange is located in the housing and through which the first threaded portion of the piston rod may rotate;
the dose dial sleeve being rotatable with respect to the housing and the insert;
the drive sleeve being releasably connected to the dose dial sleeve and connected to the piston rod for rotation with respect thereto along the second threaded portion of the piston rod;
a button is located on the dose dial sleeve and rotatable with respect to the dose dial sleeve; and

clutch means are provided which upon depression of the button permit rotation between the dose dial sleeve and the drive sleeve.

Preferably, the injector further comprises a nut which is rotatable with respect to the drive sleeve and axially displaceable but not rotatable with respect to the housing.

More preferably, the drive sleeve is provided at a first end with first and second flanges with an intermediate thread between the first and second flanges, the nut being disposed between the first and second flanges and keyed to the housing by spline means. Additionally, a first radial stop may be provided on a second face of the nut and a second radial stop may be provided on a first face of the second flange.

Preferably, the first thread of the piston rod is oppositely disposed to the second thread of the piston rod.

Preferably, a second end of the clutch is provided with a plurality of dog teeth adapted to engage with a second end of the dose dial sleeve.

Preferably, the pen-type injector further includes clicker means disposed between the clutch means and spline means provided on the housing.

More preferably, the clicker means comprises a sleeve provided at a first end with a helically extending arm, a free end of the arm having a toothed member, and at a second end with a plurality of circumferentially directed saw teeth adapted to engage a corresponding plurality of circumferentially saw teeth provided on the clutch means.

Alternatively, the clicker means comprises a sleeve provided at a first end with at least one helically extending arm and at least one spring member, a free end of the arm having a toothed member, and at a second end with a plurality of circumferentially directed saw teeth adapted to engage a corresponding plurality of circumferentially directed saw teeth provided on the clutch means.

Preferably, the main housing is provided with a plurality of maximum dose stops adapted to be abutted by a radial stop provided on the dose dial sleeve. More preferably, at least one of the maximum dose stops comprises a radial stop located between a helical rib and spline means provided at a second end of the housing. Alternatively, at least one of the maximum dose stops comprises a part of a raised window portion provided at a second end of the housing.

Preferably, the dose dial sleeve is provided with a plurality of radially extending members adapted to abut a corresponding plurality of radial stops provided at a second end of the housing.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described with reference to the accompanying drawings, in which:-

Figure 1 shows a sectional view of a pen-type injector in accordance with the present invention in a first, cartridge full, position;

Figure 2 shows a sectional view of the pen-type injector of Figure 1 in a second, maximum first dose dialed, position;

Figure 3 shows a sectional view of the pen-type injector of Figure 1 in a third, first maximum first dose dispensed, position;

Figure 4 shows a sectional view of the pen-type injector of Figure 1 in a fourth, final dose dialed, position;

Figure 5 shows a sectional view of the pen-type injector of Figure 1 in a fifth, final dose dispensed, position;

Figure 6 shows a cut-away view of a first detail of the pen-type injector of Figure 1;

Figure 7 shows a partially cut-away view of a second detail of the pen-type injector of Figure 1;

Figure 8 shows a partially cut-away view of a third detail of the pen-type injector of Figure 1;

Figure 9 shows the relative movement of parts of the pen-type injector shown in Figure 1 during dialing up of a dose;

Figure 10 shows the relative movement of parts of the pen-type injector shown in Figure 1 during dialing down of a dose;

Figure 11 shows the relative movement of parts of the pen-type injector shown in Figure 1 during dispensing of a dose;

Figure 12 shows a partially cut-away view of the pen-type injector of Figure 1 in the second, maximum first dose dialed, position;

Figure 13 shows a partially cut-away view of the pen-type injector of Figure 1 in the fourth, final dose dialed, position;

Figure 14 shows a partially cut-away view of the pen-type injector of Figure 1 in one of the first, third or fifth positions;

Figure 15 shows a cut-away view of a first part of a main housing of the pen-type injector of Figure 1; and

Figure 16 shows a cut-away view of a second part of the main housing of the pen-type injector of Figure 1.

DETAILED DESCRIPTION

Referring first to Figures 1 to 5, there may be seen a pen-type injector in accordance with the present invention in a number of positions.

The pen-type injector comprises a housing having a first cartridge retaining part 2, and second main housing part 4. A first end of the cartridge retaining means 2 and a second end of the main housing 4 are secured together by retaining features 6. In the illustrated embodiment, the cartridge retaining means 2 is secured within the second end of the main housing 4.

A cartridge 8 from which a number of doses of medicinal product may be dispensed is provided in the cartridge retaining part 2. A piston 10 is retained in a first end of the cartridge 8.

A removable cap 12 is releasably retained over a second end of the cartridge retaining part 2. In use the removable cap 12 can be replaced by a user with a suitable needle unit (not shown). A replacable cap 14 is used to cover the cartridge retaining part 2 extending from the main housing 4. Preferably, the outer dimensions of the replaceable cap 14 are similar or identical to the outer dimensions of the main housing 4 to provide the impression of a unitary whole when the replaceable cap 14 is in position covering the cartridge retaining part 2.

In the illustrated embodiment, an insert 16 is provided at a first end of the main housing 4. The insert 16 is secured against rotational or longitudinal motion. The insert 16 is provided with a threaded circular opening 18 extending therethrough. Alternatively, the insert may be formed integrally with the main housing 4 the form of a radially inwardly directed flange having an internal thread.

A first thread 19 extends from a first end of a piston rod 20. The piston rod 20 is of generally circular section. The first end of the piston rod 20 extends through the threaded opening 18 in the insert 16. A pressure foot 22 is located at the first end of the piston rod 20. The pressure foot 22 is disposed to abut a second end of the cartridge piston 10. A second thread 24 extends from a second end of the piston rod 20. In the illustrated embodiment the second thread 24 comprises a series of part threads rather than a complete thread. The illustrated embodiment is easier to manufacture and helps reduce the overall force required for a user to cause medicinal product to be dispensed.

The first thread 19 and the second thread 24 are oppositely disposed. The second end of the piston rod 20 is provided with a receiving recess 26.

A drive sleeve 30 extends about the piston rod 20. The drive sleeve 30 is generally cylindrical. The drive sleeve 30 is provided at a first end with a first radially extending flange 32. A second radially extending flange 34 is provided spaced a distance along the drive sleeve 30 from the first flange 32. An intermediate thread 36 is provided on an outer part of the drive sleeve 30 extending between the first flange 32 and the second

flange 34. A helical groove 38 extends along the internal surface of the drive sleeve 30. The second thread 24 of the piston rod 20 is adapted to work within the helical groove 38.

A first end of the first flange 32 is adapted to conform to a second side of the insert 16.

A nut 40 is located between the drive sleeve 30 and the main housing 2, disposed between the first flange 32 and the second flange 34. In the illustrated embodiment the nut 40 is a half-nut. This assists in the assembly of the injector. The nut 40 has an internal thread matching the intermediate thread 36. The outer surface of the nut 40 and an internal surface of the main housing 4 are keyed together by splines 42 (see Figures 10, 11, 15 and 16) to prevent relative rotation between the nut 40 and the main housing 4, while allowing relative longitudinal movement therebetween.

A shoulder 37 is formed between a second end of the drive sleeve 30 and an extension 38 provided at the second end of the drive sleeve 30. The extension 38 has reduced inner and outer diameters in comparison to the remainder of the drive sleeve 30. A second end of the extension 38 is provided with a radially outwardly directed flange 39.

A clicker 50 and a clutch 60 are disposed about the drive sleeve 30, between the drive sleeve 30 and a dose dial sleeve 70 (to be described below).

The clicker 50 is located adjacent the second flange 34 of the drive sleeve 30. The clicker 50 is generally cylindrical and is provided at a first end with a flexible helically extending arm 52 (shown most clearly in Figure 6). A free end of the arm 52 is provided with a radially directed toothed member 54. A second end of the clicker 50 is provided with a series of circumferentially directed saw teeth 56 (cf Figure 7). Each saw tooth comprises a longitudinally directed surface and an inclined surface.

In an alternative embodiment (not shown) the clicker means further includes at least one spring member. The at least one spring member assists in the resetting of the clutch means 60 following dispense.

The clutch means 60 is located adjacent the second end of the drive sleeve 30. The clutch means 60 is generally cylindrical and is provided at a first end with a series of circumferentially directed saw teeth 66 (see Figure 7). Each saw tooth comprises a longitudinally directed surface and an inclined surface. Towards the second end 64 of the clutch means 60 there is located a radially inwardly directed flange 62. The flange 62 of the clutch means 60 is disposed between the shoulder 37 of the drive sleeve 30 and the radially outwardly directed flange 39 of the extension 38. The second end of the clutch means 60 is provided with a plurality of dog teeth 65 (Figure 8). The clutch 60 is keyed to the drive sleeve 30 by way of splines (not shown) to prevent relative rotation between the clutch 60 and the drive sleeve 30.

In the illustrated embodiment, the clicker 50 and the clutch 60 each extend approximately half the length of the drive sleeve 30. However, it will be understood that other arrangements regarding the relative lengths of these parts are possible.

The clicker 50 and the clutch means 60 are normally engaged, that is as shown in Figure 7.

A dose dial sleeve 70 is provided outside of the clicker 50 and clutch means 60 and radially inward of the main housing 4. A helical groove 74 is provided about an outer surface of the dose dial sleeve 70.

The main housing 4 is provided with a window 44 through which a part of the outer surface of the dose dial sleeve may be seen. The main housing 4 is further provided with a helical rib 46, adapted to be seated in the helical groove 74 on the outer surface of the dose dial sleeve 70. The helical rib 46 extends for a single sweep of the inner surface of the main housing 4. A first stop 100 is provided between the splines 42 and

the helical rib 46 (Figure 15). A second stop 102, disposed at an angle of 180° to the first stop 100 is formed by a frame surrounding the window 44 in the main housing 4 (Figure 16).

Conveniently, a visual indication of the dose that may be dialed, for example reference numerals (not shown), is provided on the outer surface of the dose dial sleeve 70. The window 44 conveniently only allows to be viewed a visual indication of the dose currently dialed.

A second end of the dose dial sleeve 70 is provided with an inwardly directed flange in the form of number of radially extending members 75. A dose dial grip 76 is disposed about an outer surface of the second end of the dose dial sleeve 70. An outer diameter of the dose dial grip 76 preferably corresponds to the outer diameter of the main housing 4. The dose dial grip 76 is secured to the dose dial sleeve 70 to prevent relative movement therebetween. The dose dial grip 76 is provided with a central opening 78. An annular recess 80 located in the second end of the dose dial grip 76 extends around the opening 78.

A button 82 of generally 'T' section is provided at a second end of the pen-type injector. A stem 84 of the button 82 may extend through the opening 78 in the dose dial grip 76, through the inner diameter of the extension 38 of the drive sleeve 30 and into the receiving recess 26 of the piston rod 20. The stem 84 is retained for limited axial movement in the drive sleeve 30 and against rotation with respect thereto. A head 85 of the button 82 is generally circular. A skirt 86 depends from a periphery of the head 85. The skirt 86 is adapted to be seated in the annular recess 80 of the dose dial grip 76.

Operation of the pen-type injector in accordance with the present invention will now be described. In Figures 9, 10 and 11 arrows A, B, C, D, E, F and G represent the respective movements of the button 82, the dose dial grip 76, the dose dial sleeve 70, the drive sleeve 30, the clutch means 60, the clicker 50 and the nut 40.

To dial a dose (Figure 9) a user rotates the dose dial grip 76 (arrow A). With the clicker 50 and clutch means 60 engaged, the drive sleeve 30, the clicker 50, the clutch means 60 and the dose dial sleeve 70 rotate with the dose dial grip 76.

Audible and tactile feedback of the dose being dialed is provided by the clicker 50 and the clutch means 60. Torque is transmitted through the saw teeth 56,66 between the clicker 50 and the clutch means 60. The flexible arm 52 deforms and drags the toothed member 54 over the splines 42 to produce a click. Preferably, the splines 42 are disposed such that each click corresponds to a unit dose.

The helical groove 74 on the dose dial sleeve 70 and the helical groove 38 in the drive sleeve 30 have the same lead. This allows the dose dial sleeve 70 (arrow C) to extend from the main housing 4 and the drive sleeve 30 (arrow D) to climb the piston rod 20 at the same rate. At the limit of travel, a radial stop 104 on the dose dial sleeve 70 engages either the first stop 100 or the second stop 102 provided on the main housing 4 to prevent further movement. Rotation of the piston rod 20 is prevented due to the opposing directions of the overhauled and driven threads on the piston rod 20.

The nut 40, keyed to the main housing 4, is advanced along the intermediate thread 36 by the rotation of the drive sleeve 30 (arrow D). When the final dose dispensed position (Figures 4, 5 and 13) is reached, a radial stop 106 formed on a second surface of the nut 40 abuts a radial stop 108 on a first surface of the second flange 34 of the drive sleeve 30, preventing both the nut 40 and the drive sleeve 30 from rotating further.

In an alternative embodiment (not shown) a first surface of the nut 40 is provided with a radial stop for abutment with a radial stop provided on a second surface of the first flange 32. This aids location of the nut 40 at the cartridge full position during assembly of the pen-type injector.

Should a user inadvertently dial beyond the desired dosage, the pen-type injector allows the dosage to be dialed down without dispense of medicinal product from the cartridge

(Figure 10). The dose dial grip 76 is counter rotated. This causes the system to act in reverse. The flexible arm 52 now acts as a ratchet preventing the clicker from rotating. The torque transmitted through the clutch means 60 causes the saw teeth 56, 66 to ride over one another to create the clicks corresponding to dialed dose reduction. Preferable the saw teeth 56, 66 are so disposed that the circumferential extent of each saw tooth corresponds to a unit dose.

When the desired dose has been dialed, the user may then dispense this dose by depressing the button 82 (Figure 11). This displaces the clutch means 60 axially with respect to the dose dial sleeve 70 causing the dog teeth 65 to disengage. However the clutch means 60 remains keyed in rotation to the drive sleeve 30. The dose dial sleeve 70 and associated dose dial grip 76 are now free to rotate (guided by the helical rib 46 located in helical groove 74).

The axial movement deforms the flexible arm 52 of the clicker 50 to ensure the saw teeth 56,66 cannot be overhauled during dispense. This prevents the drive sleeve 30 from rotating with respect to the main housing 4 though it is still free to move axially with respect thereto. This deformation is subsequently used to urge the clicker 50, and the clutch 60, back along the drive sleeve 30 to restore the connection between the clutch 60 and the dose dial sleeve 70 when pressure is removed from the button 82.

The longitudinal axial movement of the drive sleeve 30 causes the piston rod 20 to rotate though the opening 18 in the insert 16, thereby to advance the piston 10 in the cartridge 8. Once the dialed dose has been dispensed, the dose dial sleeve 70 is prevented from further rotation by contact of a plurality of members 110 (Figure 14) extending from the dose dial grip 76 with a corresponding plurality of stops 112 formed in the main housing 4 (Figures 15 and 16). In the illustrated embodiment, the members 110 extend axially from the dose dial grip 76 and have an inclined end surface. The zero dose position is determined by the abutment of one of the axially extending edges of the members 110 with a corresponding stop 112.

CLAIMS

What is claimed is:

1. A housing part for a medication dispensing apparatus, said housing part comprising:

a main housing, said main housing extending from a distal end to a proximal end;

a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing;

a dose knob disposed near a proximal end of said dose dial sleeve;

a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;

a driver extending along a portion of said piston rod, said driver comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod;

a tubular clutch located adjacent a distal end of said dose knob, said tubular clutch operatively coupled to said dose knob, wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch; and

a container housing operatively coupled to said main housing, said container housing comprising a fluid container,

wherein said fluid container defines a medicament filled reservoir with a movable plunger at a proximal end and an outlet at a distal end,

said plunger movable by said piston rod to be advanced toward an outlet of said fluid container when said piston rod is moved distally.

2. The housing part of claim 1, wherein during a dose dispensing step, said dose knob is activated in a distal direction and said tubular clutch disengages such that said dose dial sleeve rotates back towards said proximal end of said main housing.

3. The housing part of claim 1, wherein

during a dose dispensing step, said driver advances axially in a distal direction relative to said main housing, and

said driver advances said piston rod in said distal direction so as to dispense said medicament from said outlet at said distal end of said fluid container.

4. The housing part of claim 1, further comprising a clicker, said clicker providing at least an audible feedback to a user when said dose knob is rotated.

5. The housing part of claim 4, wherein said clicker comprises,

at least one flexible arm, said flexible arm comprising at least one tooth member, and

at least one spline,

wherein when said dose knob is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback.

6. The housing part of claim 1, wherein

said tubular clutch comprises a plurality of teeth formed near an end of said tubular clutch,

said plurality of teeth remaining meshed during a dose setting step, and

said plurality of teeth becoming unmeshed during a dose dispensing step.

7. The housing part of claim 1,

wherein said piston rod comprises a first thread and a second thread, and

wherein at least one of said first or said second thread comprises at least one part threads rather than a complete thread.

8. The housing part of claim 1, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing.

9. The housing part of claim 1, wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along an outer surface of said dose dial sleeve.

10. The housing part of claim 1, wherein said dose dial sleeve comprises at least one radial stop, said radial stop positioned near an end of said helical groove, wherein when said dose dial sleeve is rotated to set a maximum dose of said medication dispensing apparatus, said radial stop near said end of said helical groove abuts an end of said threading provided on said inner surface of said main housing and thereby prevents rotation of said dose dial sleeve.

11. A housing part for a medication dispensing apparatus, said housing part comprising:

a main housing, said main housing extending from a distal end to a proximal end;

a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing;

a dose knob disposed near a proximal end of said dose dial sleeve;

a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;

a driver extending along a portion of said piston rod, said driver comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod; and,

a tubular clutch located adjacent a distal end of said dose knob, said tubular clutch operatively coupled to said dose knob,

wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch, and wherein said helical groove of the dose dial sleeve has a first lead and said internal threading of said driver has a second lead, and wherein said first lead and said second lead are different.

12. The housing part of claim 11, wherein during a dose dispensing step, said dose knob is activated in a distal direction and said tubular clutch disengages such that said dose dial sleeve rotates back towards said proximal end of said main housing.

13. The housing part of claim 11, wherein

during a dose dispensing step, said driver advances axially in a distal direction relative to said main housing, and

said driver advances said piston rod in said distal direction so as to dispense said medicament from said outlet at said distal end of said fluid container.

14. The housing part of claim 11, further comprising a clicker, said clicker providing at least an audible feedback to a user when said dose knob is rotated.

15. The housing part of claim 14, wherein said clicker comprises,

at least one flexible arm, said flexible arm comprising at least one tooth member, and

at least one spline,

wherein when said dose knob is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback.

16. The housing part of claim 11, wherein

said tubular clutch comprises a plurality of teeth formed near an end of said tubular clutch,

said plurality of teeth remaining meshed during a dose setting step, and

said plurality of teeth becoming unmeshed during a dose dispensing step.

17. The housing part of claim 11,

wherein said piston rod comprises a first thread and a second thread, and

wherein at least one of said first or said second thread comprises at least one part threads rather than a complete thread.

18. The housing part of claim 11, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing.

19. The housing part of claim 11, wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along an outer surface of said dose dial sleeve.

20. The housing part of claim 11, wherein said dose dial sleeve comprises at least one radial stop, said radial stop positioned near an end of said helical groove, wherein when said dose dial sleeve is rotated to set a maximum dose of said medication dispensing apparatus, said radial stop near said end of said helical groove abuts an end of said threading provided on said inner surface of said main housing and thereby prevents rotation of said dose dial sleeve.

ABSTRACT

A housing for a dispensing apparatus. The housing comprising a main housing and a dose dial sleeve. The dose dial sleeve comprising a helical groove configured to engage a threading provided by the housing. A dose knob is disposed near a proximal end of the dose dial sleeve and a piston rod is provided within the housing. The piston rod is non-rotatable during a dose setting step. A driver comprises an internal threading near a distal portion of the driver and is adapted to engage an external thread of the piston rod. A tubular clutch is located adjacent a distal end of the dose knob and operatively coupled to the dose knob. The dose dial sleeve may extend circumferentially around at least a portion of the tubular clutch.

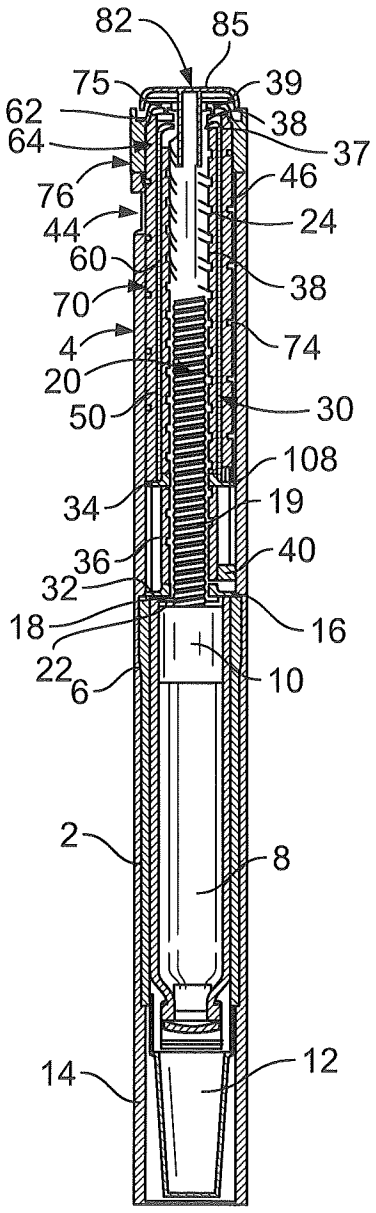

FIG. 1

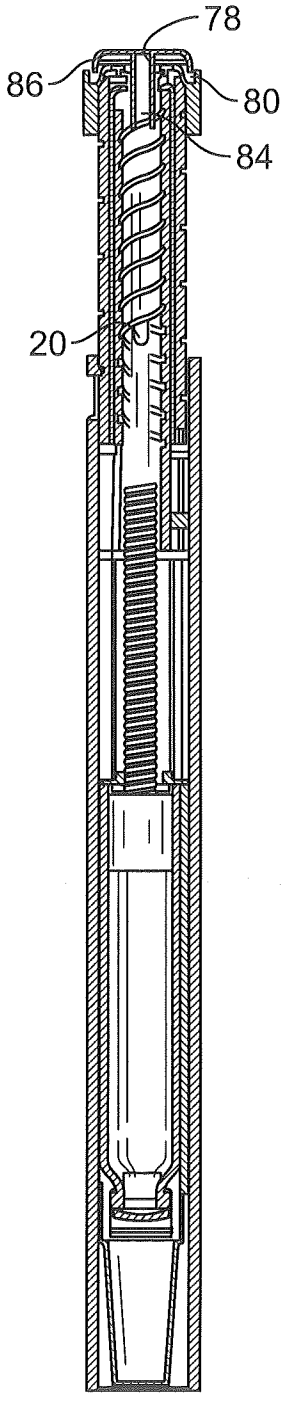

FIG. 2

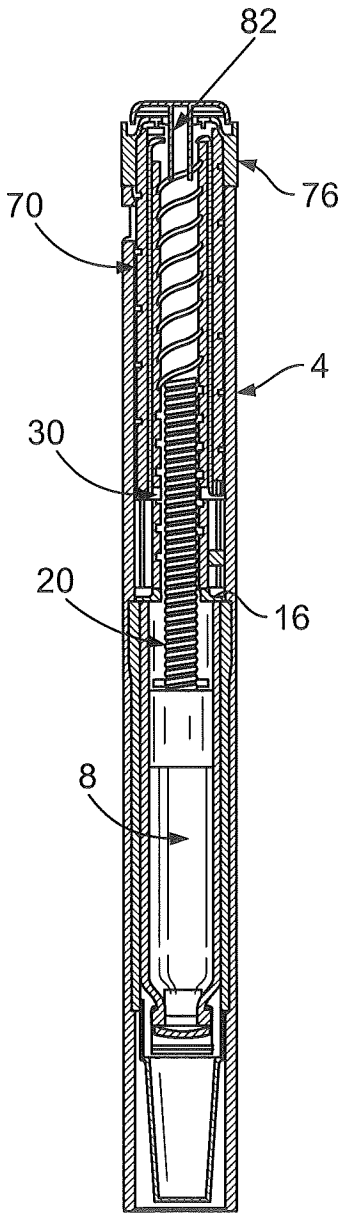

FIG. 3

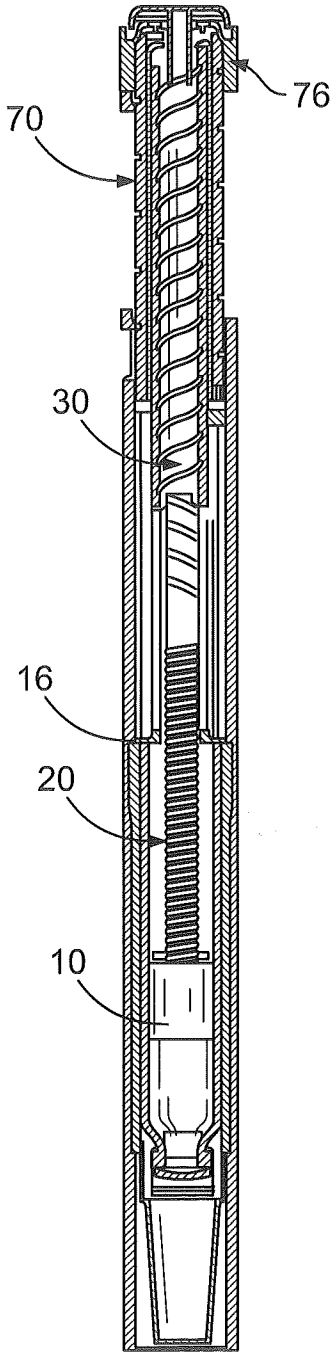

FIG. 4

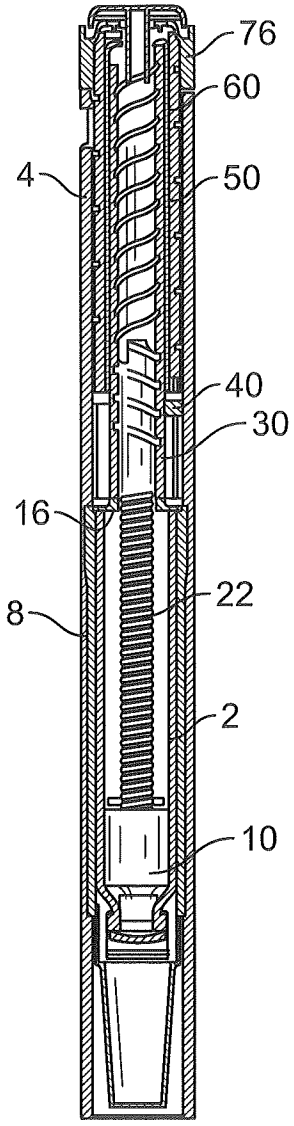

FIG. 5

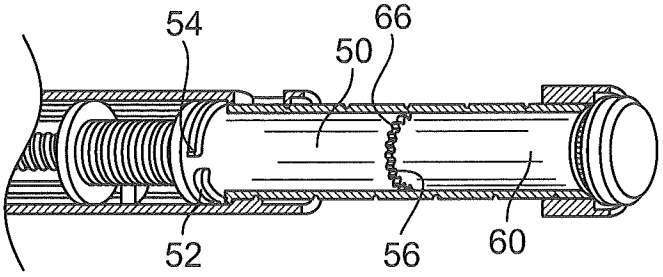

FIG. 6

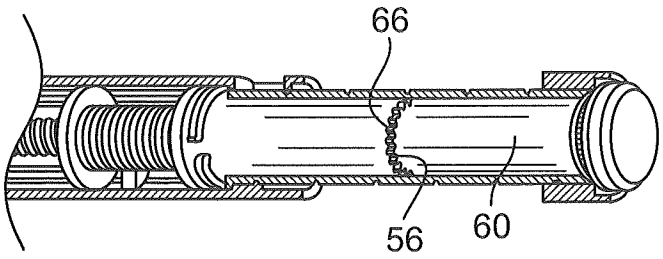

FIG. 7

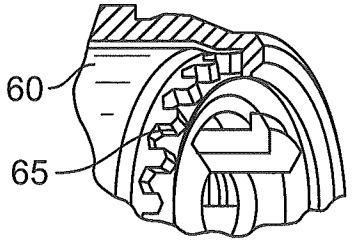

FIG. 8

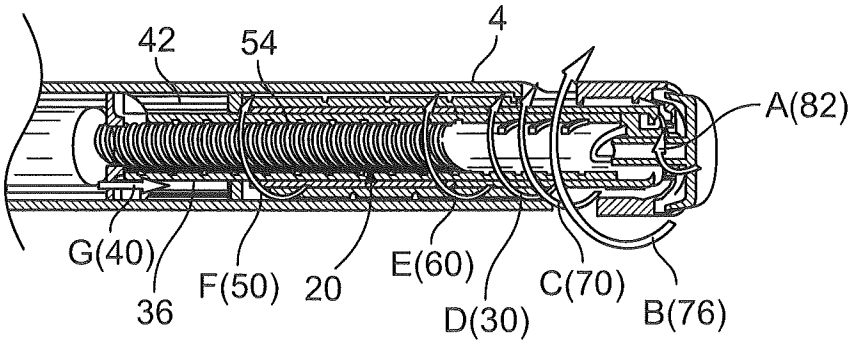

FIG. 9

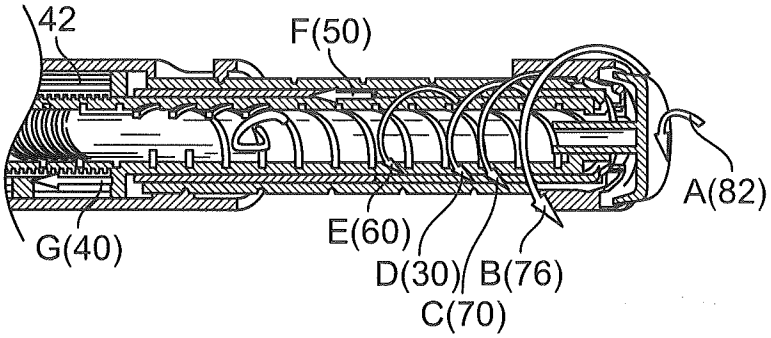

FIG. 10

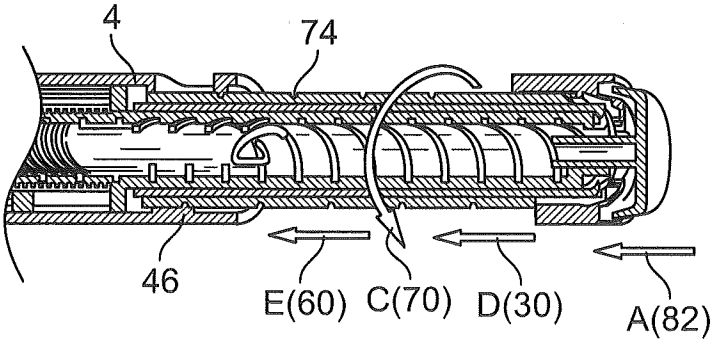

FIG. 11

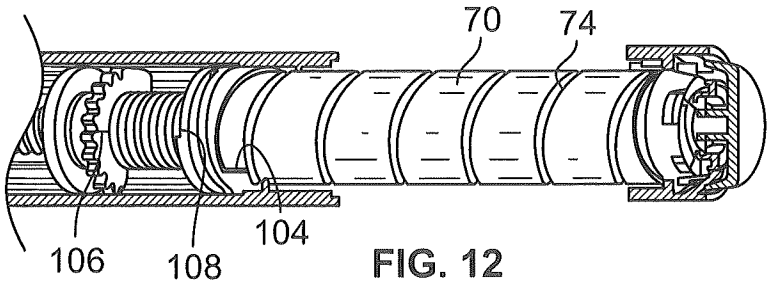

FIG. 12

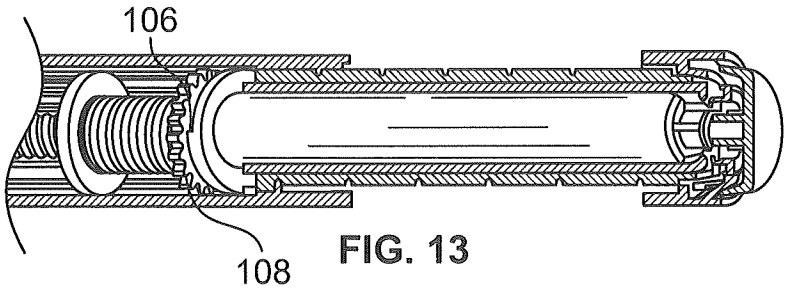

FIG. 13

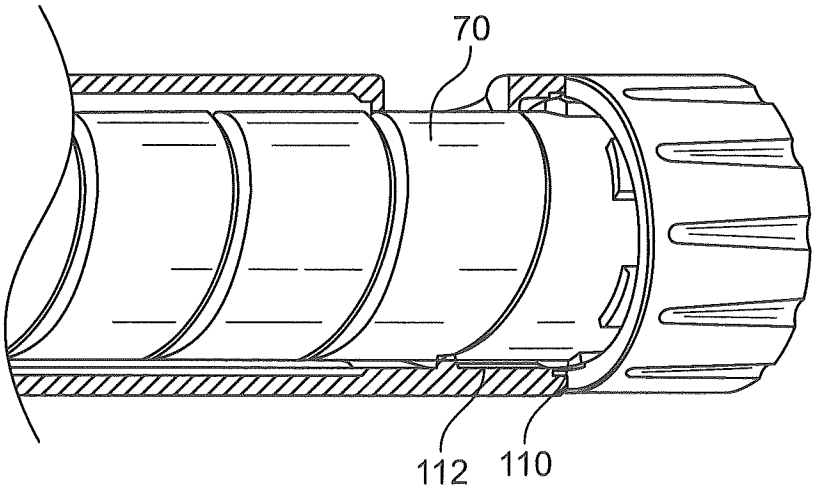

FIG. 14

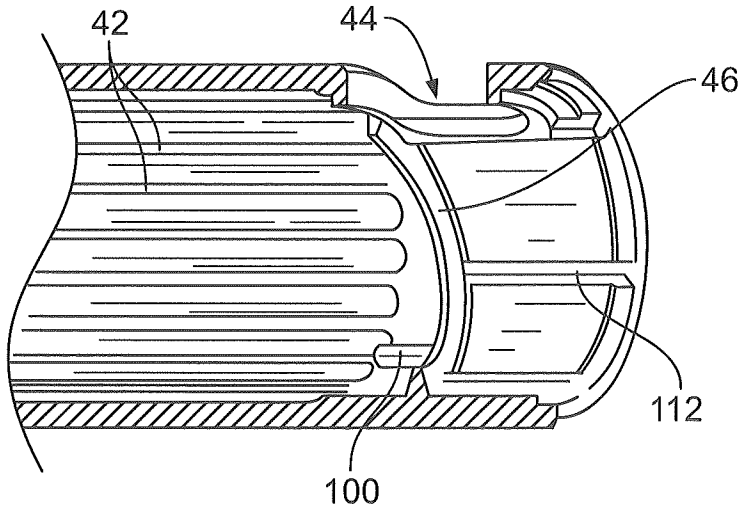

FIG. 15

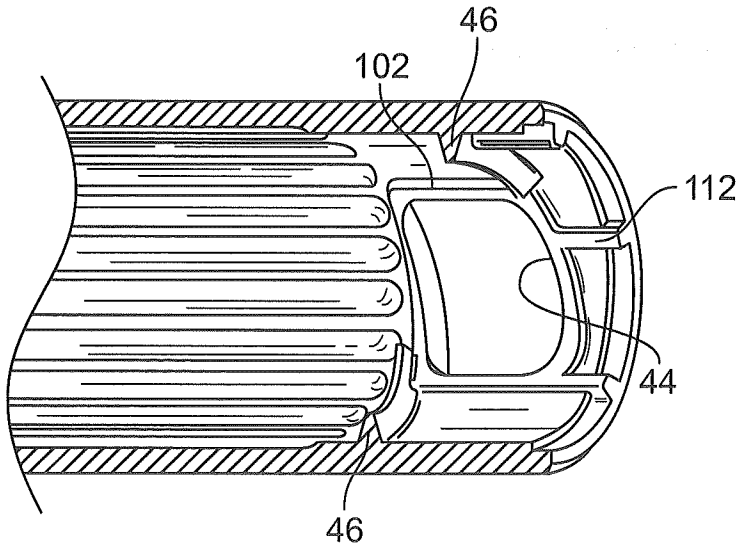

FIG. 16

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (09-12)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Robert Frederick Veasey	Nonprovisional Application Number (if known):	
Title of Invention:	Pen-Type Injector		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i), the prioritized examination fee set forth in 37 CFR 1.17(c), and if not already paid, the publication fee set forth in 37 CFR 1.18(d) have been filed with the request. The basic filing fee, search fee, examination fee, and any required excess claims and application size fees are filed with the request or have been already been paid.

2. The application contains or is amended to contain no more than four independent claims and no more than thirty total claims, and no multiple dependent claims.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. The executed inventor's oath or declaration is filed with the application. (37 CFR 1.63 and 1.64)

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Thomas E. Wettermann/	Date June 4, 2013
Name (Print/Typed) Thomas E. Wettermann	Practitioner Registration Number 41,523

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.*

☑ *Total of 1 forms are submitted.

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
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(Not for submission under 37 CFR 1.99)

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First Named Inventor	Robert Frederick Veasey
Art Unit	TBD
Examiner Name	TBD
Attorney Docket Number	10-1188-US-CON3

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	3	6221046	B1	2001-04-24	Burroughs et al.	
	4	6899698	B2	2005-05-31	Sams	
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	2	0937471	EP	A2	1999-08-25	Becton, Dickinson and Company		☐
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Signature	/Thomas E. Wettermann/	Date (YYYY-MM-DD)	2013-06-04
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(54) Low-cost medication delivery pen

(57) A medication delivery pen having very few parts allowing it to be manufactured at a very low-cost. The medication delivery pen also includes an automatic release mechanism to allow the user to easily reset the dose on the medication delivery pen and a mechanism for allowing the lead screw to easily retract back into the body of the medication delivery pen when the vial retainer has been removed to receive a new vial.

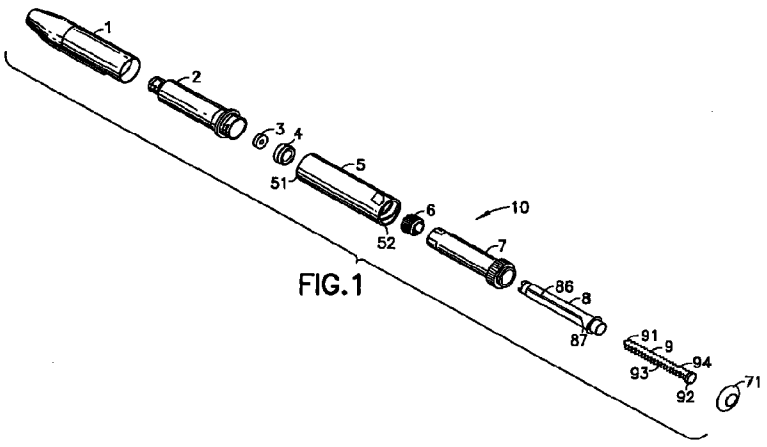


FIG.1

EP 0 937 476 A2

Description

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

[0001] The present invention relates to a medication delivery pen having a variety of features and, more particularly, a low-cost medication delivery pen having very few parts.

2. DESCRIPTION OF RELATED ART

[0002] Hypodermic syringes are used to deliver selected doses of medication to patients. The prior art hypodermic syringe includes a syringe barrel having opposed proximal and distal ends. A cylindrical chamber wall extends between the ends and defines a fluid receiving chamber. The proximal end of the prior art syringe barrel is substantially open and receives a plunger in sliding fluid tight engagement. The distal end of the prior art syringe barrel includes a passage communicating with the chamber. A needle cannula may be mounted to the distal end of the prior art syringe barrel, such that the lumen of the needle cannula communicates with the passage and the chamber of the syringe barrel. Movement of the plunger in a proximal direction draws fluid through the lumen of the needle cannula and into the chamber. Movement of the plunger in a proximal-to-distal direction urges fluid from the chamber and through the lumen of the needle cannula.

[0003] Medication to be injected with the prior art hypodermic syringe often is stored in a vial having a pierceable elastomeric seal. Medication in the prior art vial is accessed by piercing the elastomeric seal with the needle cannula. A selected dose of the medication may be drawn into the chamber of the syringe barrel by moving the plunger a selected distance in a proximal direction. The needle cannula may be withdrawn from the vial, and the medication may be injected into a patient by moving the plunger in a distal direction.

[0004] Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the course of the day. The required dose of insulin will vary from patient to patient, and for each patient may vary during the course of the day and from day to day. Each diabetes patient will establish a regimen that is appropriate for his or her own medical condition and for his or her lifestyle. The regimen typically includes some combination of a slow or medium acting insulin and a faster acting insulin. Each of these regimens may require the diabetes patient to periodically self-administer insulin in public locations, such as places of employment or restaurants. The required manipulation of the standard prior art hypodermic syringe and vial can be inconvenient and embarrassing in these public environments.

[0005] Medication delivery pens have been developed to facilitate the self-administration of medication. One prior art medication delivery pen includes a vial holder into which a vial of insulin or other medication may be received. The vial holder is an elongate generally tubular structure with proximal and distal ends. The distal end of the prior art vial holder includes mounting means for engaging a double-ended needle cannula. The proximal end also includes mounting means for engaging a driver and dose setting apparatus as explained further below. A disposable vial for use with the prior art vial holder includes a distal end having a pierceable elastomeric seal that can be pierced by one end of a double-ended needle cannula. The proximal end of this prior art vial includes a plunger slidably disposed in fluid tight engagement with the cylindrical wall of the vial. This prior art medication delivery pen is used by inserting the vial of medication into the vial holder. A prior art pen body then is connected to the proximal end of the vial holder. The pen body includes a dose setting apparatus for designating a dose of medication to be delivered by the pen and a driving apparatus for urging the plunger of the vial distally for a distance corresponding to the selected dose.

[0006] The user of the pen mounts a prior art double-ended needle cannula to the distal end of the vial holder such that the proximal point of the needle cannula pierces the elastomeric seal on the vial. The patient then selects a dose and operates the pen to urge the plunger distally to deliver the selected dose. The dose selecting apparatus returns to zero upon injection of the selected dose with this prior art medication delivery pen. The patient then removes and discards the needle cannula, and keeps the prior art medication delivery pen in a convenient location for the next required medication administration. The medication in the vial will become exhausted after several such administrations of medication. The patient then separates the vial holder from the pen body. The empty vial may then be removed and discarded. A new vial can be inserted into the vial holder, and the vial holder and pen body can be reassembled and used as explained above.

[0007] The above described medication delivery pen is effective and much more convenient for self-administration of medication than the hypodermic syringes that use separate medication vials. However, the above-described medication delivery pen requires a number of parts which make the manufacture of these pens very expensive. Hence, it is necessary to provide a medication delivery pen having a simple mechanism for setting the desired dose that uses as few parts as necessary without losing functionality or standard features.

SUMMARY OF THE INVENTION

[0008] The present invention relates to a medication delivery pen that addresses the above-identified problems. The medication delivery pen uses only tens parts and still provides numerous features that have become

expected by medical delivery pen users.

[0009] The medication delivery pen according to the present invention includes a mechanism that automatically disengages the drive mechanism from the dose control mechanism to permit the user to reset the dose on the medication delivery pen.

[0010] Another feature of the present invention is an automatic mechanism that allows the user to easily load a new vial and reposition the lead screw when the vial retainer has been removed from the body of the medication delivery pen.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011]

Fig. 1 is an exploded perspective view of a medication delivery pen according to the present invention.
Fig. 2 is a cross-sectional view of the driver in the medication delivery pen shown in Fig. 1.
Fig. 3 is a partial perspective view of the distal end of the driver shown in Fig. 2.
Fig. 4 is a perspective view of the retract nut shown in Fig. 1.
Fig. 5 is a perspective view of the reset ring shown in Fig. 1.
Fig. 6 is a cross-sectional view of the body of the medication delivery pen shown in Fig. 1.
Fig. 7 is a distal end view of the body shown in Fig. 6.
Fig. 8 is a perspective view of the dose set knob of the medication delivery pen shown in Fig. 1.
Fig. 9 is a cross-sectional view of the medication delivery pen shown in Fig. 1 fully assembled and in a dose setting condition.
Fig. 10 is a cross-sectional view of the medication delivery pen shown in Fig. 9 in a reset dose condition.

DETAILED DESCRIPTION OF THE INVENTION

[0012] A medication delivery pen 10 according to the present invention is shown in Fig. 1. Medication delivery pen 10 includes a cap 1 removably attached to a vial retainer 2 so to cover vial retainer 2 between uses of medication delivery pen 10. Vial retainer 2 receives a vial (not shown) that is commonly used in such medication delivery pens to provide medication and/or insulin for an injection. Medication delivery pen 10 includes a body 5 having a distal end 51 and a proximal end 52, with vial retainer 2 being attached to distal end 51 of body 5. Medication delivery pen 10 also includes a dose set knob 7, a driver 8, a lead screw 9, a lead screw spinner 3, a retract nut 4, a reset ring 6, and a thumb button 71. Each of these elements are more clearly shown in Figs. 2-8 and are more fully described below.

[0013] Fig. 2 is a cross-sectional view of driver 8 having a distal end 81 and a proximal end 82, wherein distal end 81 includes a snap ring 83 used to attach retract nut 4 onto distal end 81 of driver 8. In addition, driver 8 includes a plurality of ratchet fingers 84 at distal end 81, as more clearly shown in Fig. 3. These ratchet fingers 84 engage a ratchet 53, shown in Fig. 6, within body 5 to allow driver 8 to rotate only in one direction with respect to body 5. Driver 8 also includes a set of threads 85 that interface with a matching set of threads 93 on lead screw 9, shown in Fig. 1.

[0014] Fig. 4 is a perspective view of retract nut 4 that more clearly shows an attachment ring 41 that mates with snap ring 83 on distal end 81 of driver 8 to rotatably attach retract nut 4 onto driver 8. Retract nut 4 also includes an opening 42 therethrough having a pair of flat sides 43 that mate with set of flat sides 94 on lead screw 9, shown in Fig. 1, to prevent lead screw 9 from rotating with respect to retract nut 4. Retract nut 4 also has a distal surface 45 and a proximal end 46, proximal end 46 having a set of radial splines 44 that mates with a set of radial splines 54 within body 5 to prevent retract nut 4 and lead screw 9 from rotating when these splines 44 and 54 are engaged. As more clearly shown in Fig. 9, these splines 44 and 54 are fully engaged when vial retainer 2 is mounted onto body 5 and accordingly prevent retract nut 4 and lead screw 9 from rotating with respect to body 5. However, when vial retainer 2 is not mounted into body 5, retract nut 4 and lead screw 9 are free to rotate which permits lead screw 9 to be free to backdrive into body 5 as the user pushes a new vial into place. A lead screw spinner 3 is attached to a distal end 91 of lead screw 9 and is allowed to spin freely on lead screw 9, shown in Fig. 1, in relation to a rubber plunger (not shown) within the vial as lead screw 9 is backdriven into body 5.

[0015] When vial retainer 2 locks retract nut 4 into mating radial splines 54 within body 5, lead screw 9 is locked against rotation which then enables threads 85 within driver 8 to drive lead screw 9 in the distal direction towards and against the rubber plunger within the vial during a dispensing operation. Snap ring 83 on driver 8 also allows retract nut 4 to float captive thereon thus trapping it from spinning down lead screw 9, when exchanging vials should a user invert medication delivery pen 10 when changing vials.

[0016] Fig. 5 is a perspective view of reset ring 6 having a plurality of keys 63 therein that travel within a respective set of keyways 86 on driver 8, shown in Fig. 1. Reset ring 6 also includes a distal end 61 and a proximal end 62, proximal end 62 having a flange 65 and a plurality of ratchets 64 extending from flange 65 to distal end 61. Ratchets 64 engage with a plurality of ratchet fingers 73 on a distal end 71 of dose set knob 7, shown in Fig. 8 and discussed further below.

[0017] Fig. 6 is a cross-sectional view of body 5 more clearly showing distal end 51 and proximal end 52 having a set of dose setting threads 54 therein together with a dose viewing window 55. Another set of threads 56 located within distal end 51 are used to attach vial

retainer 2 in this embodiment. Of course, other means for attaching vial retainer 2 to body 5 could also be used and fall within the scope of the present invention as long as sufficient force is applied to retract nut 4 to prevent rotation of retract nut 4 and lead screw 9 within body 5 when vial retainer 2 is attached to body 5. Fig. 7 is a distal end view of body 5 more clearly showing radial splines 54.

[0018] Fig. 8 is a perspective view of dose set knob 7 having a distal end 71 and a proximal end 72, with a textured section 76 near proximal end 72 to aide the user in turning dose set knob 7 to set a desired dose when using medication delivery pen 10. Distal end 71 includes the plurality of ratchet fingers 73 that engage ratchet 64 on reset ring 6 when setting a dose, as shown in Fig. 9, until medication delivery pen 10 is in a reset condition, as shown in Fig. 10. When medication delivery pen 10 is in the reset condition, reset ring 6 has disengaged from dose set knob 7 as clearly seen in Fig. 10. Alternatively, as shown in Fig. 9 during a dose setting condition, reset ring 6 is within dose set knob 7 such that ratchet 64 are engaged with ratchet fingers 73. When a user is turning dose set knob 7 and thereby turning reset ring 6 because of the engagement of ratchet 64 and ratchet fingers 73, keys 63 within reset ring 6 interact with keyways 86 on driver 8 to cause driver 8 to rotate about lead screw 9 and move driver 8 in a proximal direction along lead screw 9. After a desired dose has been set by the user using dose set knob 7 and the desired dose is to be dispensed, movement of dose set knob 7 in a distal direction will cause driver 8 to push lead screw 9 in the distal direction and thereby dispense medication from the vial.

[0019] The user sets a desired dose by rotating dose set knob 7 in a counter clockwise direction until the desired dose is displayed in dose display window 55 in body 5. Dose set knob 7 includes a plurality of dosage numerals 74 that show through window 55 and an "R" 75 that identifies a "reset condition" for medication delivery pen 10. When the desired dose is reached, the user depresses a thumb button 71 attached to proximal end 72 of dose set knob 7 until dose set knob 7 has fully returned within body 5.

[0020] A significant function of the drive mechanism within medication delivery pen 10 is that if the user overshoots the desired dose, medication delivery pen 10 can be reset so that the user may redial for the desired dose. This is accomplished by rotating dose set knob 7 completely past the maximum value (30 or 60) until an "R" on dose set knob 7 is displayed in window 55 within body 5. This disengages ratchet fingers 73 within dose set knob 7 from ratchet 64 on reset ring 6 by forcing them apart and releasing reset ring 6 from within dose set knob 7. This action is caused by keys 63 engaging with a set of stops 87, shown in Fig. 1, at a proximal end of each keyway 86 on driver 8. Dose set knob 7 is then free to rotate back to an initial dose position ("0") upon which ratchet fingers 73 are forced to reengage with ratchet 64 on reset ring 6. Disengaging and re-engaging ratchet 64 and ratchet fingers 73 requires significant tactile manipulation and results in an audible click which alerts the user that the resetting function has been performed.

[0021] While the present invention has been described with respect to a preferred embodiment, it is apparent that various changes can be made without departing from the scope of the invention as defined by the appended claims.

Claims

1. A medication delivery pen comprising:

   a body having a distal end and a proximal end and including:

   a dose control mechanism for setting a desired dose to be delivered;
   a drive mechanism for dispensing the desired dose; and
   a reset mechanism for disengaging said drive mechanism from said dose control mechanism to permit a new desired dose to be set by said dose control mechanism without delivering the previously set desired dose.

2. A medication delivery pen according to Claim 1, wherein said drive mechanism includes:

   a leadscrew having a set of threads; and
   a driver having a set of threads that engage with the set of threads on said leadscrew to drive said leadscrew in a distal direction during dispensing.

3. A medication delivery pen according to Claim 2, wherein said dose control mechanism includes a dose set knob rotatably mounted within said body and attached to said drive mechanism by said reset mechanism during a dose setting condition.

4. A medication delivery pen according to Claim 3, wherein said reset mechanism disengages said dose set knob from said driver when said dose set knob is moved to a reset condition.

5. A medication delivery pen according to Claim 4, wherein said body further includes a dose display window and said reset condition is defined by a "R" on said dose set knob that is displayed in said dose display window.

6. A medication delivery pen according to Claim 4, wherein said reset mechanism includes a reset ring that travels on said driver and rotates said driver as

said dose set knob is rotated during a dose setting condition.

7. A medication delivery pen according to Claim 6, wherein said reset ring includes a ratchet that engages with a ratchet finger on said dose set knob to cause said reset ring to rotate with said dose set knob, wherein said ratchet finger and said ratchet are disengaged when said dose set knob is moved from the dose setting condition to a reset condition.

8. A medication delivery pen according to Claim 7, wherein said reset ring further includes a key that engages with a keyway on said driver to rotate said driver as said dose set knob and reset ring are rotated during the dose setting condition.

9. A medication delivery pen according to Claim 1, further comprising:

a vial retainer that mounts to said distal end of said body; and
a reload mechanism that disengages said drive mechanism when said vial retainer is removed from said body to allow a user to reload said medication delivery pen.

10. A medication delivery pen according to Claim 9, wherein said reload mechanism includes a retract nut in said body between said vial retainer and said drive mechanism that causes the drive mechanism to disengage when said vial retainer is removed from said body to allow a user to reload said medication delivery pen.

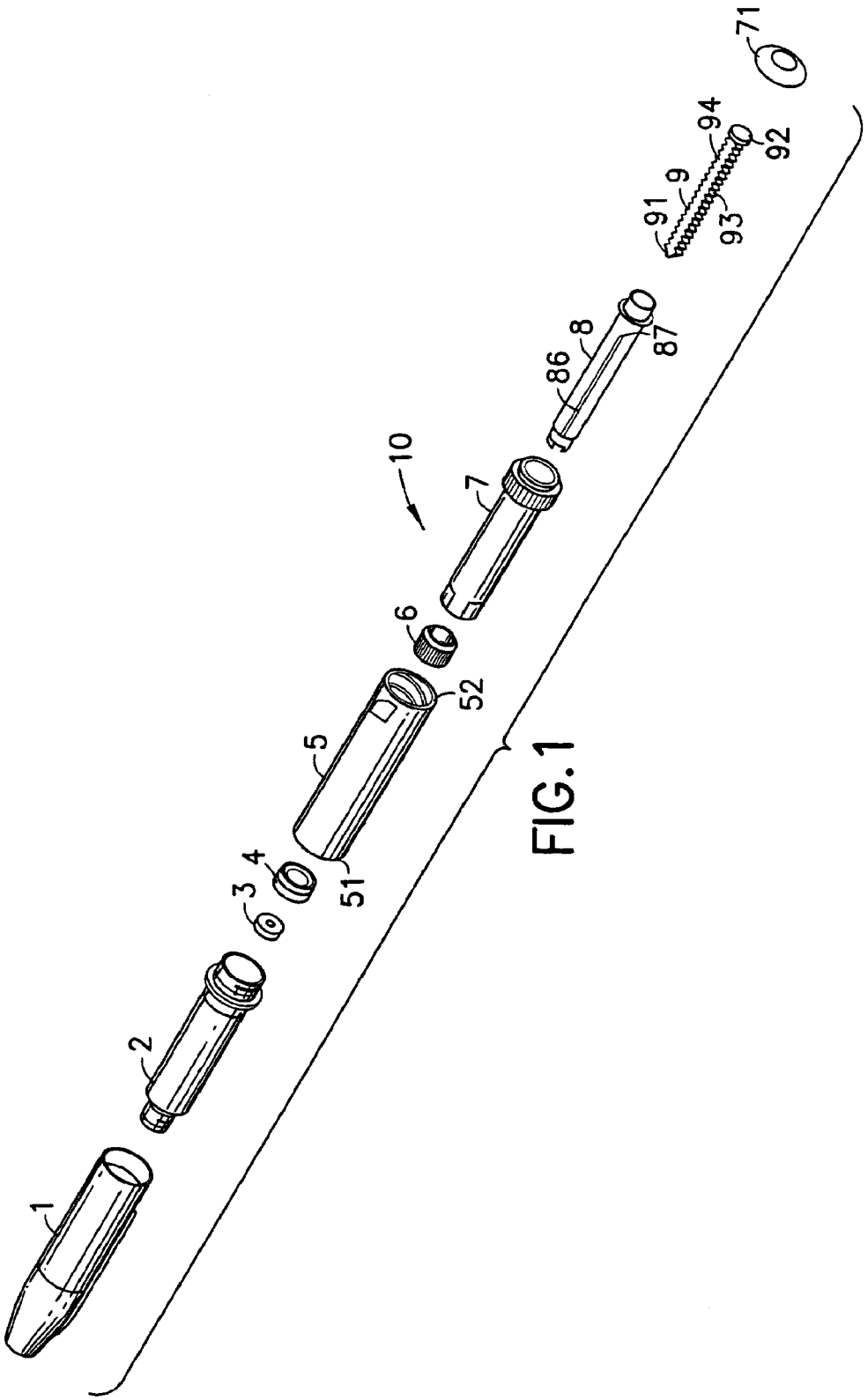


FIG. 1

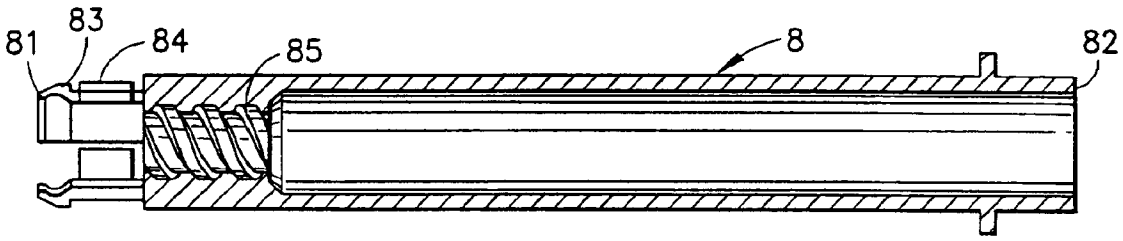


FIG.2

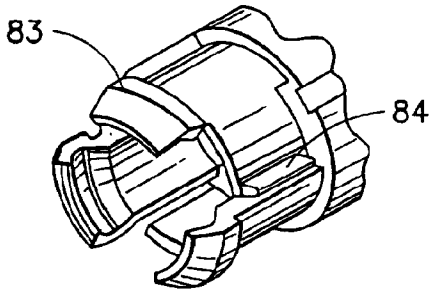


FIG.3

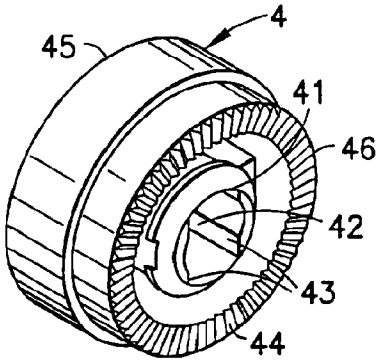
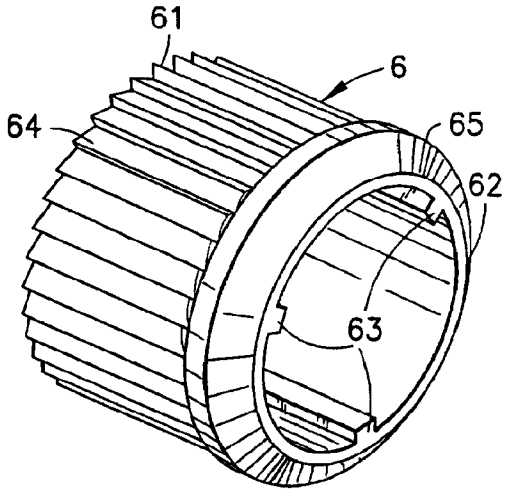


FIG.4



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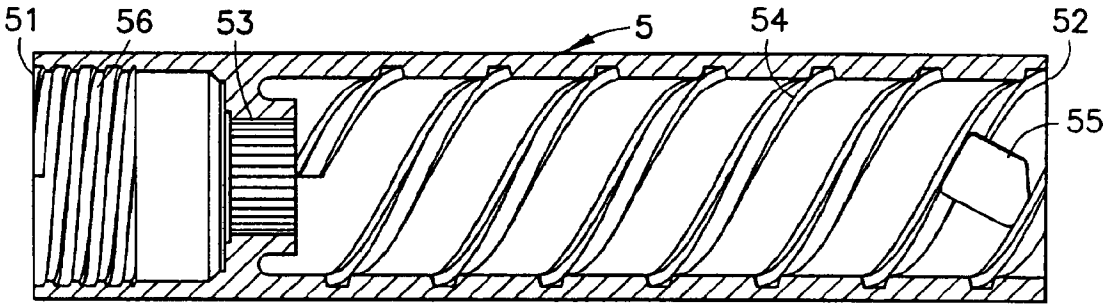

FIG.6

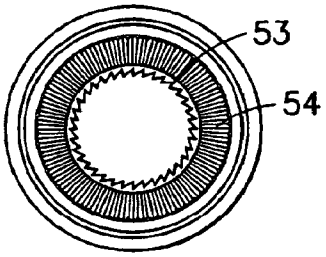

FIG.7

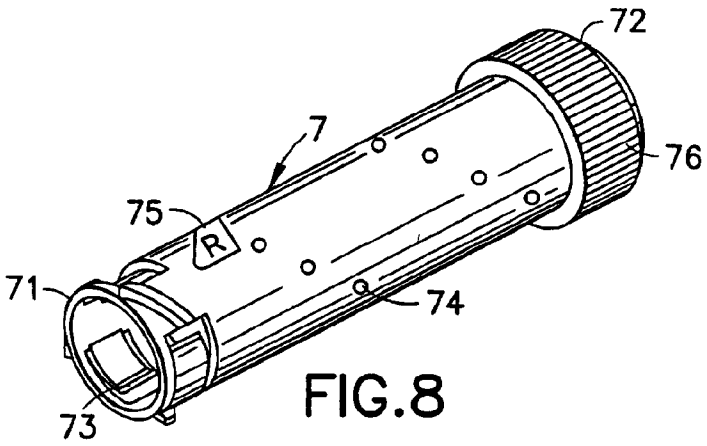

FIG.8

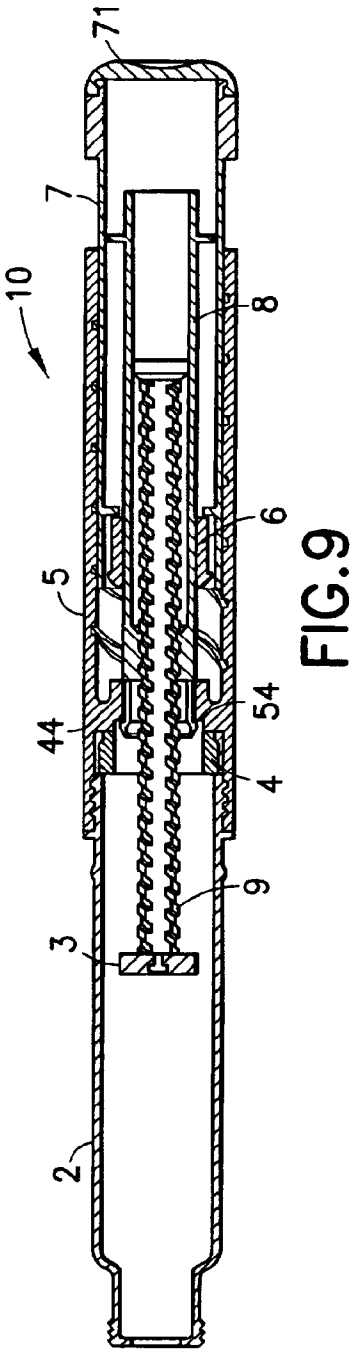

FIG.9

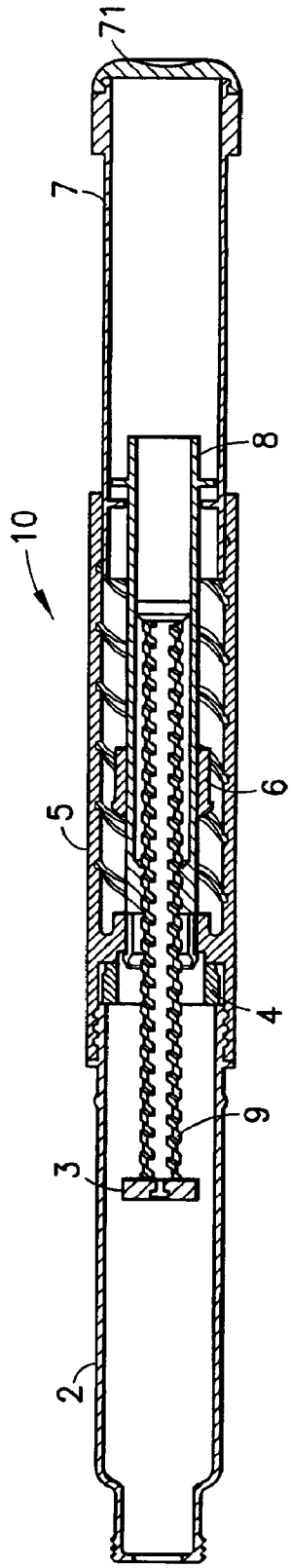

FIG.10

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(54) Medication delivery pen

(57) A medication delivery pen having a repeat-dose feature that limits motion of the dose control mechanism using an adjustable repeat-dose stop on the dose knob. In addition, the medication delivery pen also provides the user a simple mechanism for setting and correcting the dose and a drive mechanism that makes the dispensing operation as easy as possible requiring as little force as necessary.

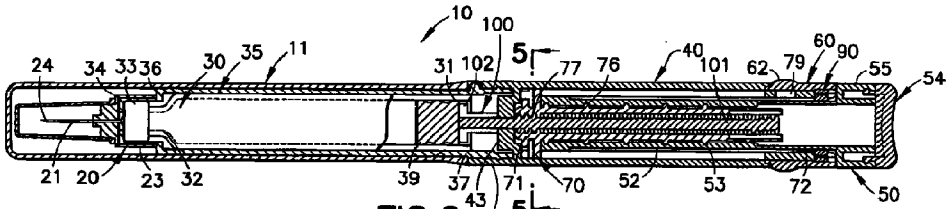


FIG.2

EP 0 937 471 A2

Description

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

[0001] The present invention relates to a medication delivery pen having a variety of features and, more particularly, a medication delivery pen that provides a mechanical advantage that uses less force to delivery the selected dose than would be needed to push directly on a plunger within a vial, a re-settable and/or repeatable dosing feature, and a self-priming feature all within the device using relatively few components.

2. DESCRIPTION OF RELATED ART

[0002] Hypodermic syringes are used to deliver selected doses of medication to patients. The prior art hypodermic syringe includes a syringe barrel having opposed proximal and distal ends. A cylindrical chamber wall extends between the ends and defines a fluid receiving chamber. The proximal end of the prior art syringe barrel is substantially open and receives a plunger in sliding fluid tight engagement. The distal end of the prior art syringe barrel includes a passage communicating with the chamber. A needle cannula may be mounted to the distal end of the prior art syringe barrel, such that the lumen of the needle cannula communicates with the passage and the chamber of the syringe barrel. Movement of the plunger in a proximal direction draws fluid through the lumen of the needle cannula and into the chamber. Movement of the plunger in a proximal-to-distal direction urges fluid from the chamber and through the lumen of the needle cannula.

[0003] Medication to be injected with the prior art hypodermic syringe often is stored in a vial having a pierceable elastomeric seal. Medication in the prior art vial is accessed by piercing the elastomeric seal with the needle cannula. A selected dose of the medication may be drawn into the chamber of the syringe barrel by moving the plunger a selected distance in a proximal direction. The needle cannula may be withdrawn from the vial, and the medication may be injected into a patient by moving the plunger in a distal direction.

[0004] Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the course of the day. The required dose of insulin will vary from patient to patient, and for each patient may vary during the course of the day and from day to day. Each diabetes patient will establish a regimen that is appropriate for his or her own medical condition and for his or her lifestyle. The regimen typically includes some combination of a slow or medium acting insulin and a faster acting insulin. Each of these regimens may require the diabetes patient to periodically self-administer insulin in public locations, such as places of employment or restaurants. The required manipulation of the standard prior art hypodermic syringe and vial can be inconvenient and embarrassing in these public environments.

[0005] Medication delivery pens have been developed to facilitate the self-administration of medication. One prior art medication delivery pen includes a vial holder into which a vial of insulin or other medication may be received. The vial holder is an elongate generally tubular structure with proximal and distal ends. The distal end of the prior art vial holder includes mounting means for engaging a double-ended needle cannula. The proximal end also includes mounting means for engaging a driver and dose setting apparatus as explained further below. A disposable vial for use with the prior art vial holder includes a distal end having a pierceable elastomeric seal that can be pierced by one end of a double-ended needle cannula. The proximal end of this prior art vial includes a plunger slidably disposed in fluid tight engagement with the cylindrical wall of the vial. This prior art medication delivery pen is used by inserting the vial of medication into the vial holder. A prior art pen body then is connected to the proximal end of the vial holder. The pen body includes a dose setting apparatus for designating a dose of medication to be delivered by the pen and a driving apparatus for urging the plunger of the vial distally for a distance corresponding to the selected dose.

[0006] The user of the pen mounts a prior art double-ended needle cannula to the distal end of the vial holder such that the proximal point of the needle cannula pierces the elastomeric seal on the vial. The patient then selects a dose and operates the pen to urge the plunger distally to deliver the selected dose. The dose selecting apparatus returns to zero upon injection of the selected dose with this prior art medication delivery pen. The patient then removes and discards the needle cannula, and keeps the prior art medication delivery pen in a convenient location for the next required medication administration. The medication in the vial will become exhausted after several such administrations of medication. The patient then separates the vial holder from the pen body. The empty vial may then be removed and discarded. A new vial can be inserted into the vial holder, and the vial holder and pen body can be reassembled and used as explained above.

[0007] The above described medication delivery pen is effective and much more convenient for self-administration of medication than the hypodermic syringes that use separate medication vials. However, the above-described medication delivery pens require the user to continually set or reset the desired dose before each injection. As a result, users with impaired vision and fine motor skills have found it difficult to readily set the dose on such pens especially when using a medication delivery pen having a wide range of dosage settings available. Since it is particularly common among patients with diabetes to have complications of the disease causing impaired vision and fine motor skills even more of a

need has been found to address this problem. Hence, it is necessary to provide a medication delivery pen having a simple mechanism for setting the desired dose, repeating the dose when necessary, and priming the medication delivery pen prior to use. It is also important to provide a medication delivery pen that makes the dispensing operation as easy as possible requiring as little force as necessary.

SUMMARY OF THE INVENTION

[0008] The present invention relates to a medication delivery pen that addresses the above-identified problems. The medication delivery pen has a repeat-dose feature that limits motion of the dose control mechanism using an adjustable repeat-dose stop on the dose knob. In addition, the medication delivery pen also provides the user a simple mechanism for setting and correcting the dose and a drive mechanism that makes the dispensing operation as easy as possible requiring as little force as necessary.

[0009] Another feature of the present invention is that the medication delivery pen provides a simple means for retracting the plunger when reloading the medication delivery pen with a new vial.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010]

Fig. 1 is an exploded perspective view of a medication delivery pen according to the present invention.

Fig. 2 is a cross-sectional view of the medication delivery pen shown in Fig. 1 fully assembled and in a ready for use condition.

Fig. 3 is a cross-sectional view of the medication delivery pen shown in Fig. 2 in a set dose condition and ready for dispense of medication.

Fig. 4 is a cross-sectional view of the rod barrel tube shown in Fig. 1.

Fig. 5 is a cross-sectional view of the medication delivery pen shown in Fig. 2 along line A-A.

Fig. 6 is a cross-sectional view of a portion of an alternative medication delivery pen that has a feature that it allows it to be reloadable.

Fig. 7 is a cross-sectional view of yet another medication delivery according to the present invention having means for setting a desired dose and repeating delivery of that desired dose in consecutive injections.

DETAILED DESCRIPTION OF THE INVENTION

[0011] A multi-feature medication delivery pen 10 according to the present invention is shown in Fig. 1. Medication delivery pen 10 includes a cap 11 removably attached to a body 40 so to cover a vial retainer 35 containing a vial 30. As shown in Fig. 2 vial 30 includes a proximal end 31 and a distal end 32 having a vial cap 33 that securely holds a vial septum 34 on distal end 32. Vial 30 also includes a vial piston 39 therein to form a sterile sliding seal within vial 30 to hold medication therein. As shown in Fig. 2 a pen-needle assembly 20 is releasably engaged to a distal end 36 of vial retainer 35. Pen-needle assembly 20 includes a double-ended needle cannula 21 having a distal point 24 and a proximal point (not shown). Double-ended needle cannula 21 is mounted on a hub 23 including means for attaching hub 23 to distal end 36 of vial retainer 35. A proximal end 37 of vial retainer 35 is snap-fit onto a distal end 42 of body 40 or can be mounted thereto by other means, e.g., threads.

[0012] As shown in Figs. 1-3, medication delivery pen 10 includes a rod barrel tube 70, a clicker 90, a lens and ring assembly 60, and a dose knob 50. Rod barrel tube 70 includes a distal end 71 and a proximal end 72, with an outer barrel 73 extending from distal end 71 and surround a rod barrel 74. As shown in Fig. 1 outer barrel 73 may have a pair of openings 75 through its outer surface. Rod barrel 74 includes a set of external threads 76 that mate with a set of internal threads 53 within dose knob 50, described below, and a set of internal threads 77 that mate with a threaded shaft 101 on a plunger 100 having a distal face 102 and a proximal end 105. Plunger 100 also includes a pair of keyways 104 extending from distal face 102 to a keyway stop 103 near proximal end 105. Rod barrel tube 70 also include a plurality of ratchet pawls 78 at distal end 71 that are received within body 40 and engage with ratchet 41 located within body 40 near its distal end 42. Distal end 42 of body 40 also includes a pair of keys 43, shown in Fig. 2, that extend into body 40 to engage with the pair of keyways 104 on plunger shaft 101 of plunger screw 100. Rod barrel tube 70 also includes a window 79 located near its proximal end 72 through which a plurality of dosage numerals 51 printed on dose knob 50 are visible to a user for setting of the desired dose. Dose knob 50 also includes a dose knob cap 54 that is permanently attached to a proximal end 55 of dose knob 50. Dose knob 50 also includes internal threads 53 that engage rod barrel outer diameter threads 76 on rod barrel 74 so that dose knob 50 is threaded out of rod barrel tube 70 as a dose is being set, as shown in Fig. 3. During the dose setting operation rod barrel tube 70 is prevented from rotating within body 40 by interaction of ratchet pawl 78 on rod barrel tube 70 and ratchet 41 within body 40.

[0013] Dose knob 50 also includes a plurality of key slots 52 arranged axially on the outer surface of dose

knob 50 so to receive a matched plurality of keys 91 on the inside of clicker 90 as clicker 90 is mounted onto dose knob 50. Clicker 90 also includes a plurality of clicker fingers 92 on its outer circumference that interacts with a plurality of slots 61 within lens and ring assembly 60. Interaction between clicker fingers 92 and slots 61 occur during the dose setting operation to provide the user with audible and/or tactile feedback during this operation. Lens and ring assembly 60 provide a feature of magnifying the dosage numeral 51 on the outside surface of dose knob 50 to aide the user in setting the dose during the setting operation using lens 62 integrated thereto.

[0014] Dose knob 50 has an enlarged proximal end 55 onto which dose knob cap 54 has been attached and may have a textured surface and/or an indentation to provide easy operator manipulation of dose knob 50 during dose setting of medication delivery pen 10. In addition, it should be appreciated that dose knob cap 54 could be integrally molded at proximal end 55 of dose knob 50.

[0015] Fig. 5 is a cross-sectional view of medication delivery pen 10 shown in Fig. 2 along lines A-A and more clearly show the interaction between the ratchet 41 within body 40 and ratchet pawl 78 at distal end 71 of rod barrel tube 70. Fig. 5 also shows that ratchet pawl 78 at ratchet surface 41 only prevent rotation in one direction so that after a dose has been set as shown in Fig. 3 and pressure is applied to dose knob cap 54 rod barrel tube 70 is free to rotate within body 40. As rod barrel tube 70, rotates interaction between rod barrel internal threads 77 and threaded shaft 101 of plunger screw 100 occurs to move plunger screw 100 in the distal direction a distance corresponding to the desired dose that was set. Plunger screw 100 moves in the distal direction because it is prevented from rotation by interaction of keys 43 in body 40 and keyways 104 on plunger screw 100.

[0016] Fig. 6 is a cross-sectional view of a section of an alternative medication delivery pen that provides the pen with the ability to be reloaded when vial has been filly used and must be replaced. This embodiment is substantially similar to the earlier embodiment except that key 43 within body 40 has been replaced with a plunger screw key 200 that is free to rotate when vial retainer 235 is removed from body 240, but when vial retainer 235 is filly threaded to pen body 240 plunger screw key 200 is prevented from rotating. Plunger screw key 200 includes a proximal face 201 having a plurality of teeth that engage with matching plurality of teeth 244 within body 240. Plunger screw key 200 also includes a shoulder 202 around the circumference that is received in a circumferencial internal diameter clearance slot 245 within body 240 to retain plunger screw key 200 within body 240. Plunger screw 200 also includes a pair of keys 203 that engage keyway 104 and plunger screw 100, discussed above. Interaction between key 203 and keyway 104 prevent plunger screw 100 from rotating when plunger screw key 200 is prevented from rotating because of the interaction between key 204 on plunger screw key 200 and key 244 within body 240 when a proximal end 237 of vial retainer 235 applies sufficient pressure on shoulder 202.

[0017] Fig. 7 is yet another embodiment of a medication delivery pen according to the present invention and, more particularly, shows a feature that allows the user to set a desired dose for repeated delivery. As shown in Fig. 7 this feature is provided by the incorporation into the first embodiment of a dose knob having a distal end 301 and a proximal end 302, wherein proximal end 302 includes a well about its outer surface and a plurality of stop adjuster rotation detents 304 are located within proximal end 302 of dose knob 300. A stop adjuster 310 includes a distal end 311 and a proximal end 312 with distal end 311 being inserted into circumferencial well 303 in dose knob 300. Stop adjuster 310 also includes a set of external threads 313 and a plurality of stop adjuster rotational detents 314 within an inner surface that engage with corresponding stop adjuster rotational detents 304 on dose knob 300. Stop adjuster rotation detents 304 and 314 provide the user with tactile feedback during the operation of setting the repeat dose.

[0018] A dose stop 320 includes a plurality of dose stop keys 321 extending radially from dose stop 320 and a set of internal threads 322 that engage with outer threads 313 on stop adjuster 310. A dose knob cap 330 is attached to dose knob 300 after stop adjuster 310 has been mounted on dose knob 300 to retain stop adjuster 310 thereon. In addition, dose knob cap 330 can provide a textured surface and/or indentations for use during dose setting, as described above.

[0019] After a dose has been set by the user, the user would rotate stop adjuster 310 to move dose stop 320 in a proximal direction until a proximal face 323 of dose stop 320 comes into contact with a distal face 393 on a clicker 390. Of course, clicker 390 provides the same features and functions as clicker 90 in the earlier embodiment. Rotation of stop adjuster 310 cause dose stop 320 to move because of interaction between internal threads 322 and stop adjuster outer diameter thread 313 and interaction between dose stop key 321 and a dose knob keyway 305 on dose knob 300. When dose stop is in the position desired by the user further proximal movement of the dose knob is prevented beyond the set desired dose. Dose stop 320 remains in the position it has been set to until change at a later point by the user via stop adjuster 310.

[0020] While the present invention has been described with respect to a preferred and a number of alternative embodiments, it is apparent that various changes can be made without departing from the scope of the invention as defined by the appended claims.

Claims

1. A medication delivery pen comprising:

a pen-needle assembly;

a vial retainer including a vial containing a medication to be delivered and having said pen-needle removably attached to a distal end;

a housing having said vial retainer mounted to a distal end and including;

a dose control mechanism for setting a desired dose to be delivered from the vial;

a drive mechanism for dispensing the desired dose from the; and

a rod barrel tube for interfacing said dose control mechanism with said drive mechanism.

2. A medication delivery pen according to Claim 1, wherein said rod barrel tube includes an outer thread for engaging said dose control mechanism and an inner thread for engaging said drive mechanism.

3. A medication delivery pen according to Claim 1, further comprising means for preventing rotation of said rod barrel tube and said drive mechanism when said dose control mechanism is being used to set the desired dose.

4. A medication delivery pen according to Claim 3, wherein said means for preventing rotation of said rod barrel tube and said drive mechanism includes a ratchet mechanism between said housing and said rod barrel tube to prevent rotation of said rod barrel tube and said drive mechanism within said housing when said dose control mechanism is being used to set the desired dose.

5. A medication delivery pen according to Claim 1, further comprising a means on said rod barrel tube for displaying the dose set by said dose control mechanism.

6. A medication delivery pen according to Claim 5, wherein said means for displaying the dose includes a window within said rod barrel tube.

7. A medication delivery pen according to Claim 1, further comprising means within said housing for resetting said drive mechanism when a new vial is loaded into said vial retainer.

8. A medication delivery pen according to Claim 1, further comprising means for repeating the desired dose.

9. A medication delivery pen according to Claim 8, wherein said means for repeating the desired dose includes an adjustable repeat dose stop in said dose control mechanism that limits axial motion of said dose control mechanism when setting the desired dose.

10. A medication delivery pen according to Claim 9,

wherein said dose control mechanism includes a dose knob, and

wherein said adjustable repeat dose stop is mounted in said dose knob to limit motion of said dose knob when repeating the desired dose.

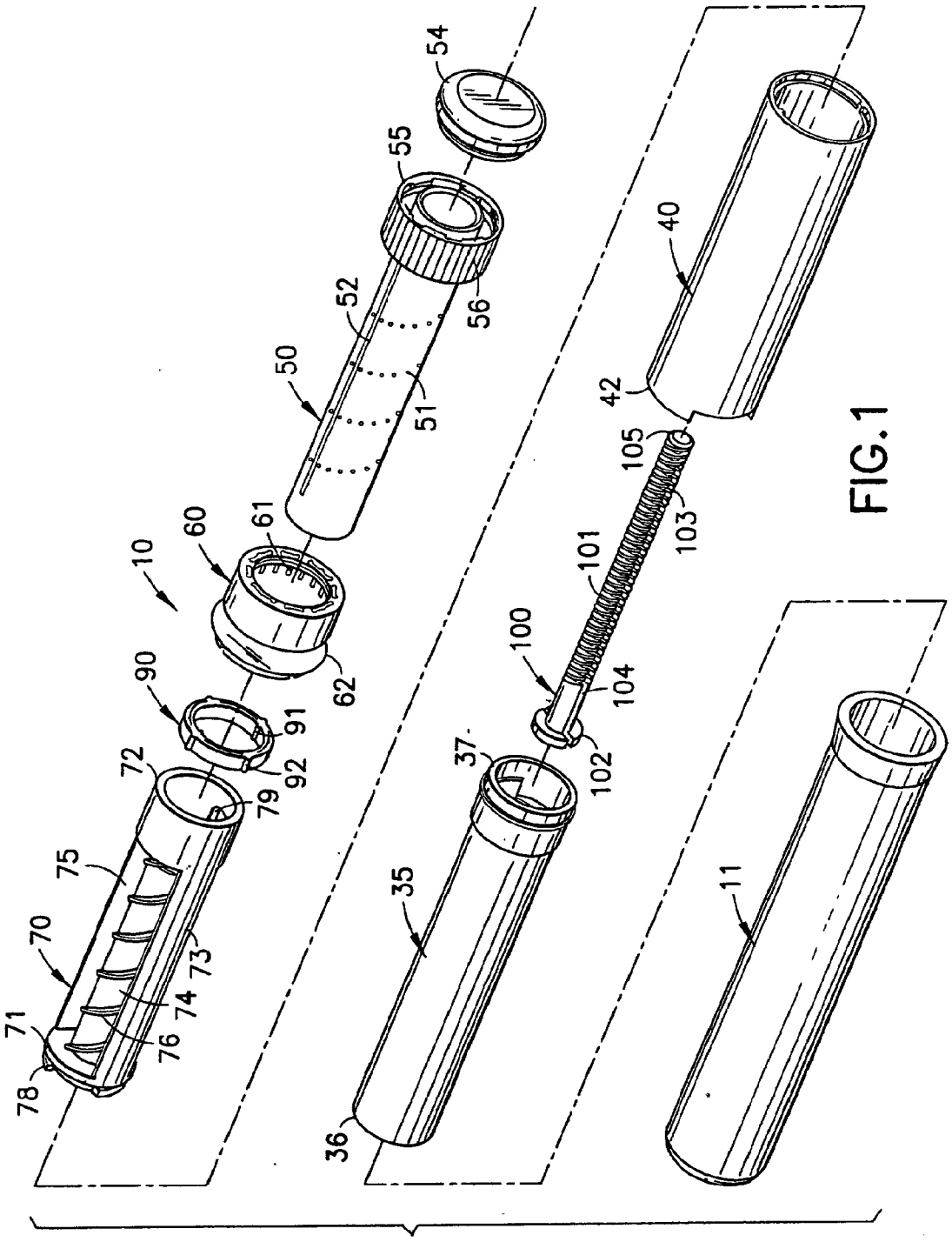


FIG.1

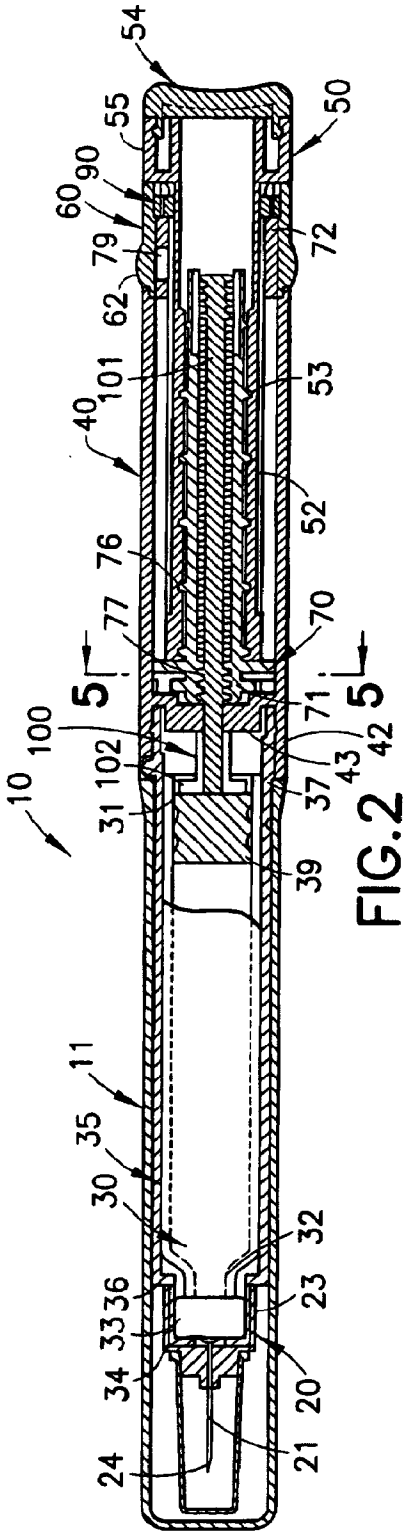
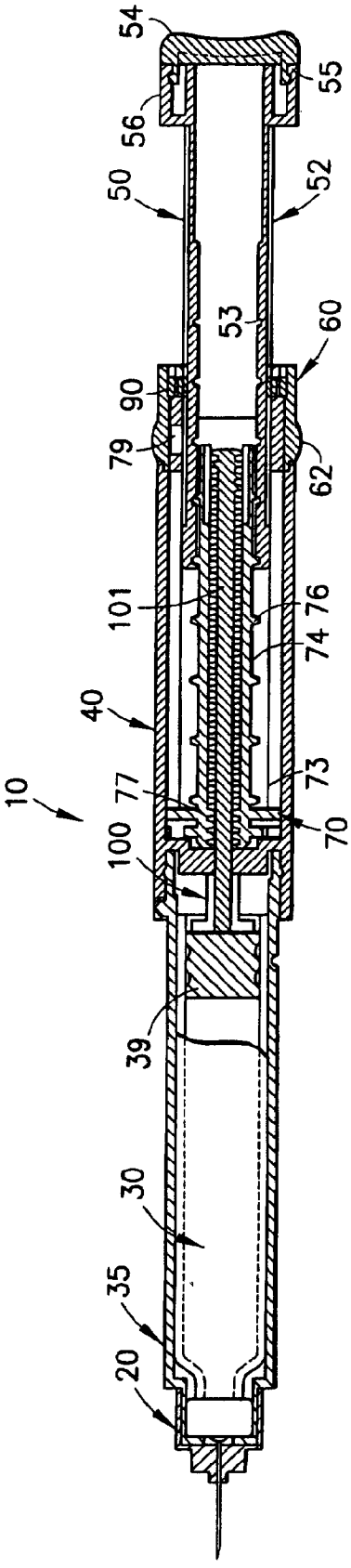


FIG.2



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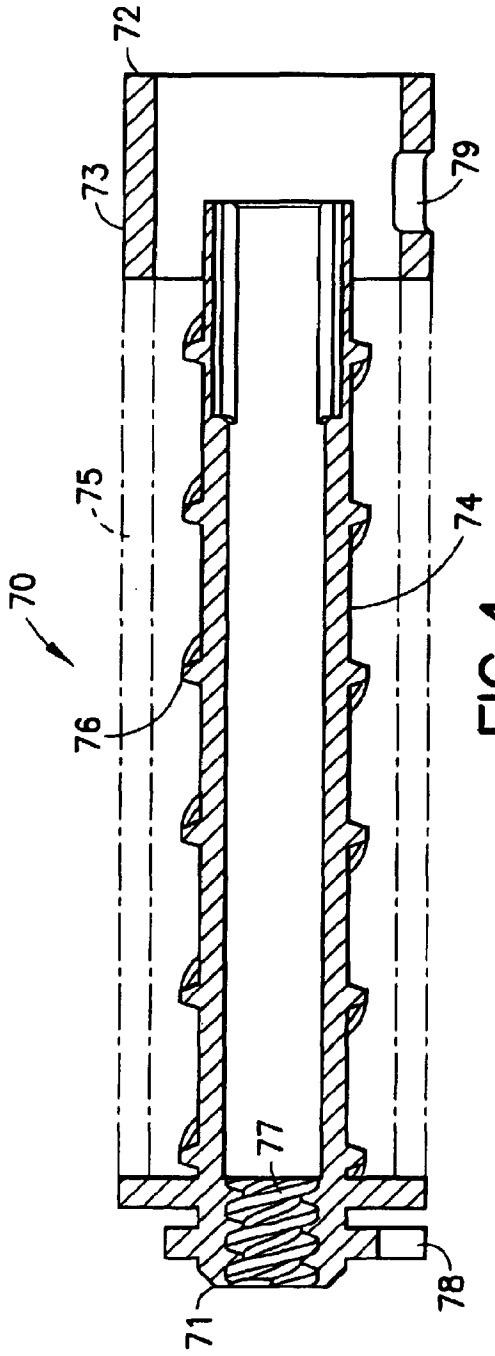

FIG.4

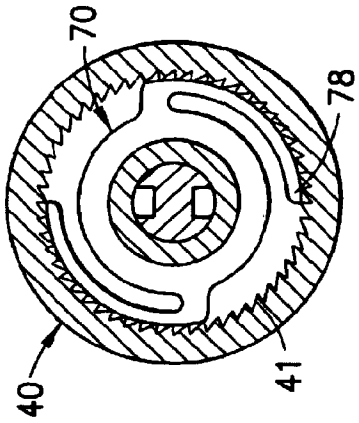

FIG.5

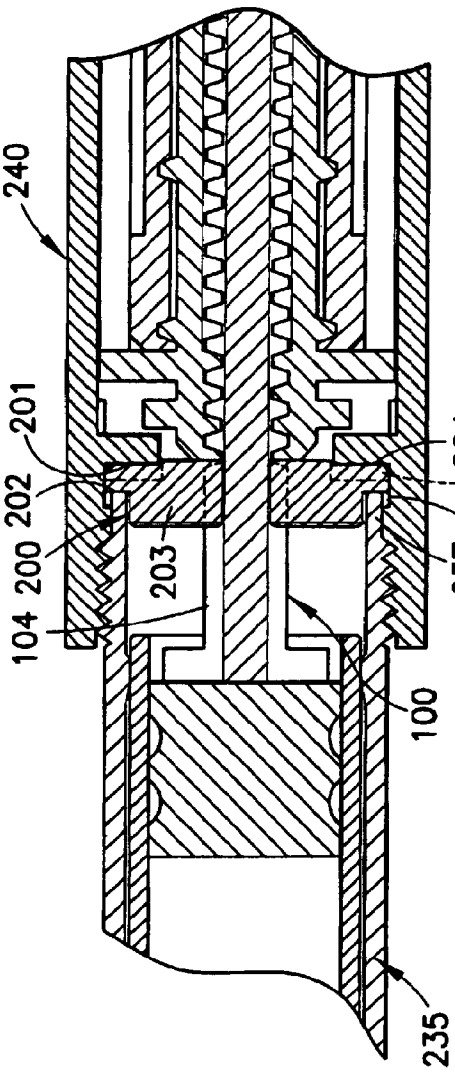

FIG.6

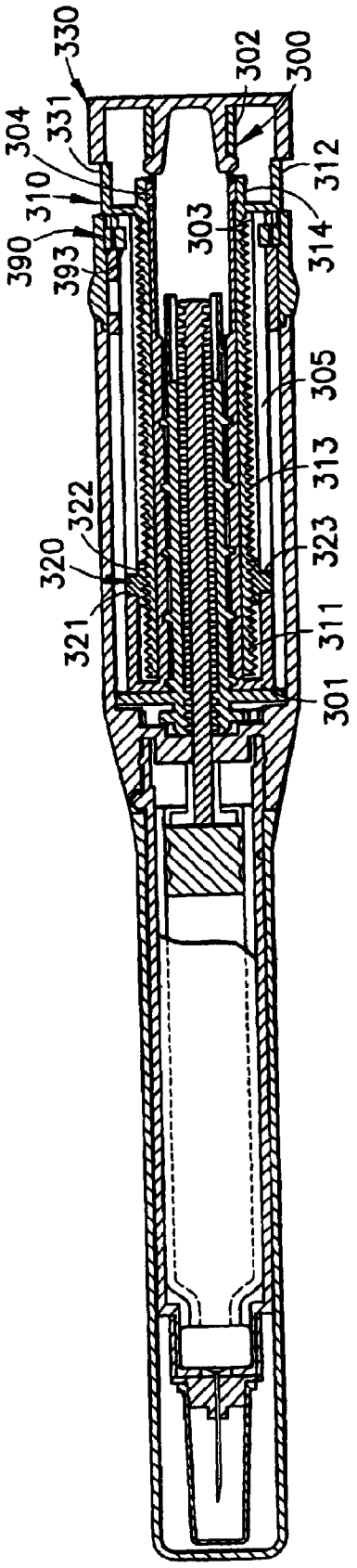

FIG.7

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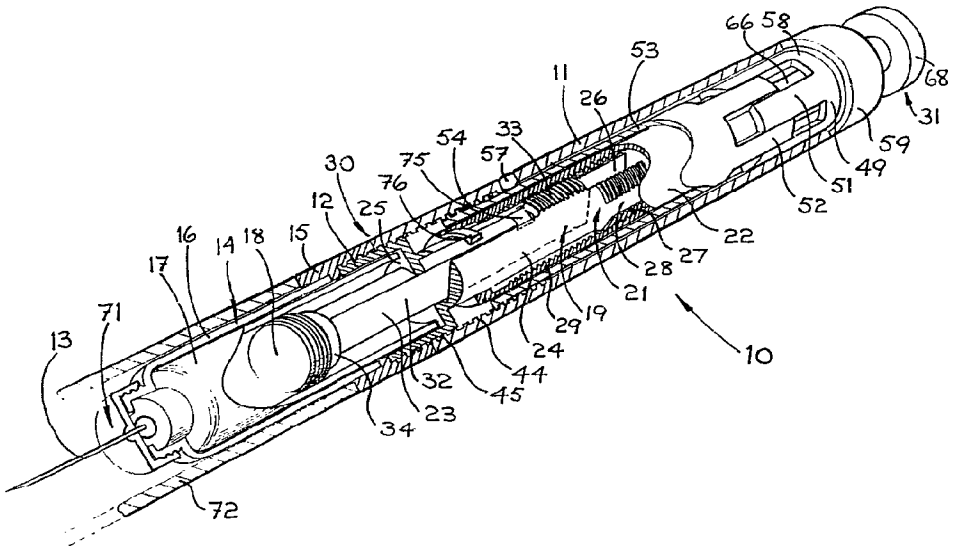
(54) Title: DISPENSING DEVICE

(57) Abstract

A dispensing device has a shell (11) which may be connected to a container (14) for a fluid to be dispensed, such as an injectable pharmaceutical compound. The device has a fixed first threaded member (21) and a second threaded member (22) surrounding the first member, the first and second members each having equi-spaced threaded segments (27 and 29) with non-threaded segments (28) therebetween whereby the second member will be wound axially when rotated about the first member but may be positioned for axial sliding movement with respect to the first member. A plunger (23) is slidably mounted within the first member (21) and has a portion (33) engageable with the threads of the second member. A dose setting sleeve (53) surrounds the second member and has threads (54) engaged with the device shell, the sleeve being coupled to the second member for rotation therewith. A dose is set by winding the second member (22) away from a fixed stop (25) until the sleeve (53) indicates the required dose amount, whereafter the second member (22) is slid axially back to the fixed stop (25), the plunger (23) being thrust forwardly thereby to expel fluid from the container.



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DISPENSING DEVICE

The present invention relates to a dispensing device which is arranged to dispense an accurate and measured dose of a fluid. Typically such a fluid may be one which is itself or which contains a therapeutically or otherwise active compound or composition, such as insulin.

European Patent Specification No. 0,037,696 A discloses a dispensing device suitable for use in dispensing a predetermined quantity of material from a container comprising a tubular body member having an outlet at one end, and a plunger slidably movable in said body member towards said outlet. The dispensing device comprises an elongate body having a chamber for receiving a container with its outlet held in a first end portion of the elongate body, and a first drive member mounted in said body for use in driving said plunger. In the disclosed device said first drive member is slidably mounted for driving engagement via a unidirectional drive transmission with a second drive member having a free end drivingly engagable with said plunger of the container. In that manner said second drive member and said plunger can be driven by the first drive member via said unidirectional drive transmission means only in a direction towards the container outlet and the first end portion of the elongate body whilst permitting return movement of the first drive member. Preferably, the unidirectional drive transmission comprises a ratchet means.

For setting the dose to be dispensed the adjust knob is turned to align a pin with one of a series of channels of varying length (dependent on the size of dose required) in the push button (or vice versa). The length of the channel dictates the movement forward of the plunger and the multiple of doses is decided by how

many channels one can safely have around the circumference consistent with side walls to each channel and the size of the readout on the circumference.

A usable diameter gives eight variable doses. One could increase the diameter to give more channels and more variations of dose. However, the device would become more and more unwieldy as the number of channels is increased.

Another serious fault with this device is that it is easy to pump the push button so that the plunger moves forward without the pin ever reaching the bottom of its channel. This is unsafe.

European Patent Specification No. 0,295,075 A relates to a device for dispensing a fluid from a container by means of the axial movement of a piston within the container under the influence of a plunger moved by the device. The device is adapted to receive the container at its forward end and to move the plunger axially forward towards the container so as to dispense a selected amount of fluid from the container upon each actuation of the device. The device comprises a drive mechanism adapted to be reciprocated axially of the device and to be positively engaged with the plunger for the forward stroke of the drive mechanism so as to prevent relative movement between the plunger and the drive mechanism and to move the plunger forward. The drive mechanism requires a positive action to disengage it from the plunger so as to permit relative movement between the plunger and drive mechanism for at least rearward movement of the drive mechanism. Also, the forward travel of the drive mechanism is limited by a fixed stop mechanism and the extent of the forward stroke of the drive mechanism is individually selectable for each actuation of the device by withdrawing the drive mechanism or a part

operatively associated therewith a selected distance from the said fixed stop.

The device of EP-0,295,075 A is designed to give a maximum of 36 units of insulin. For dose setting opposed jaws are pulled back in a slot by rotating a screw, the length of slot being determined by the length of the movement forward of the plunger at maximum dose. A larger dose means a longer slot and a corresponding lengthening of the device. In addition, to wind back the screw for an additional dose means a lengthening of the screw in the main body, thereby adding another additional dose length to the device. Also, in line with the jaws and screw is the readout which needs an additional dose length and a corresponding increase in body length. Thus, there is a ratio of 3:1 between body length and plunger length, which means that each time the does is increased there is an additional three millimetres of body length for every millimetre of plunger length necessary to give the higher dose setting.

In prior art dispensing devices, such as those outlined above, the usual dispensing increment is 2 units, but the amount dispensed for a given standard length of device is limited. Thus, in the case of a patient wishing to use a relatively large dose it may be necessary to use the device twice or even more times, each time to dispense a smaller dose.

This invention aims at overcoming the above-mentioned problems of the described prior art devices, and in particular at providing a dispensing device which can dispense relatively large doses and yet which has a body length to plunger length ratio of about 1:1.

Accordingly, in one aspect the present invention provides a device for dispensing a controlled amount of fluid from a container, which device comprises a device for dispensing controlled doses of fluid from a

container having a piston movable axially in increments thereby to dispense doses of fluid from an outlet of the container, which device comprises means to connect the device to a container, a plunger engageable with the container piston, and a dose setting and dispensing arrangement having first and second threaded members, the first member being fixed in relation to the device and the second member being mounted for rotation about the first member and having threads engageable with those of the first member, the plunger being slidably mounted within the first member and having a portion engageable with the threads of the second member, and the second member being rotatable to any one of a plurality of settings where its threads are engaged with said portion of the plunger but free of the first member whereby the second member and plunger may slide axially relative to the first member, movement of the second member in a direction towards the container connection means being limited by a fixed stop, the device further comprising dosage indicator means connected to the second member and arranged to indicate an ascending series of measured doses as the second member is rotated to move along the threads of the first member away from said fixed stop whilst the plunger remains stationary, and for each indicated dose the second member is disposed in one of its said settings relative to the first member where axial movement of the second member is permitted, the second member during such movement driving the plunger to act on the piston of a connected container and the dose expelled thereby being controlled by the axial distance of travel of the second member to the fixed stop from the position to which said member has been turned to indicate a desired dose.

The device of the invention is generally intended to be used as a hand portable device and preferably as

the dose dispensing portion of a syringe. Typically, such a syringe is of the kind used by diabetics to dispense insulin on a regular daily basis, but of course may be used by other patients and for other situations.

For use as a syringe the device is connected to a container provided with a reservoir of fluid which either itself may be an active material or may be the carrier for and contain an active material. The container at its outlet end typically may include connection means for a hypodermic needle and at its opposite end may include means for connection to the connecting means of the device. The latter means may comprise a threaded portion or a bayonet fixing arrangement. Known containers are generally tubular, and adapted to receive a fluid cartridge having a piston moveable therein.

The device preferably includes a cylindrical shell in which is fixed the first member, and within which the second member may rotate about the first member. The first member may be threaded externally with a plurality (and preferably four) of equi-spaced threaded arcuate sectors separated by a like plurality of non-threaded sectors. In this case, the second member should comprise a hollow cylinder threaded internally with threaded and non-threaded sectors arranged in essentially the same configuration as that of the first member. The second member will thus be free of the first member and free to move axially at some rotational dispositions, but at others will be engaged with the first member and so moved axially on being turned. To allow re-engagement of the respective threads when the second member has been moved axially to the fixed stop, the threads are preferably of multi-start form, advantageously of the same number of starts as threaded sectors. It will (of course) be understood

that other numbers of threaded and non-threaded sectors besides four may be used as desired, and that the invention is not limited to the described four.

In the above arrangement the second member may be wound backwards and forwards on the first member, but may be disposed relative to the first member to have their respective threads disengaged, whereby the second member is slidable axially of the first member and device shell.

The plunger is preferably slidably received within a slot in the first member, said portion engageable with the threads of the second member projecting through a non-threaded sector of the first member.

Said portion of the plunger may comprise one of an arcuate threaded portion of the same thread form as that of the second member. Alternatively, said portion may comprise a toothed wheel rotatably mounted on the plunger and having teeth formed to be engageable with the threads of the second member. Axial sliding movement of the second member will thus also slide the plunger by virtue of the interengagement of said plunger portion with the second member threads. Where said portion comprises a simple thread, the plunger will move together with the second member, but in the case of the said portion comprising a toothed wheel, a rack may be formed on a fixed part of the device and with which the wheel meshes, so that the wheel rotates on axial movement of the plunger; then the plunger will move through one half of the axial sliding movement of the second member as the wheel rolls along the rack.

Dose setting and dispensing is performed by initially winding the second member away from the fixed stop, the plunger remaining stationary, until the second member is spaced from that stop by some predetermined instance. The second member is set to permit axial sliding movement and is then slid back to

contact the fixed stop. During this, the plunger is thrust forward, so driving the cartridge piston and dispensing the required, set dose.

In order to permit the selection of a required dose, and so the distance from the fixed stop to which the second member is wound, the second member is linked to a dosage indicator means. Such means may comprise a sleeve carrying an ascending series of dose numbers, the sleeve being arranged to be threaded along the device shell as the second member is rotated, whereby the more the second member is threaded away from the fixed stop, the higher will the indicator dose number.

For each dose displayed by the indicator means, the second member is advantageously in one of its settings where its threads are disengaged from those of the first member. At each displayed dose, axial movement of the second member and linked plunger is permitted, to dispense the displayed dose by the plunger acting on the cartridge piston.

Said sleeve preferably has external threads engaged with internal threads on the device shell, said threads being of the same pitch as those of the first and second members so that the sleeve and second member move the same axial distance on each rotation thereof. A rotatable but axially fixed dose control knob may be provided linked to said sleeve and the second member by a splined connection.

In the device of the invention, the indicator means is preferably linked to the second member through a clutch arrangement. This conveniently is a form of dog-clutch having a like number of dogs and recesses as threaded sectors on the second member. After dispensing a set dose, the indicator sleeve may be wound back to zero, the dog clutch picking up the second member as the sleeve returns to its zero position, ready to be wound out together with the

second member to set a new dose.

Preferably lock means are provided to restrain rotation of the second member in a sense which moves the second member away from the fixed stop when the plunger projects from the second member by more than a pre-determined amount. Thus, should a user try to set a dose greater than that remaining in a cartridge connected to the device, the second member will be locked at the maximum possible dose from the connected cartridge, the indicator means indicating (at lock) the amount of that dose.

This invention extends to the combination of a dose dispensing device as described above in combination with a body defining a chamber for receiving a container for fluid, support means for a dispensing needle communicating with an outlet from the container. Such a combination may take the form of a medical syringe, typically for dispensing medications such as insulin.

By way of example only, specific embodiments of the device of the invention will now be described by way of example only and with reference to the accompanying drawings, in which:

Figure 1 is a cut-away perspective view of a dispensing device according to the invention;

Figure 2A is a cut-away perspective view from the rear of the device of Figure 1;

Figure 2B is a sectional view on the rear of the device;

Figures 3A and 3B are diagrammatic section views showing the cooperation between first and second threaded members and a plunger, firstly when set for dispensing and secondly after dispensing a dose;

Figures 3C and 3D are views similar to those of Figures 3A and 3B, but of a second embodiment of plunger having a toothed wheel;

Figures 4A and 4B are exploded perspective views respectively of the arrangements of Figures 3A and 3B, and of Figures 3C and 3D; and

Figures 5A and 5B show a lock which limits the rotation of the second threaded member.

Referring to Figure 1, the device 10 comprises a main body shell 11 which includes at its front end a threaded connector 12 by means of which the shell may be connected to a container 14 having a connector portion 15, to hold the device 10 and the container 14 in a fixed relationship. The container 14 is of known type comprising an outer protective plastics housing 16 in which is received an inner glass cartridge 17 having a captive piston 18 and containing the fluid to be dispensed (not shown) out of a hypodermic needle 13.

Within the body shell 11 there is a dose setting and dispensing arrangement 19 comprising first and second threaded members 21 and 22, and a plunger 23. First member 21 comprises side elements 24 held by ring 25 in a fixed relationship to form a slot 26 in which is slidable the plunger 23. The ring 25 is formed integrally with connector 12, which serves to hold member 21 in a fixed relationship to the shell 11.

Each element 24 comprises upper and lower threaded segments 27 separated by a non-threaded channel 28 so that member 21 overall comprises four threaded segments 27, each separated by one of four plain non-threaded segments as provided by channels 28 and slot 26.

First member 21 carries on its threaded segments 27 the second member 22 which is a hollow cylindrical collar having four threaded inner segments 29 the configuration of which matches that of the threaded segments 27. Thus, the member 22 may be wound e.g. towards the rear end 31 of the device 10, upon rotation of member 22, by the interengagement of the threaded segments 27 and 29, but that member 22 also

may slide e.g. towards the front end 30 of the device 10, when opposed threaded segments 29 are in register with channels 28. In the arrangement shown, each 90° of rotation of member 22 initially moves member 22 axially by the interaction of its threaded segments 29 with segments 27 of member 21, and then segments 29 come into alignment with the non-threaded portions of member 21, allowing member 22 to be pushed forwards or backwards with respect to member 21. The depth of the channels 28 thus need be only sufficiently deep to give clearance for the threaded segments 29 of member 22.

It would be possible to configure the members 21 and 22 with different numbers of threaded segments to permit sliding movement at positions other than at 90° spacings, and any suitable number of positions may be employed as desired.

Plunger 23 is elongate, as shown, and includes flat sides 32 which enable it freely to slide axially in slot 26. The plunger 23 has an upper threaded segment 33 which together with segments 27 form an arcuate thread on which member 22 is carried. However, when the device is in the dose dispensing mode where segments 29 are free of segments 27, segment 33 remains meshed with a segment 29 of the member 22, whereby forward movement of member 22 towards the fixed stop ring 25 carries the plunger 23 forward, to ensure that the correct measured dose is dispensed. The forward end 34 of the plunger 23 acts on the piston 18, to move the piston 18 within cartridge 17 and dispense the required dose.

When the member 22 is pushed forward to hit the stop ring 25, the member 22 will be in one of four rotational positions spaced by 90° (or some other number for different configurations). In order to pick up the threads on member 21 at each of the four possible positions of member 22 at the stop ring, the

thread helix should have a like number of starts as possible positions, and the threaded segment 33 of plunger 23 must have the same thread pitch. Therefore, in the preferred case of four possible positions spaced by 90°, a four start thread form should be used; and each 90° turn on the member 22 will move it a pre-set axial distance corresponding to one dose for the cartridge 17, on moving the piston 18 the same distance.

The front end 30 of shell 11 includes threads 44 into which connector 12 (which is part of member 21) is permanently screwed via its threads 45. Alternatively, the threads 45 may be omitted, the connector 12 being secured in place by other means, such as an adhesive.

To provide a visual indication of a dose set by winding member 22 away from the stop ring 25, the device includes a cylindrical shell 49 having a number of splines 51. These splines 51 mesh with and rotatably drive splines 52 on a rotating indicator sleeve 53, whilst allowing relative axial movement therebetween. Any suitable number of splines may be provided, and typically 2, 4, 6 or 8 splines may be furnished.

Indicator sleeve 53 surrounds with clearance member 22, and has on its outer surface a helical thread 54 which corresponds to and meshes with thread 44 at the front end 30 of shell 11. These threads have the same lead as the threads of the members 21 and 22, such that one full turn of sleeve 53 gives the same axial movement as one turn of member 22. Carried on the outer surface of the indicator are a multiplicity of numbers such as 0 to 52 in steps of 2 (i.e. 0, 2, 4, 6, etc. up to 52), or 0 to 26 in steps of 1 (i.e. 0, 1, 2, 3 etc. up to 26). Those numbers can be viewed through a window 57 in the shell 11.

Indicator sleeve 53 at its end most remote from

container 14 is prevented from moving beyond the position at which it indicates the highest reading (say 52 or 26) through window 57 by the bottoming of the splines 51 and 52 in the shell 49 and indicator 53, respectively. Ring 58 is part of shell 49 and acts both as a stop for rearward movement of sleeve 53, and as a mounting for a rotatable end piece 59 which provides a dose setting control knob. End piece 59 is held on shell 49 by a retention lip 60, and splines 61 on end piece 59 engage splines 62 on shell 49 (as shown in Figures 2A and 2B), whereby a required dose can be set to appear in window 57 by gripping end piece 59 between finger and thumb and rotating it. The turning movement is transmitted via spines 51 and 52 to indicator sleeve 53, to move the shell 53 on threads 54 and 55 either towards the front end of the device or away from that end, to show various dose numbers through window 57. The extent of forward movement towards the front end (zero reading) is limited by member 22 engaging stop 25.

At its end most remote from container 14, sleeve 53 includes a ring 63 (Figure 2) on which are formed two or preferably four sprung raised blocks 64, through other numbers of such blocks could be provided. The ring 63 includes a central circular through-aperture 65 which carries stem 66 of a pusher including an outer button 68 for performing actual dose dispensing when pushed to move stem 66 towards the front end of the device 10. The sprung blocks 64 may cooperate with four recesses 69 on the outer face 70 of member 22. There are the same number of recesses 69 on the face 70 as thread starts - namely four, at 90^{o} spacings in the case of a four-start thread, as illustrated.

A ball 80 is positioned in an opening in the end face of the cylindrical shell 49, which ball is urged rearwardly by spring blade 81 and may be partially

received in a recess 82 in lip 83 of the outer shell 11. For the described embodiment, four equi-spaced recesses are provided, to give four click-stop positions on each dose-setting turn of end piece 59.

In use, a fresh cartridge 17 containing a fluid to be dispensed (for example, insulin) is placed in container 14, and the container is connected to the device 10 via the threaded connector 12 of member 21. The captive piston 18 is of a sufficiently tight fit in cartridge 17 so that as the container is fitted, the piston bears on the front end 34 of plunger 23 and slides the plunger back in slot 26. Alternatively, plunger 23 may be pushed back by hand. To the front end of the container 14, at the outlet to cartridge 17, there is attached a needle arrangement 71, usually with a safety cap in place (not shown). Also, an additional or alternative safety cap 72 may cover the combination of needle arrangement and container.

For the purpose of dispensing a measured dose the device is set to dose zero by winding end piece 59 clockwise until indicator 53 is wound forward sufficiently to indicate "0" through window 57. In that configuration, blocks 64 engage with recesses 69 of face 70 and button 68 abuts or is closely adjacent end piece 59.

If a dose had fully been dispensed beforehand, member 22 rests on ring 25, whilst sleeve 53 still shows the set dose. The sleeve is wound clockwise by turning end piece 59, which drives the sleeve through splines 51 and 52, advancing the sleeve towards the front. As the blocks 64 protrude by a lesser dimension than the axial motion of member 22 when turned through 90°, re-engagement of the blocks 64 in recesses 69 takes place during the last 90° of movement of sleeve 53 to show "0" through window 57, so re-establishing a connection between member 22 and sleeve 53.

If the dose had not fully been dispensed, turning the end piece 59 will pick up member 22, and thread it forward before the sleeve 53 is reset to "0" by the action of the blocks 64 engaging in recesses 69.

When the member 22 bears on ring 25 and the blocks 64 are engaged in recesses 69, end piece 59 can be turned anti-clockwise to set a new dose to be dispensed.

Dose control knob (end piece 59) is turned anti-clockwise, this motion being transmitted to shell 49 through splines 61. Then, via splines 51 and 52, the dose indicator sleeve 53 is moved helically within the main body shell 11. The pitch on the threads 44 and 54 are the same as the lead on the four-start threads on the members 21 and 22 and plunger 23, and as the sleeve 53 rotates, it moves axially with member 22 and shows successive numbers corresponding to the dose being set by member 22. The numbers are arranged in staggered columns as shown in Figure 2 so that for each dose indicated the member 22 is set with its threaded segments 29 aligned with channels 28 and spaced from the fixed stop ring 25 by such a distance that corresponding movement of the piston 18 transmitted via the front end 34 of plunger 23 dispenses the indicated dose through the needle 13. Member 22 is then thrust forward by pressing button 68, stem 66 bearing on face 70 of member 22.

Referring now to Figures 3A and 3B, these show the arrangement of the two threaded members 21 and 22 and plunger 23 with threaded segment 33. In Figure 3A, member 22 is wound back on member 21 and plunger 23 to the position shown. Figure 3B shows the position of plunger 23 when member 22 is pushed forward by button 68 (not shown). This shows that the forward movement of member 22 gives an equivalent forward movement of plunger 23. The members and plunger are shown in

Figure 4A with member 22 sectioned and displaced from fixed member 21 and plunger 23, for clarity.

In the alternative arrangement shown in Figures 3C and 3D, the threaded segment 33 of member 23 is replaced by a toothed wheel 73 having a helically-formed teeth the pitch of which is the same as that of the threads on member 21. In the base of slot 26 of member 21 is a section of thread which is the same pitch form as the threads on members 21 and 22. In Figure 3C, member 22 is shown wound back on member 21 and wheel 73; in Figure 3D member 22 is shown pushed forward. Because wheel 73 rolls between the moving thread 29 of member 22 and the fixed thread 74 of member 21, the plunger 23 is moved forward half the distance travelled by member 22. Thus for the same dose setting arrangement as already described above, either half doses may be dispensed for each dose setting or, more importantly, if a larger (usually wider) cartridge is employed, similar doses to those of narrower cartridges can be dispensed by halving the forward movement of the plunger.

Figures 5A and 5B show a stop arrangement for the second member 22, to prevent that member being turned to select a greater dose than remains for dispensing within the container. The member 22 has four pawls 76 arranged on its front end and which bear on the outer surface of the first member 21 or on the upper surface of the plunger 23, as the member 22 is rotated. The plunger has a recess 75 on its upper surface adjacent its threaded segment 33, into which recess one of the pawls 76 will drop to restrain further rotation of the member 22 in a dose-setting sense when the plunger has been advanced by a pre-determined distance into a container. The splines 61 connecting the end piece 59 to member 22 may be arranged to slip in the event that a pawl 76 locks member 22; once this occurs, member 22

has to be wound back through 45° to release the lock, so that the plunger 23 can be pushed back without also pushing back member 22. Should however member 22 be pushed back as well on replacing cartridge 17, the user need merely wind the member 22 until "0" is showing once more through window 57, to reset the mechanism. It will be appreciated that at the point at which the lock occurs the dose indicator sleeve 53 will show the number of doses remaining in the cartridge.

CLAIMS

1. A device for dispensing controlled doses of fluid from a container having a piston movable axially in increments thereby to dispense doses of fluid from an outlet of the container, which device comprises means to connect the device to a container, a plunger engageable with the container piston, and a dose setting and dispensing arrangement having first and second threaded members, the first member being fixed in relation to the device and the second member being mounted for rotation about the first member and having threads engageable with those of the first member, the plunger being slidably mounted within the first member and having a portion engageable with the threads of the second member, and the second member being rotatable to any one of a plurality of settings where its threads are engaged with said portion of the plunger but free of the first member whereby the second member and plunger may slide axially relative to the first member, movement of the second member in a direction towards the container connection means being limited by a fixed stop, the device further comprising dosage indicator means connected to the second member and arranged to indicate an ascending series of measured doses as the second member is rotated to move along the threads of the first member away from said fixed stop whilst the plunger remains stationary, and for each indicated dose the second member is disposed in one of its said settings relative to the first member where axial movement of the second member is permitted, the second member during such movement driving the plunger to act on the piston of a connected container and the dose expelled thereby being controlled by the axial distance of travel of the second member to the fixed stop from

the position to which said member has been turned to indicate a desired dose.

2. A device according to claim 1, configured as the dose dispensing portion of a medical syringe, which device is adapted for connection to the body of the syringe, with the plunger acting on the syringe piston.

3. A device according to any of the preceding claims, wherein the first member is threaded externally with a plurality of equi-spaced threaded arcuate sectors separated by a like plurality of non-threaded sectors, and the second member comprises a hollow cylinder threaded internally with threaded and non-threaded sectors arranged in essentially the same configuration as that of the first member.

4. A device according to claim 3, wherein the first and second members each have four threaded and four non-threaded sectors, and the threads of both members are four-start threads.

5. A device according to claim 3 or claim 4, wherein the plunger is slidably received within a slot in the first member, said portion of the plunger projecting through a non-threaded sector of the first member to be engageable with the threads of the second member.

6. A device according to any of the preceding claims, wherein said portion of the plunger comprises one of an arcuate threaded portion or a toothed wheel rotatably mounted on the plunger whereby the threads of the second member may mesh with the teeth of the wheel.

7. A device according to claim 6 and wherein said plunger portion comprises a toothed wheel, there being a rack formed on a fixed part of the device and with which the toothed wheel meshes, so that the wheel rotates on axial movement of the plunger.

8. A device according to any of the preceding claims, which includes an actuation member at its end opposed to the container connection means and arranged to move

the second member and linked plunger axially towards the fixed stop, the actuation member moving with the second member away from the fixed stop during dose setting.

9. A device according to any of the preceding claims, wherein the indicator means comprises a rotatable sleeve surrounding the second member and carrying a series of dose numbers, and rotation means to rotate the sleeve and the second member so that the more the second member is threaded away from the fixed stop, the higher will be the indicated dose number.

10. A device according to claim 9, wherein co-operating threads are formed on the sleeve and on a fixed part of the device whereby the sleeve is moved axially as it is rotated.

11. A device according to any of claims 8 to 10, wherein there is provided a rotatable dose-setting piece linked through a sliding connector to the indicator means and the second member to effect rotation thereof whilst permitting axial movement of the indicator means and second member.

12. A device according to any of the preceding claims, wherein lock means are provided to restrain rotation of the second member in a sense which moves the second member away from the fixed stop when the plunger projects from the second member by more than a pre-determined amount.

13. A medication dispensing device comprising a body defining a chamber for receiving a container for fluid, support means for a dispensing needle communicating with an outlet from the container, and a dispensing device according to any of claims 1 to 12, the body having connection means interengageable with the connection means of said device and the plunger of the device being arranged to contact the piston of a received container.

1/4

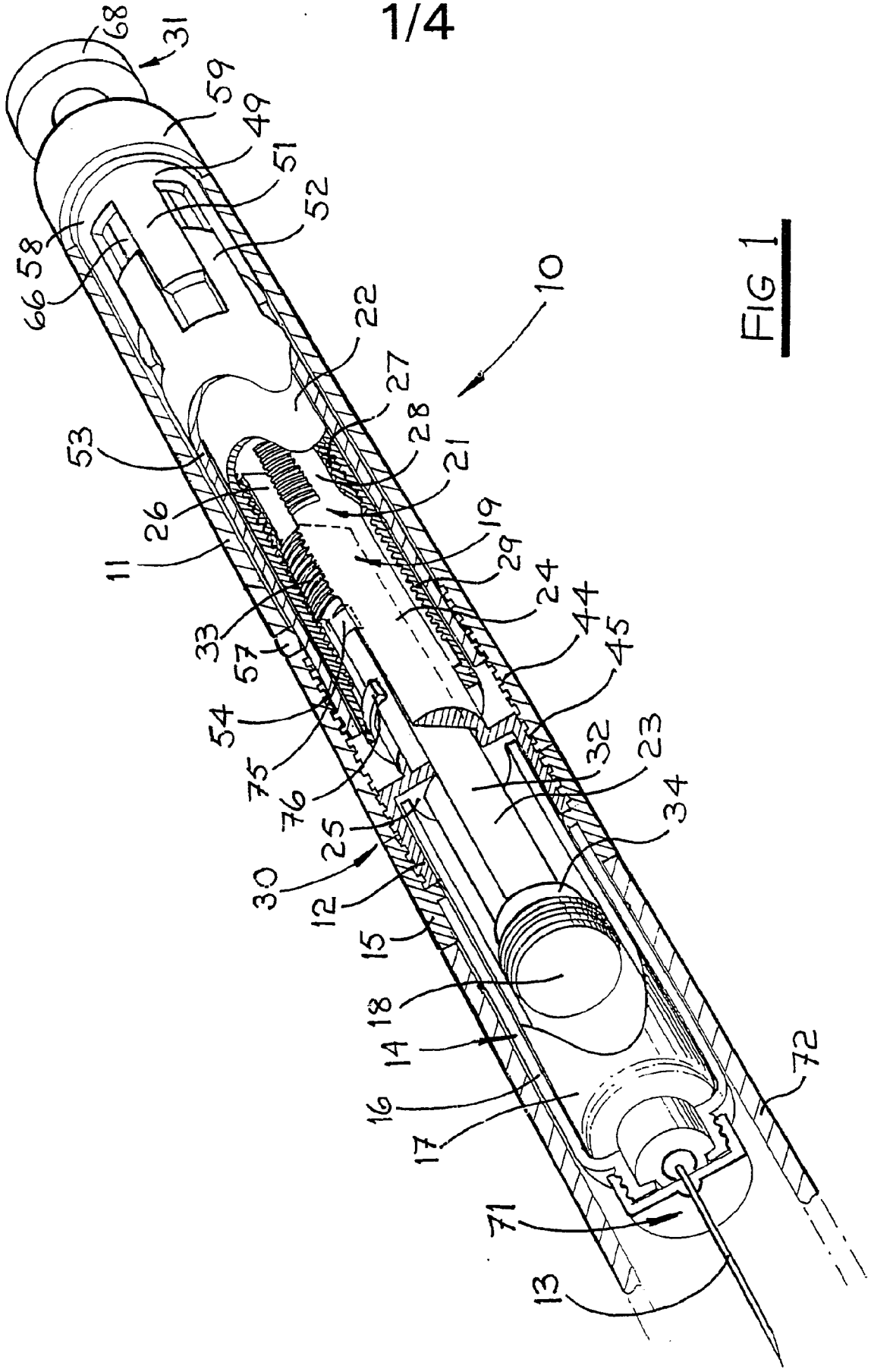

FIG 1

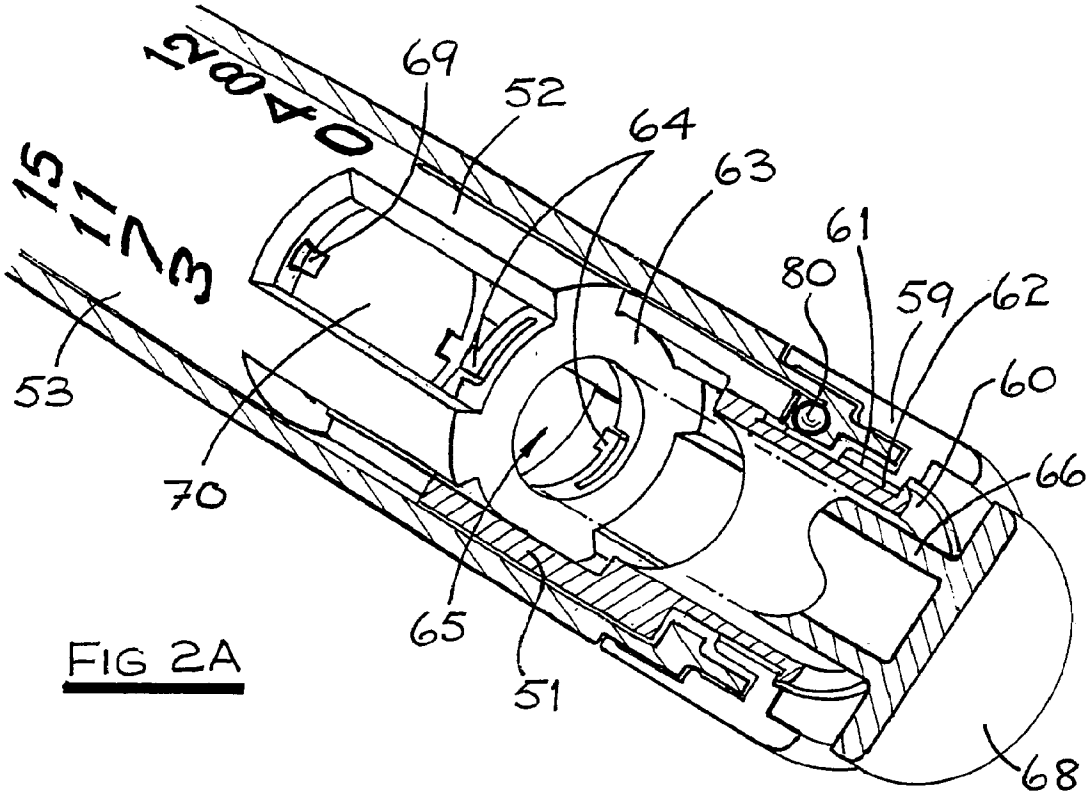

FIG 2A

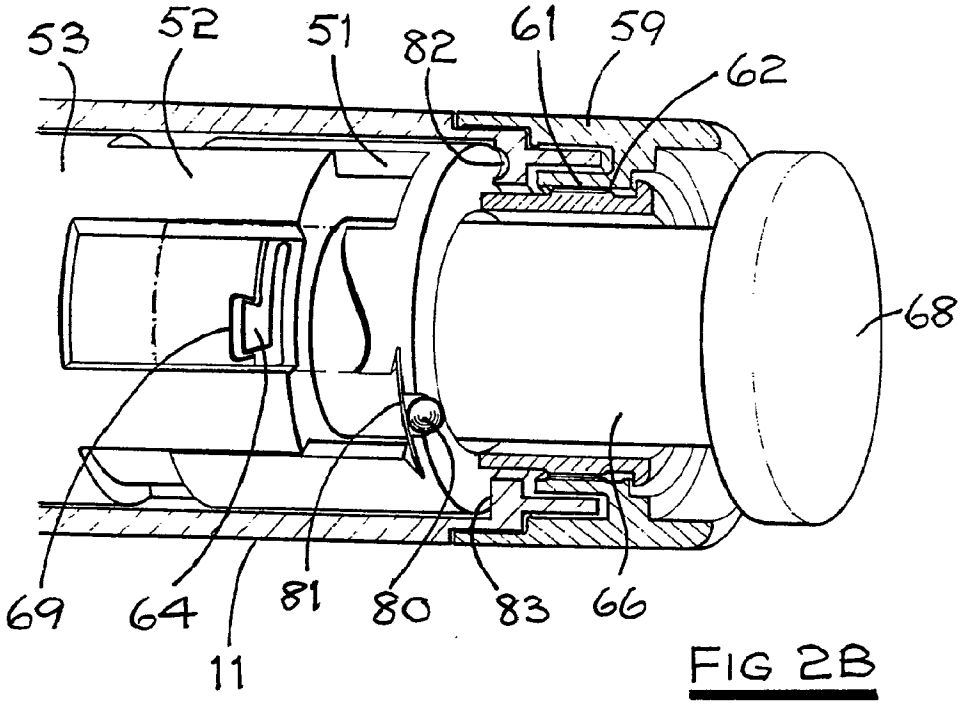

FIG 2B

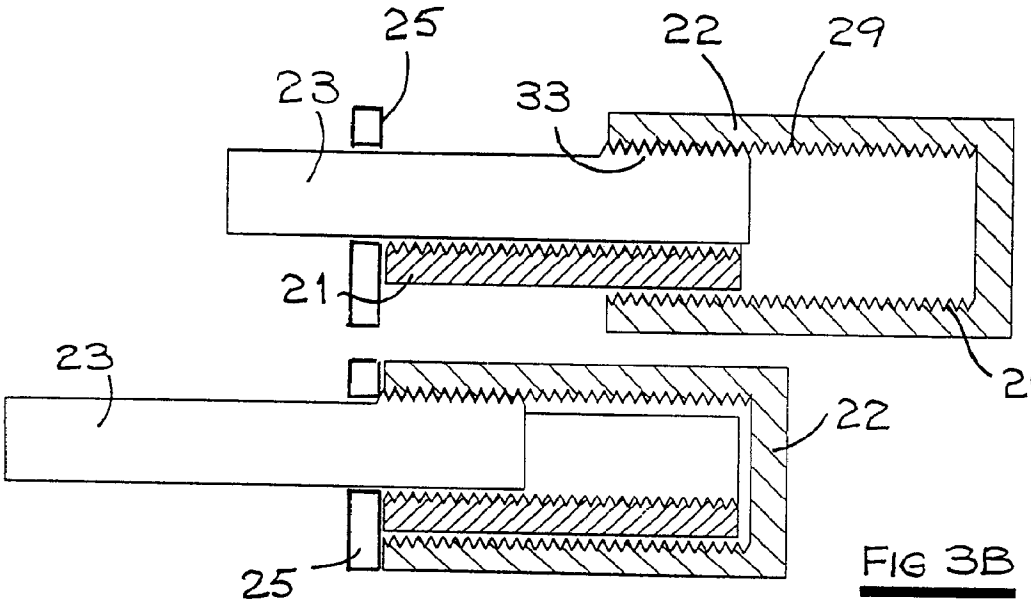

FIG 3A

FIG 3B

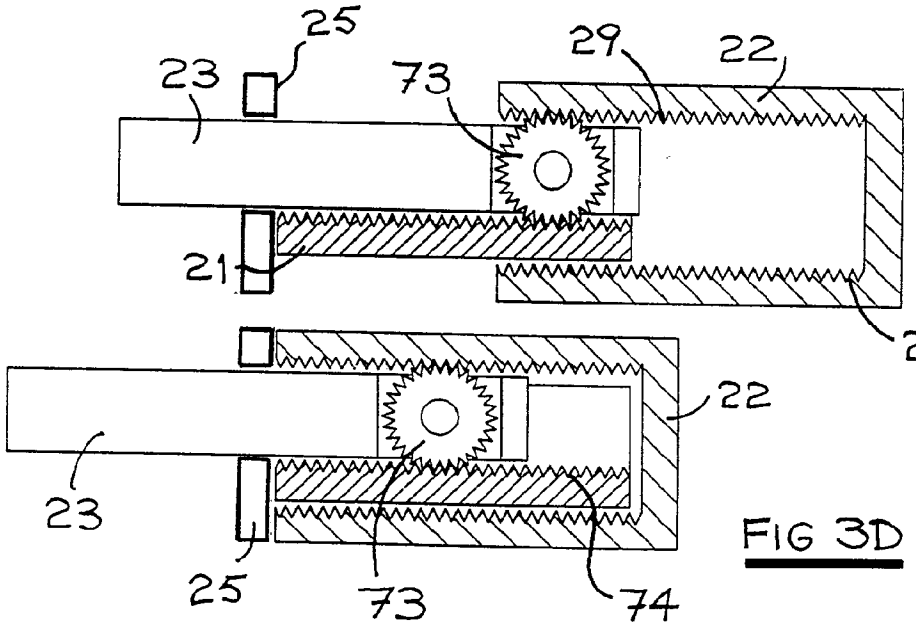

FIG 3C

FIG 3D

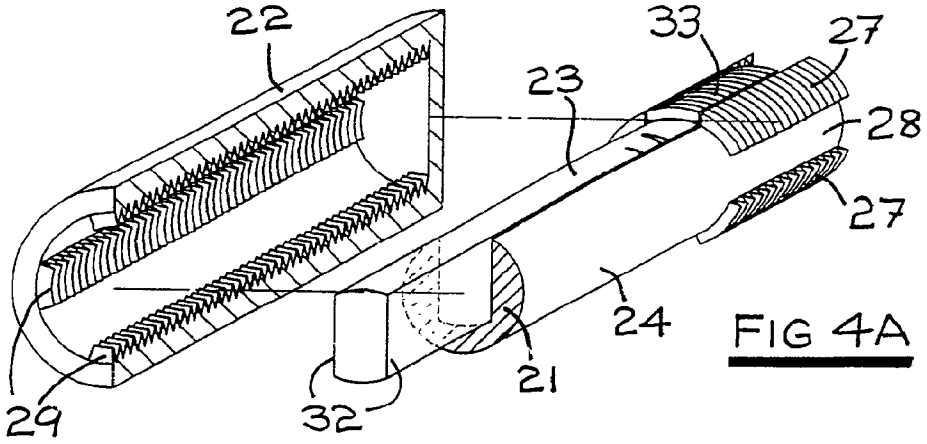

FIG 4A

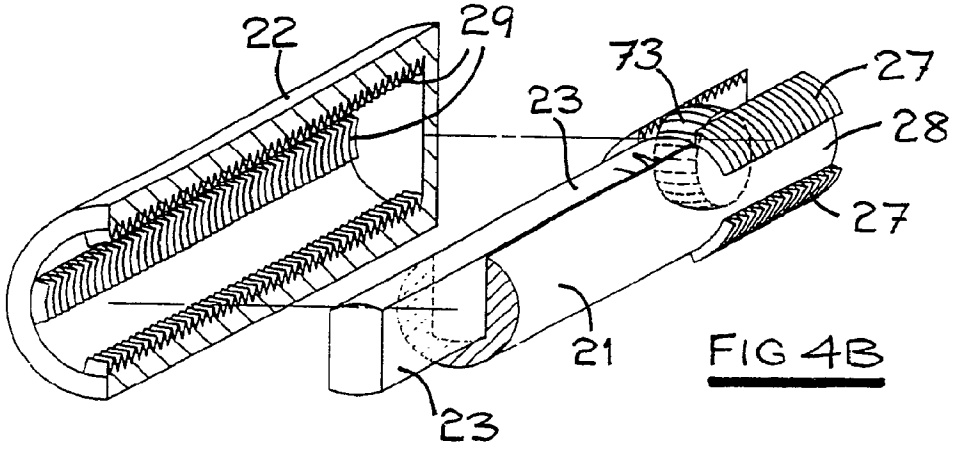

FIG 4B

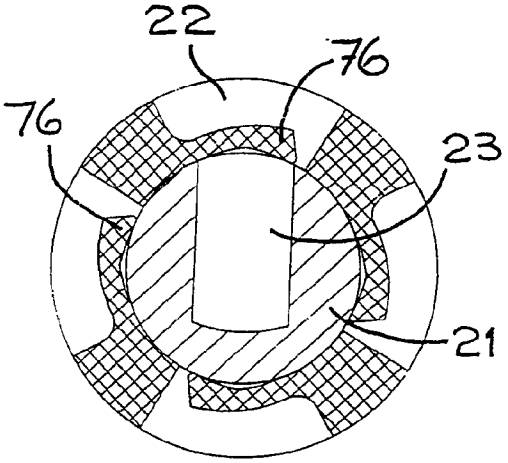

FIG 5A

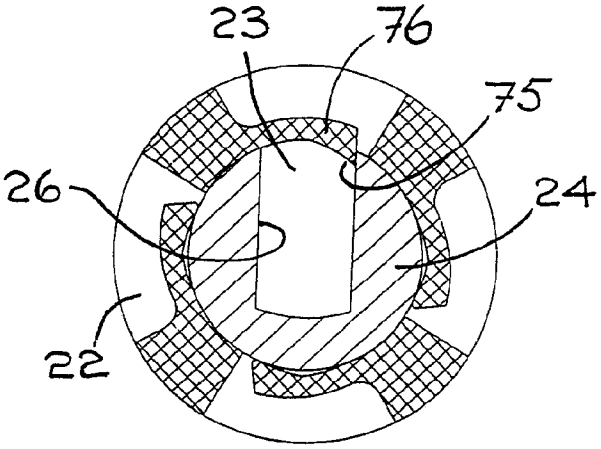

FIG 5B

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 91/00489

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M5/315

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
X	WO,A,8 907 463 (HOLM ET AL.) August 24, 1989 see page 1, line 5 - line 21 see page 2, line 21 - page 3, line 25 see page 4, line 4 - line 14 see page 9, line 2 - page 10, line 21 see abstract; claims 1-4; figures 1-5	1,2,6,8, 9,12,13
A	DE,A,3 840 000 (NOSTA AG) July 27, 1989 see abstract; claim 1; figure 1	1

[10] 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

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IV. CERTIFICATION

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21 JUNE 1991	10 JUL 1991
International Searching Authority	**Signature of Authorized Officer**
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		EP-A- 0327910	16-08-89
		US-A- 4973318	27-11-90
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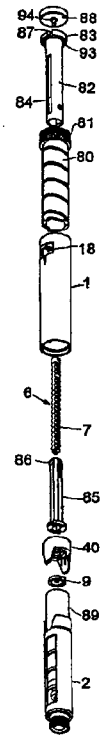
(57) Abstract

In an injection syringe comprising a housing (1), a piston rod (6) with a not circular cross section and an outer thread (7), a piston rod drive comprising a piston rod guide (85) mating the cross section of the piston rod (6) and a nut (4) which is not axially displaceable and mates the thread (7) of the piston rod (6) to form a self locking thread connection, and a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element (81) is screwed out to project from the housing (1) and which thread connection by axial returning of the injection button (88) transforms this axial movement into a rotation of one of the piston drive elements (85) relative to the other one (4). A unidirectional coupling between the nut member (4) and the piston rod guide (85) allows rotation in one direction by which the piston rod (6) is transported in a distal direction. The coupling has an initial reluctance to be overcome before rotation takes place said reluctance being large enough to resist torques exerted during the dose setting.



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An injection syringe

The invention relates to injection syringes of the kind apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses.

Such syringes are mainly made for users who have to inject themselves frequently, e. g. diabetics. A number of demands are set to such syringes. The setting of a dose must be easy an unambiguous and it must be easy to read the set dose. It must be possible with a minimum of trouble to cancel or change a wrongly set dose and when the dose is injected the dose setting must return to zero. When a disposable syringe is in question, i.e. a syringe which is disposed of when the cartridge is empty, the syringe must further be cheap and made of materials suited for recycling or burning without producing noxious gases. For these purposes the number of parts from which the syringe is constructed and the number of different kinds of materials used in the syringe should be kept at a minimum.

Most dose setting devices work with a threaded piston rod co-operating with a nut where the nut and the piston rod may be rotated relative to each other. The dose setting may be obtained by screwing the nut away from a stop to which it is returned during the injection by pressing the piston rod until the nut member abuts the stop. By other dose setting devices one of the elements, the nut or the piston rod, is kept inrotatable and the other is allowed to rotate a set angle depending on the set dose, whereby the piston rod is screwed a distance through the nut.

In most syringes for apportioning set doses it is preferred that the piston rod is backing up the piston upon which it works during the injection. To obtain this precaution is taken to prevent the piston rod from moving in a proximal direction.

The syringe according to EP 327 910 is of the type wherein a nut is screwed away from a stop. During the setting of the dose the screwing may be performed in both direction so that a too large set dose may be lowered just by rotating the nut in an opposite direction. Means are provided preventing that negative doses are set. The mutual rotation of the piston rod and the nut is obtained by rotating a cap relative to the pen housing and a set dose may be

read on a scale and a pointer provided at adjacent edges of the housing and the cap, these edges being so shaped that the cap can only be mounted firmly on the housing when the pointer points zero on the scale. It may be seen as a weak point that doses larger than the one obtained by rotating the parts 360° must be calculated by adding the number pointed at on the scale and a number printed on the side of a tubular extension of the nut which is moved out from the proximal end of the housing proportionally with the dose set and which tubular extension is closed at its proximal end to form an injection button.

In EP 450 905 the above drawback is overcome by writing the numbers along a helical line on a tubular extension of the nut so that these number may successively be seen in a window in a housing element enclosing said tubular extension. Hereby the size of the dose is indicated unambiguously but the user have to remember to set the dose setting device on zero before the next setting of a dose is performed. If this is forgotten a wrong dose may be set and the number may not be seen clearly in the window.

In EP 608 343 is described a pen having a dose setting mechanism wherein the dose is set by rotating a button relative to a housing to set a dose. By the rotation the button is screwed up from the end of the housing in a thread having a pitch so large that the thread connection is not self blocking, i. e. when the button is presses back to the end of the housing it will rotate back in the thread. The button is through a ratchet coupled to a driver, the ratchet forming a unidirectional coupling which during the rotation of the button in one direction to set a dose rides or clicks over the teeth of the ratchet. The cylindrical side of the button carries numbers which shows the size of the set dose in a window when the button is screwed outward. When the button is screwed back the unidirectional coupling will transmit the rotation to the driver which has a nut co-operating with a threaded piston rod which is made inrotatable in a housing . This thread connection has a pitch which makes the nut self locking on the piston rod. A set dose may be cancelled by drawing the engaging parts of the ratchet out of engagement against the force of a spring so that the rotation of the button is not transmitted to the driver and then press the button back to the housing . This pen fulfils all the objects mentioned only the dose cancelling procedure is a little troublesome as the dose set button cannot as it will come most naturally just be screwed back if a too large dose is set. Concomitantly forcing the coupling parts apart against the force of the spring and pressing or screwing the button back may be a little difficult and the demand for a spring necessitates use of metal parts in the syringe.

It is an object of the invention to provide a syringe which has the mentioned advantageous features without having the drawbacks known from existing syringes.

This is obtained by an injection syringes for apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses, comprising

a housing

a piston rod having a not circular cross-section and an outer thread

a piston rod drive comprising two elements

a) a piston rod guide in relation to which the piston rod is axially displaceable but not rotatable, and

b) a nut member which is rotatable but not axially displaceable in the housing and which has an inner thread mating the thread of the piston rod to form a self locking thread connection,

a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element relative to said housing is screwed out from the proximal end of the housing to project from this proximal end a distance determined by the angle of said rotation and which thread connection by axial returning of the injection button transforms this axial movement to a rotation of one of the piston drive elements relative to the other,

which syringe according to the invention is characterised in that

a unidirectional coupling is provided between the nut member and the piston rod guide allowing rotation of these parts relative to each other in one direction but not in the opposite direction, the allowed rotation being one by which the piston rod is transported in a distal di-

rection in the syringe, the coupling being so designed that a set initial reluctance has to be overcome before the rotation takes place.

During the setting of a dose a torque is exerted on the unidirectional coupling in the direction in which this coupling allows rotation after a set initial reluctance has been overcome. As this torque is a weak one resulting when the male and the female part of a not self locking thread connection is rotated relative to each other the initial reluctance can be made large enough to allow this rotation without causing any relative rotation of the parts in the coupling.

When the injection button is pressed the movement of this button is transformed into a rotation of the piston rod (or the nut member) relative to the nut member (or the piston rod). When the button is pressed hard enough the initial reluctans is overcome so that the two elements, the piston rod and the nut member, are rotated relative to each other.

According to the invention a click coupling providing an moderate resistance against rotation is established between the housing and the element rotated relative to the housing to set a dose. Hereby it is ensured that the position corresponding to a set dose is maintained and is not inadvertently altered. The clicks may be taken as an audible signal indicating the size of the set dose.

The unidirectional coupling may be a coupling comprising a pawl sliding over a pawl wheel with teeth having a steep front edge and a ramp shaped trailing edge, and the initial reluctance may be obtained by the fact that the trailing edges of the pawl wheel teeth has a depression engaged by a mating protrusion on the pawl.

A dose scale drum which has in its surface a helical track engaged by a helical rib on the inner side of the housing to form a not self locking thread connection between the housing and the drum may be coupled to the injection button to be moved axially with this button. This way the dose scale drum will be rotated relative to the housing when it is axially displaced with the injection button in said housing.

The thread connection by which the injection button is screwed out from the housing by setting a dose may be the thread connection between the dose scale drum and the housing. In this case the dose scale drum must be coupled to a driver rotating the piston rod (or the nut member) relative to the nut member (or the piston rod) when the injection button is pressed.

A dose is set by rotating an element relative to the housing, and this element may be an element carrying the nut member and the unidirectional coupling so that the rotation is transmitted through said unidirectional coupling to the dose setting drum. The rotation transmitted is in the direction in which the coupling can run free when an initial reluctance is overcome. However, the force needed to screw the dose scale drum up along its thread is not large enough to overcome said reluctance and consequently the rotation is transmitted through the coupling.

In one embodiment of the syringe according to the invention the element rotated relative to the housing may be a part carrying the nut member and the unidirectional coupling through which the rotation is transmitted to the dose setting drum.

In another embodiment of the syringe according to the invention the element rotated relative to the housing may be the injection button and the not self locking thread connection which determines the lifting of the injection button may be an inner thread in a bore in the injection butt on engaging an outer thread on an enlargement of the piston rod. When the injection button is screwed up along the piston rod to project from the housing a torque is exerted on the piston rod trying to rotate this piston rod in a direction which will move it in a distal direction in the syringe. Such a rotation is just the rotation which is allowed by the uniderectional coupling which blocks rotation in the opposite direction. Due to the initial reluctance against rotation of the coupling parts relative to each other the piston rod will not be rotated when the injection button is screwed up along it in a proximal direction in the syringe. If the injection button is screwed in the opposite direction the unidirectional coupling will definitively block a relative rotation of the piston rod and the nut member in the direction which would draw the piston rod in a proximal direction.

In the last mentioned embodiment of the injection syringe the dose scale drum may be mounted rotateable but not axially displaceable on the injection button. When the dose scale drum is moved with the injection button in the axial direction of the syringe the drum will be rotated due to the not self locking thread connection between said drum and the housing so that a number on the drum corresponding to the set dose is visible in a window provided in the wall of the housing. In this embodiment the pitch of the dose drum thread need not be identical with the pitch of the thread along which the injection button is screwed to set a

dose, only both thread connections must have a pitch large enough to make the thread connection the not self locking type, i.e. of the type by which an axial movement can be transformed into a rotation.

In an appropriate embodiment of the syringe according to the invention the dose scale drum is mounted rotatable but not axially displaceable on the injection button.

During the injection the injection button must be kept inrotatable but axially displaceable relative to the housing in the angular position to which the injection button is rotated during the setting of a dose. This may be obtained by letting the click coupling between the housing and the injection button comprise protrusions on one part engaging axial grooves in the other. When the injection button is pressed home into the housing the internal thread in the bore of this button will act on the engaging outer thread on the enlargement at the end of the piston rod and convert the axial movement of the injection button to a rotational movement of the piston rod in a direction by which the piston rod is screwed through the nut member in a distal direction in the syringe. The piston rod guide which is connected to one part of the unidirectional coupling is allowed to rotate when the initial reluctance against rotation in the direction else allowed by the coupling is overcome. Also a rotational movement of the dose scale drum is induced by the axial movement of the injection button so that the scale is returned to its zero position when the button is pressed home. When rotation of the dose scale drum and the piston rod is induced by the axial movement of the injection button this button is reacted upon by a torque which must be taken up by the click connection between the injection button and the housing which connection must consequently be strong enough to absorb this force without rotating.

In the following the invention is described in further details with references to the drawing, wherein

Figure 1 shows a front view of an embodiment of an injection syringe according to the invention,

Figure 2 shows a sectional view along the line II-II in figure 1,

Figure 3 shows in a reduced scale an exploded view of the syringe in figure 1,

Figure 4 shows a sectional view along the line IV-IV in figure 1,

Figure 5 shows a sectional view along the line V-V in figure 1,

Figure 6 shows a front view of another embodiment of an syringe according to the invention,

Figure 7 shows a sectional view along the line VII-VII in figure 6,

Figure 8 shows in a reduced scale an exploded view of the syringe in figure 6,

Figure 9 shows a sectional view along the line IX-IX in figure 6,

Figure 10 shows a sectional view along the line X-X in figure 6.

Figure 11 shows a sectional side view of another embodiment of a syringe according to the invention,

Figure 12 shows a sectional side view perpendicular to the view in figure 11,

Figure 13 shows in a reduced scale an exploded view of the syringe in figure 11 and 12,

Figure 14 shows a sectional side view of the dose setting part of another embodiment of a syringe according to the invention,

Figure 15 shows a sectional side view of still another embodiment of a syringe according to the invention,

Figure 16 shows a sectional side view perpendicular to the view in figure 15,

Figure 17 shows in a reduced scale an exploded view of the syringe in figure 15 and 16,

Initially it may be convenient to define that in this application directions of rotation are always seen from the proximal end of the pen and designed as clockwise or anticlockwise seen in this direction.

Figure 1 shows an injection syringe of the kind by which a liquid from an ampoule can be apportioned in a number of individually set does. Figure 3 shows an exploded view of this syringe and the figures 2, 4 and 5 sectional views taken along different lines in figure 1.

The syringe comprise a tubular housing 1 which is by a partition 15 divided into a first and a second division into the first one of which an ampoule holder 2 is snapped by a snap lock comprising a ring shaped bead 3 on the ampoule holder 2 which bead is snapped into a corresponding circumferantial grove in the inner wall of the housing 1 near an open end thereof. By this snap connection the ampoule holder 2 is secured in the housing 1 so that it can be rotated but not axially displaced relative to this housing.

In the syringe ready for use an ampoule is mounted in the ampoule holder which is then at its distal end closed by an end wall provided with a needle hub receiving part onto which a needle hub can be mounted having a needle with one end communicating with the content of the ampoule and the other end free to be inserted into a patient. In the shown syringe, however, neither ampoule, end wall nor needle hub are shown.

The end of the ampoule holder 2 inserted in the housing 1 is closed by a wall 4 having a central bore with an internal thread 5. A piston rod 6 having an external thread 7 mating the thread 5 of said bore extends through said bore. The threads are so designed that a clockwise rotation of the piston rod will drive this rod into an ampoule accommodating compartment 8 in the first division of the housing 1. At its end projecting into the compartment 8 the piston rod 6 is provided with a pressure foot 9 designed to abut a piston closing the rear end of an ampoule accommodated in the ampoule holder 2.

In the proximal side of the end wall 4 the bore is enlarged and the internal side of the enlargement is provided with pawl wheel teeth 10 having a steep front edge 11 facing the clockwise direction and a ramp shaped rear edge 12 facing the anticlockwise direction. At

least one pawl 13 mounted on a piston rod guide 14 co-operates with the pawl teeth 10 so that said piston rod guide can only be rotated clockwise in the ampoule holder 2.

On the inner wall of the second division of the housing 1 a helical protruding rib 16 is provided defining an inner thread with a high pitch. A dose scale drum 17 is in its outer wall provided with a helical grove defining a corresponding external thread mating the inner thread just mentioned. The pitch angle of the threads exceeds the angle of friction for the materials forming the parts of the thread connection and consequently the thread connection is of the not self locking type which induce a relative rotation of the parts of the connection when these part are moved axially relative to each other.

Numbers indicating set doses are printed on the outer wall of the dose drum 17 and the number corresponding to a set dose is shown in a window 18 provided in the side wall of the housing 1.

The dose scale drum 17 is provide with a tubular extension 21 having an end near the proximal end of the syringe. Said end of the extension is closed by an end wall 19 having a central outer protrusion 20. In a part of the wall adjacent to the end wall 19 the extension 21 is provided with slots 22. The said end of the extension is covered by a cup shaped cap 23 forming an injection button. Internal hooks 24 at the open end of this cap snaps over an external circumferential bead 25 on the extension 21 and the protrusion 20 on the end wall 19 abuts the inner side of the bottom of the cap 23 to form a journal about which the injection button can rotate relative to the extension 21 whereas it cannot be axially displaced relative to this extension.

A driver tube 26 integral with the piston rod guide 14 extends from this piston rod guide to the end wall 19 of the dose scale drum extension 21 and is at its proximal end divided into tongues 27 terminated by external hooks 28 engaging the slots 22 in the extension 21. This way the dose scale drum 17 is bound to rotate with the driver tube 26 but is axially displaceable relative to this tube.

To set a dose the ampoule holder 2 is rotated anticlockwise in the first division of the housing 1. This rotation is performed against a resistance presented due to the fact that a protrusion 30 on the outer wall of the ampoule holder rests in one of a number of depressions 31

circumferentially provided in the inner wall of said first division of the housing as shown in the cross-sectional view in figure 3. The angular spacing of the depressions are appropriately made so that a dose of one unit is set when the protrusion is moved from one depression to the neighbouring depression so that the number of clicks heard and felt during the dose setting rotation corresponds to the size of the set dose.

The rotation of the ampoule holder is due to the friction in the engaging threads 5 and 7 transmitted to the piston rod 6 and further through the unidirectional coupling to the piston rod guide 14 although the torque is transmitted in a such a direction that the pawl will intend to click over the pawl wheel teeth 10. However, before this click function is performed a reluctance have to be overcome. This reluctance is obtained by providing the pawl 13 with a protrusion 29 at its end engaging the pawl wheel teeth 10 and by providing depressions 32 in the ramp shaped edges 12 of the pawl wheel teeth into which depressions the protrusion 29 on the pawl 13 will rest. Before the clicking release of the coupling is obtained a torque sufficient to lift up the protrusion 29 of the pawl 13 from the depression 32 in the ramp shaped edge 12 must be provided. Altogether a moderate torque can be transmitted from the rotated ampoule holder 2 to the driver tube 26. As the hooks 28 at the proximal end of the driver tube 26 engage the slots 22 in the dose scale drum extension 21 the dose scale drum will be rotated and be screwed upwards in the second division of the housing 1 and the injection button 23 will be lifted to protrude from the proximal end of the housing 1. As only a small torque is needed to screw up the dose scale drum this is obtained without releasing the unidirectional coupling to its clicking release function mode. The size of the set dose can currently be seen on the part of the dose scale drum which is presented in the window 18. If a too large dose has been set the ampoule holder can be rotated in a clockwise direction until the number corresponding to the size of the wanted doe is presented in the window 18.

To inject the set dose the injection button 23 is pressed home into the housing 1. Thereby the dose scale drum 17 is pressed in the distal direction and due to the thread connection between said drum and the housing 1 a torque is exerted on the drum rotating this drum in a clockwise direction. Said torque is via the slots 22 in the drum extension 21 and the hooks 28 at the end of the driver tube 26 and this tube itself transmitted to the piston rod guide 14. The pawls 13 on the piston rod guide are allowed to rotate in the clockwise direction when the torque is strong enough to overcome the reluctance provided by the protrusions 29 on the pawls engaging the depressions 32 in the ramp shaped edges of the pawl wheel teeth.

Such a strong torque is provided if only the inject button 23 is pressed hard enough. The piston rod guide 14 will now rotate clockwise with the unidirectional coupling working in its clicking released mode and the piston rod will be rotated clockwise too and will thereby be screwed through the wall 4 further into the ampoule accommodating compartment 8. The unidirectional coupling will never allow an anticlockwise rotation of the piston rod guide and the piston and this way it is ensured that the pressure foot 9 will never be drawn out of abutment with the piston in a not shown ampoule in the compartment 8.

In the shown embodiment the end wall 4 with its threaded bore forms a nut member relative to which the piston rod is rotated by the piston rod guide 14 and the driver tube 26. Embodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the invention.

Another embodiment is described with reference to the figures 6-10. Elements corresponding to elements in the embodiment described with references to the figures 1-5 are provided with the same reference numbers. Different from the embodiment in figure 1-5 is the fact that the injection button 23 and not the dose scale drum 17 is provided with an extension 33, and that the driver tube 26 is omitted. Further the injection button 23 is provided with a flange 32 which abuts the end of the housing when the injection button is pressed home. The extension 33 serves as a journal for the dose scale drum 17 which is free to rotate on this journal but bound to follow axial movements of the injection button 23 due to hooks 34 at the end of the extension 33. A longitudinal bore 35 in the injection button and its extension 33 is provided with an internal helical rib 36 engaging a corresponding helical groove in an enlargement 37 at the proximal end of the piston rod to form a thread connection between said button 23 and said piston rod 6. The pitch of this thread connection is so that a not self locking thread connection is formed.

To set a dose the injection button 23 is manually rotated in a clockwise direction Thereby this button is screwed outwards from the housing 1 as the piston rod 6 will through the piston rod guide 14 and the unidirectional coupling be kept inrotatable although said unidirectional coupling in influenced by a torque in its release direction, however, due to the provided initial reluctance the piston rod guide 14 will not immediately be rotatable. In its movement outwards the injection button 23 will draw the dose scale drum 17 with it. When this drum is

moved axially in the housing it will be rotated due to the not self locking thread connection between said drum 17 and the housing 1.

By this construction the thread along which the injection button is screwed outwards and the tread along which the dose scale drum is rotated in the housing may be different.

A click connection corresponding to the one established between the cartridge holder 2 and the housing 1 in the embodiment according to figure 1 is in the embodiment according to figure 6 appropriately provided between the injection button 23 and the housing 1 where one or more protrusions 38 provided on the inner wall of the housing engages grooves 39in a cylindrical outer wall of the button 23. Thereby axial movement of the injection button is allowed in all its possible angular positions.

When the injection button is pressed to inject a set dose said button will be maintained inrotatable during its axial movement as the locking between the above mentioned protrusions on the inner wall of the housing and grooves on the outer wall of the button is strong enough to absorb the torque exerted on the injection button when it drives the piston rod to rotation in a clockwise direction after having overcome the reluctance against rotation in the release direction of the unidirectional coupling.

The embodiment shown in figure 11, 12 and 13 has the housing 1 with the window 18. The end wall 4 with the internal thread 5 is provided in a separate member 40 which is mounted in an end of the housing, the member 40 having protrusions 41 engaging slots 42 in the housing to lock the member 40 to the housing 1. Further the member 40 has at its periphery longitudinal recesses 43 which are engaged by not shown internal ribs in the housing to lock the member 40 against rotation relative to the housing 1. Further protrusions 44 on the ampoule holder 2 engage the slots 42 to lock the ampoule holder 2 to the housing 1.

The piston rod 6 engages by its external thread 7 the internal thread of the end wall 4 and is at its end in the ampoule holder terminated by a pressure foot 9 relative to which the piston rod 6 is rotatable. A driver tube 45 is at one end provided with the pawl 13 which engages pawl wheel teeth in the member 40 and is held between a ring shaped wall 46 in the housing and the end wall 4 in the member 40 to keep the driver tube 45 from axial movement but allowing it to rotate. On its inner wall the driver tube 45 has a key engaging a longitudinal re-

cess in the piston rod 6. Thereby rotation of the driver tube is transmitted to the piston rod 6 whereas the piston rod can move freely in the axial direction of the driver tube 45. On its outer wall the driver tube 45 has an outer thread 47 which engages an inner thread 50 in a nut member 48 which has at its distal end a flange 49 and is at its proximal end provided with a part 51 with reduced diameter to which part one end of a tubular part 52 which at its other end carries a button 23 is secured.

In the proximal end of the housing 1 a bushing 53 is secured to be non rotatable an non displaceable relative to said housing 1 the rotational locking being obtained by lugs 54 at the proximal end of the housing engaging recesses 55 at the periphery of the bushing 53. A guide member 56 is longitudinally displaceable in the bushing 53 but inrotatable relative to said bushing and consequently relative to the housing 1. The guide member has at its distal end an annular end wall 57. The part 51 of the nut member 48 is passed through the opening of said end wall 57 and has a bead 58 gripping into a circuferential inner recess in the wall of annular opening through said end wall to keep the bushing 53 secured to said part 51 so that this part can be rotated but not axially displaced in relation to the bushing 53. The scale drum 17 is journalled on the nut member 48 and is held on this nut member by having a flange 90 held between the end wall 57 of the guide member 56 and the shoulder formed where the part 51 connects to the nut member 48.

The button 23 is held rotatably on the guide member 56 which has a ring bead 59 engaging a circumferential recess 60 in the inner wall of the button 23 which recess 60 is somewhat broader than than the bead 59 so that the button in excess of being rotatable on said bushing 53 can be axially displaced a distance defined by the width of the recess 60 relative to the width of the bead 59. The button 23 is coupled to the nut member 48 by internal ribs 61 in the tubular part 52 engaging slots 62 in the proximal part of the part 51 of the nut member 48. This coupling forces the button 23 and the nut member 48 to follow each other in rotational movements but allow a minor relative axial displacement.

The proximal end surface of the guide member 56 has one or more axially directed protrusions 63 which can co-operate with radial recesses 64 in the bottom of the button 23, but mainly a biasing keeps these recesses and protrusions out of engagement. Further the guide member has at its proximal end at least one radial protrusion 65 which is biased to engage axial recesses 66 in an inner wall of the button to produced a click sound each time the

button is rotated relative to the bushing so that the protrusion jump from one recess to the neighbour recess.

To set a dose the button 23 is rotated in a clockwise direction. This rotation is due to the coupling between the ribs 61 and the slots 62 transmitted to the nut member 48 which is then screwed in distal direction along the driver tube 45 which is held inrotatably in the housing due to the reluctans of the pawl 13 to move along the pawl teeth in the member 40. The movement of the nut member 48 in proximal direction makes the scale drum 17, the guide member 56, and the tubular part 52 with the button move in proximal direction so that the button is elevated over the end proximal end of the housing 1. A to high set dose can be reduced by rotating the button in an anti clockwise direction.

During the rotation of the button the radial protrusion 65 of the guide member 56 clicks from one axial recess 66 to the other. The distance between can appropriately be chosen so that a click corresponds to a changing of the set dose by one international unit up or down. Due to engagement between the helical grove on the cylinder wall of the scale drum and a helical rib on the inner wall of the housing the movement of the dose scale drum 17 will rotate and displace said drum so that the set dose is shown in the window 18.

When the dose scale drum is displaced outwardly in the housing a steep front side of a saw tooth 91 at the proximal end of the dose scale drum 18 will abut a steep front side of a similar tooth 92 on the bushing whereby the rotation of the dose scale drum is stopped to indicate that a maximum dose has been set.

To inject the set dose the button 23 is pressed. Thereby the bias keeping the protrusions 63 and the recesses 64 out of engagement is overcome and the said engagement is established. The button 23 is now locked relative to the guide element 56 which is again locked against rotation relative to the bushing 53 and consequently relative to the housing 1. The coupling between the tubular part 52 and the nut member 48 makes this nut member inrotatable relative to the housing so an axial movement of said nut member in a distal direction will due to the not self locking thread coupling between this nut element and the driver tube 45 make this driver tube 45 rotate in a clockwise direction and due to the key/groove coupling between the driver tube 45 and the piston rod 6 said piston rod will be screwed through the end wall 4 further into the ampoule holder compartment. The locking of the button 23

against rotation during the injection ensures that the set dose is not inadvertently changed during the injection.

In the embodiment shown in figure 14 separate buttons are provided for the dose setting and the injection. Corresponding to previously described embodiments this one has a housing 1 and a driver tube 67 which is rotatable in only one direction due to a pawl which engage pawl wheel teeth in a part secured in the distal end of the housing. Trapping of the pawl between the member 40 and a ring shaped wall 46 in the housing fixes the driver tube against axial movement. On the outer wall of the driver tube 67 an axial rib 68 is provided which rib engages an axial recess 69 in a tubular injection element 70 to transmit rotation of said injection element to the driver tube 67.

At the proximal end of the housing 1 a dose setting button 71 is mounted so that this button can be rotated but not axially displaced relative to the housing 1. This is obtained by the fact that the dose setting button 71 on a part fitting into the housing has a ring shaped bead 72 which engages a mating circuferential recess 73 in the inner wall of the housing. Outside the housing the dose setting button has a part having a diameter corresponding to or being larger than the diameter of said housing which part can be provided with axial ribs 74 to ensure a good grip by the setting of a dose. The dose setting button 71 has a central bore the inner wall of which has a helical recess 75 engaging a helical rib 76 provided on the outer wall of the proximal part of the injection element 70 which element passes through the bore of the dose setting button 71. The outer wall of the distal part of the injection element 70 forms a journal for the scale drum 17 which through an outer helical recess engaged by an internal helical rib 16 in the housing is rotated to show the set dose in the window 18 when the scale drum is displaced axially in the housing. The proximal end of the injection member is terminated by an end wall 77 which carries an injection button 78 which is by a pivot pin 79 journaled in a central bore in said end wall 77.

To set a dose the dose setting button 71 is rotated in a clockwise direction. As the injection member is kept non rotatable by its coupling to the driver tube 67 the collaboration between the helical recess 75 in the inner wall of the dose setting button 71 and the helical rib 76 on the outer wall of the injection element 70 will screw the injection element out through the dose setting button so that the injection button 78 is lifted up from the proximal end of the housing. Although the driver tube 67 with its pawl can be rotated in the clockwise direction

an initial torque is needed which is larger than the torque transmitted from the dose setting button to the injection element.

To inject a set dose the injection button 78 is pressed and the injection element is moved back into the housing. The co-operation of the helical recess 75 in the inner wall of the dose setting button 71 and the helical rib 76 on the outer wall of the injection element 70 will now make the injection element rotate in a clockwise direction and if only the injection button is pressed hard enough a torque is produced large enough to overcome the initial reluctance of the pawl mechanism against rotation in said clockwise direction.

The separation of the dose setting button 71 and the injection button 78 makes it less likely that the dose setting button is inadvertently operated during the injection.

Figure15, 16 and 17 illustrates still another embodiment. To maintain a clockwise rotation of a dose setting button for increasing the set dose the pawl mechanism working between the driver tube and the housing is turned so that it bars clockwise rotation and reluctantly allows anticlockwise rotation of the driver tube. Further the thread of the piston rod and the thread in the end wall of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment. The piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section. This way rotation is transmitted whereas the piston rod is allowed to move longitudinally through the driver tube.

A scale drum 80 is in its outer wall provided with a helical track which is engaged by a helical rib16 along the inner wall of the housing 1. At its proximal end the scale drum 80 has a diameter exceeding the inner diameter of the housing to form a dose setting button 81 which on its cylindrical outer wall is knurled to ensure a good finger grip.

A bushing 82 having a flange 83 at its proximal end and having a pair of opposite longitudinal slots 84 through its side walls fits into the scale drum 80 and over the driver tube 85 which tube has on its outer wall hooks 86 engaging the slots 84 of the bushing 82 whereby the bushing 82 and the driver tube 85 is coupled to each other so that rotation but not longitudinal displacement is transmitted between said two elements.

In the dose setting button a compartment is provided having a cylindrical side wall circumferentially provided with longitudinal recesses and a bottom with a rosette of teeth having a triangular cross-section. The flange 83 of the bushing 82 is adopted in said compartment and has at its periphery a radial protrusion 87 which is biased toward the side wall of the compartment. At its distal side the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment.

The bushing 82 is mounted in the scale drum 80 with protrusion on the outer wall of the bushing 82 engaging recesses in the inner wall of the scale drum 80 so that a limited movement of the bushing in the scale drum is allowed so that the bushing can be moved axially relative to the scale drum to make or not make the teeth of said rosettes engage each other. An injection button 88 is rotatably mounted with a pivot pin 94 journaled in an end wall of the bushing 82.

When a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing and the dose setting button is lifted away from the proximal end of the housing. The bushing is kept non rotated due to its coupling to the driver tube which is locked against clockwise rotation and if a set dose is reduced by rotating the dose setting button 81 in an anticlockwise direction the pawl mechanism working between the driver tube and the housing is sufficient reluctant to rotate in its not blocking direction to prevent the bushing 82 from following this anticlockwise rotation. Therefore by the rotation of the dose setting button 81 in any direction the radial protrusion 87 on the flange 83 of the bushing 82 will click from one of the axial recess in the inner wall of the dose setting button 81 to the next one, the recesses being so spaced that one click corresponds to a chosen change of the set dose, e. g. one unit or a half unit. During the setting the rosette in the dose setting button forces the rosette 93 on the flange 83 of the bushing 82 out of engagement.

When the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81 which is induced by the thread engagement between the helical track of the scale drum 80 and the rib 16 in the housing when the scale drum 80 is pressed back into said housing. The bushing will rotate the driver tube 85 in an anticlockwise direction which

the pawl mechanism reluctantly allows an the piston rod is thereby screwed further into an ampoule 89 in the ampoule holder 2.

By this device the risk for inadvertent operation of the dose setting button 81 during the injection is eliminated. Further the device consist of a minimum of parts whereby the manufacturing is made easy.

CLAIMS

An injection syringes for apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses, comprising

a housing

a piston rod having a not circular cross-section and an outer thread

a piston rod drive comprising two elements

a) a piston rod guide mating the not circular cross-section of the piston rod to allow axially displacement but not rotatation of the piston rod in relation to said piston rod guide, and

b) a nut member which is not axially displaceable in the housing and which has an inner thread mating the thread of the piston rod to form a self locking thread connection,

a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element relative to said housing is screwed out from the proximal end of the housing to project from this proximal end a distance determined by the angle of said rotation and which thread connection by axial returning of the injection button transforms this axial movement to a rotation of one of the piston drive elements relative to the other,

characterised in that

a unidirectional coupling is provided between the nut member and the piston rod guide allowing rotation of these parts relative to each other in one direction but not in the opposite direction, the allowed rotation being one by which the piston rod is transported in a distal direction in the syringe, the coupling being so designed that an initial reluctance set large

enough to resist a torque exerted on the coupling by the dose setting has to be overcome before rotation takes place.

2. An injection syringe according to claim 1, characterised in that a click coupling providing an moderate resistance against rotation in either directions is established between the housing and the element rotated relative to this housing to set a dose.

3. An injection syringe according to claim 1 or 2, characterised in that the unidirectional coupling comprises a pawl sliding over a pawl wheel with teeth having a steep front edge and a ramp shaped trailing edge.

4. An injection syringe according to claim 3, characterised in that the trailing edges of the pawl wheel teeth has a depression engaged by a mating protrusion on the pawl.

5. An injection syringe according to anyone of the preceding claims, characterised in that a dose scale drum has in its surface a helical track engaged by a helical rib on the inner side of the housing to form a not self locking thread connection between the housing, and that the dose scale drum is coupled to the injection button to be moved axially with this button.

6. An injection syringe according to claim 5, characterised in that the thread connection by which the injection button is lifted by setting a dose is the thread connection between the dose scale drum and the housing.

7. An injection syringe according to claim 1, 2, 3, or 4 characterised in that the element rotated relative to the housing is the injection button and that the not self locking thread connection which determines the lifting of the injection button is an inner thread in a bore in the injection button engaging an outer thread on a part with enlarged diameter of the piston rod.

8. An injection syringe according to claim 1, 2, 3 or 4, characterised in that the piston rod guide is mounted in a driver tube in which tube the piston rod is axially displaceable but is rotated with said tube, and that the not self locking thread connection which determines the lifting of the injection button is provided between the driver tube and a part which is axially displaceable with the injection button.

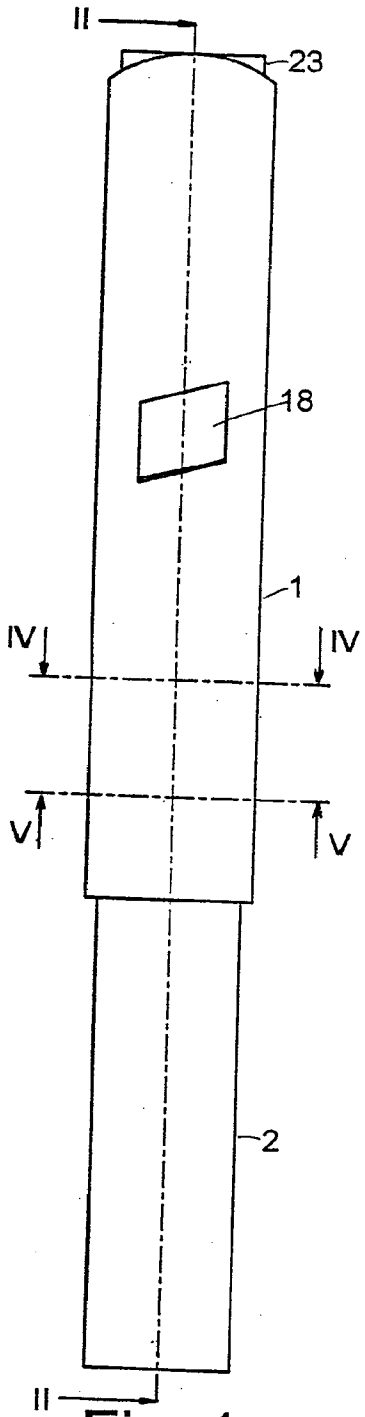

Fig. 1

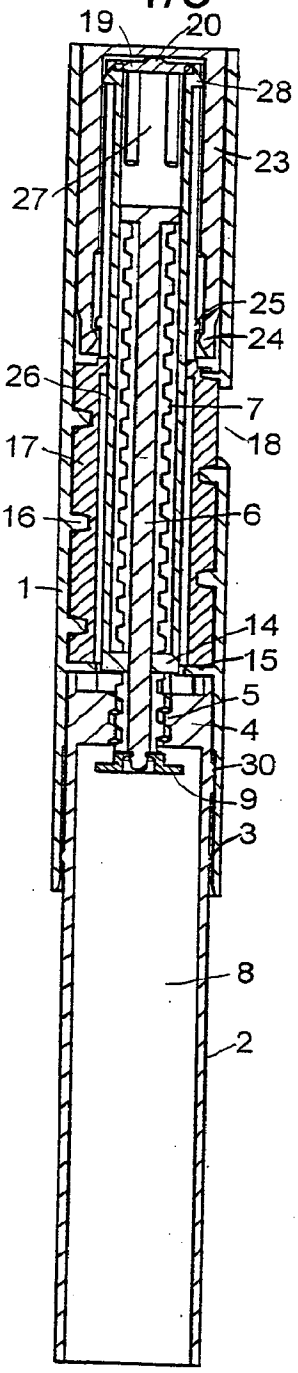

Fig.2

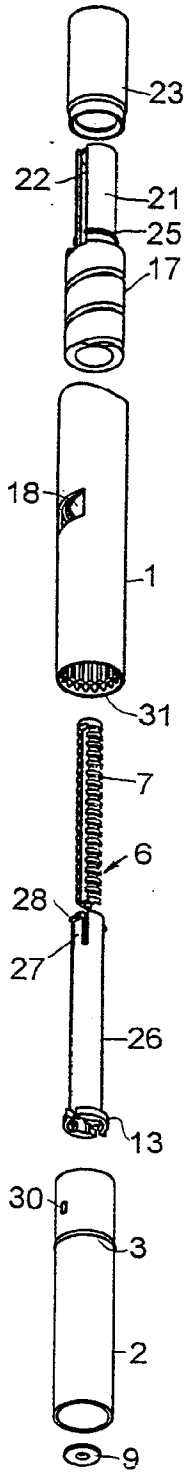

Fig.3

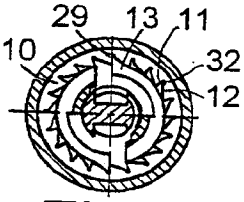

Fig.4

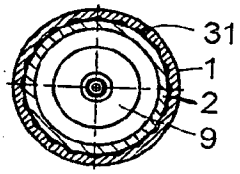

Fig. 5

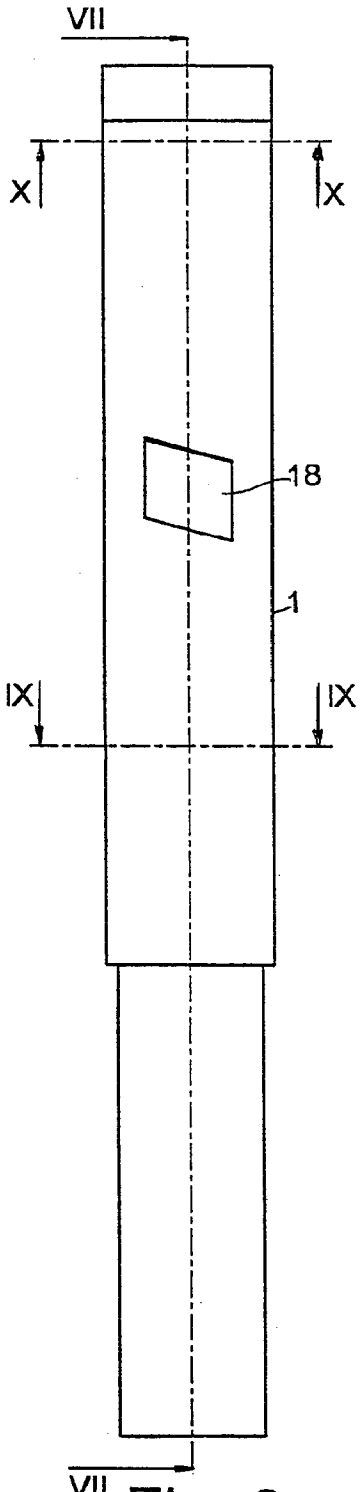

Fig. 6

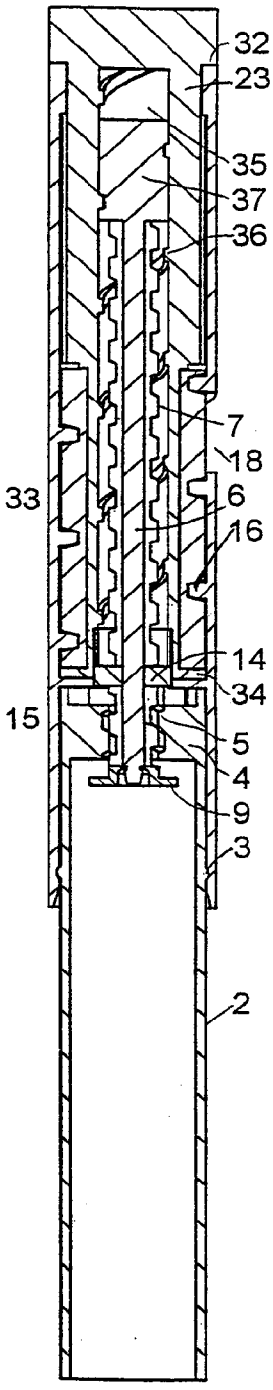

Fig. 7

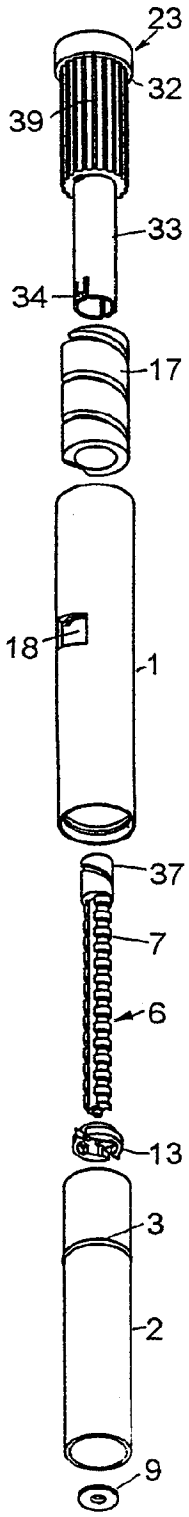

Fig.8

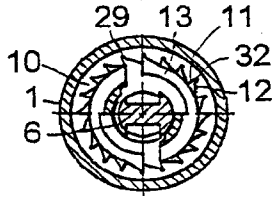

Fig. 9

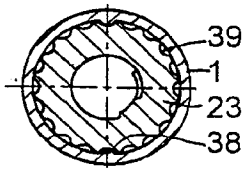

Fig.10

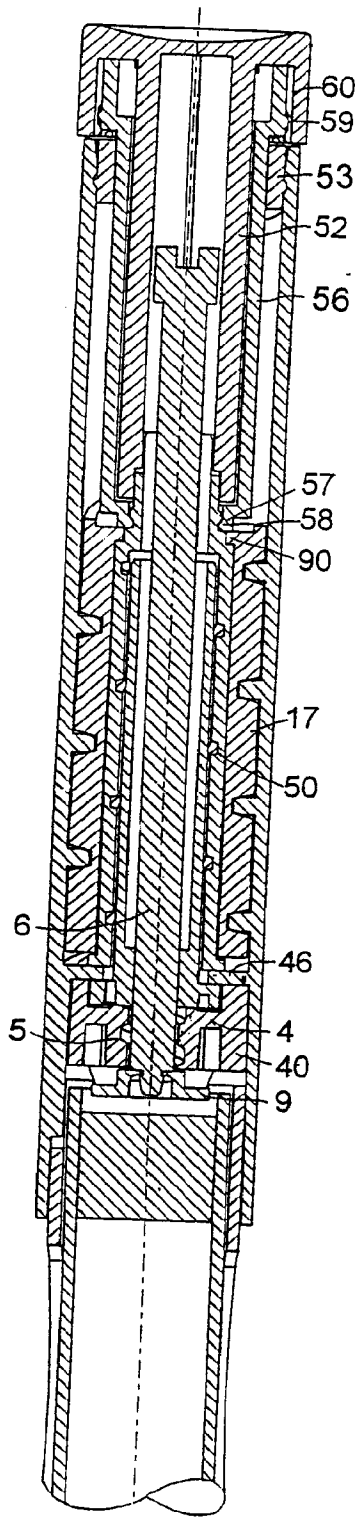

Fig. 11

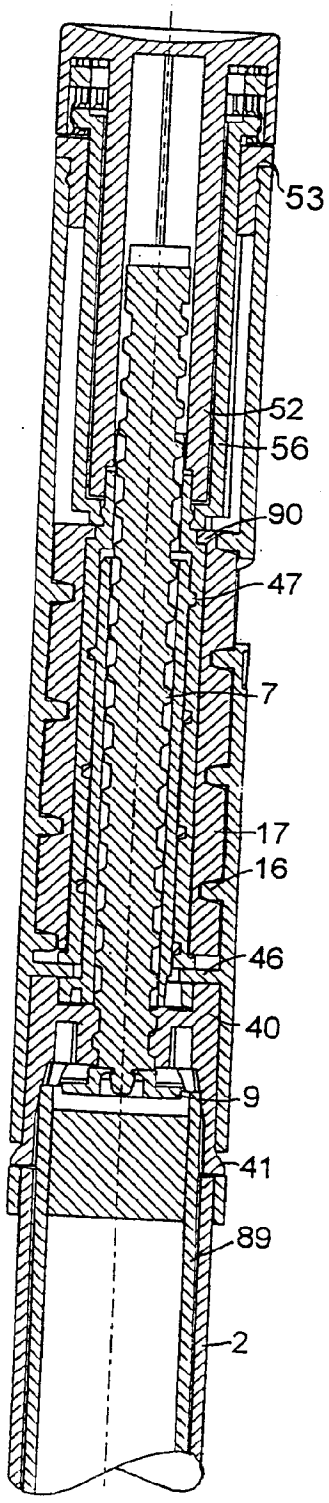

Fig. 12

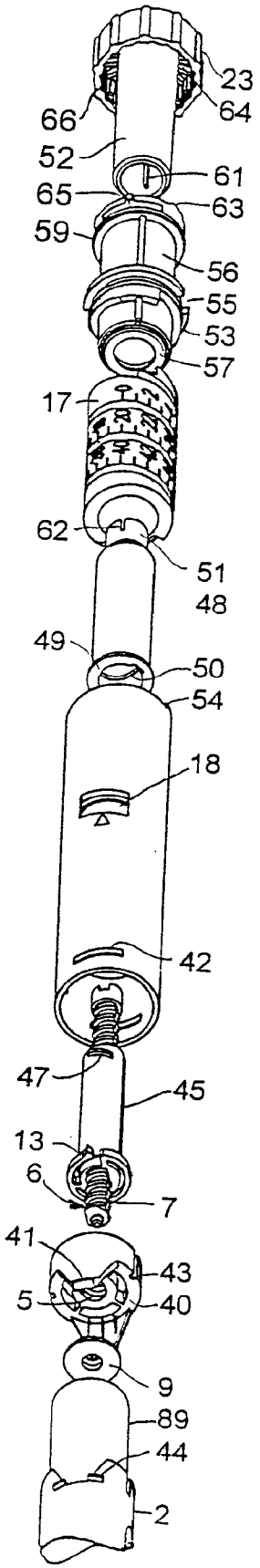

Fig. 13

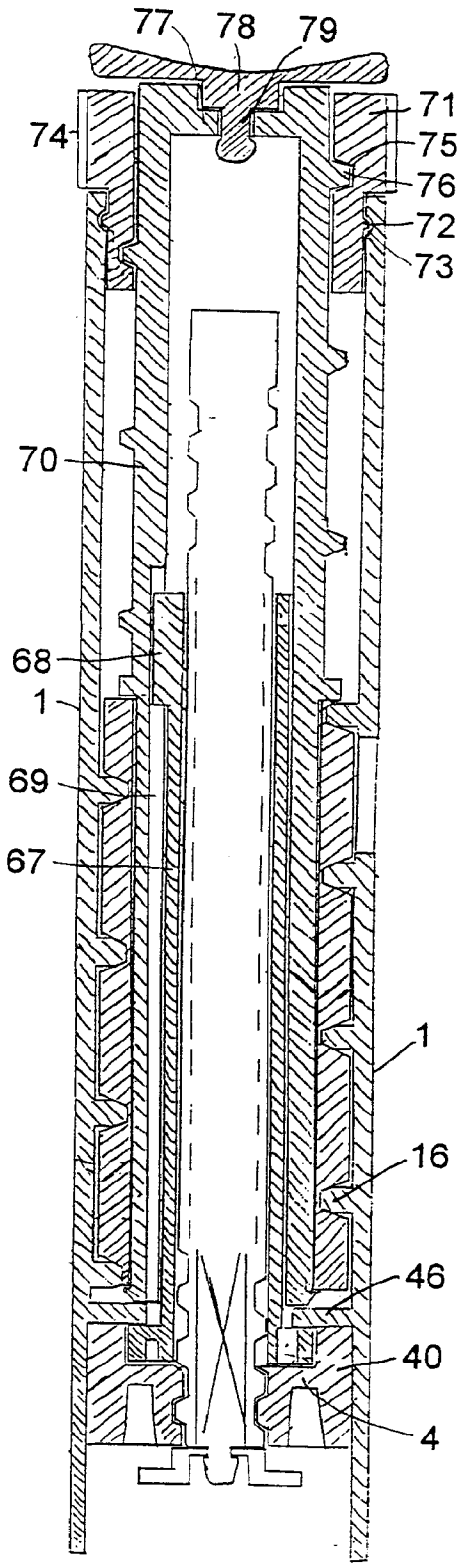

Fig. 14

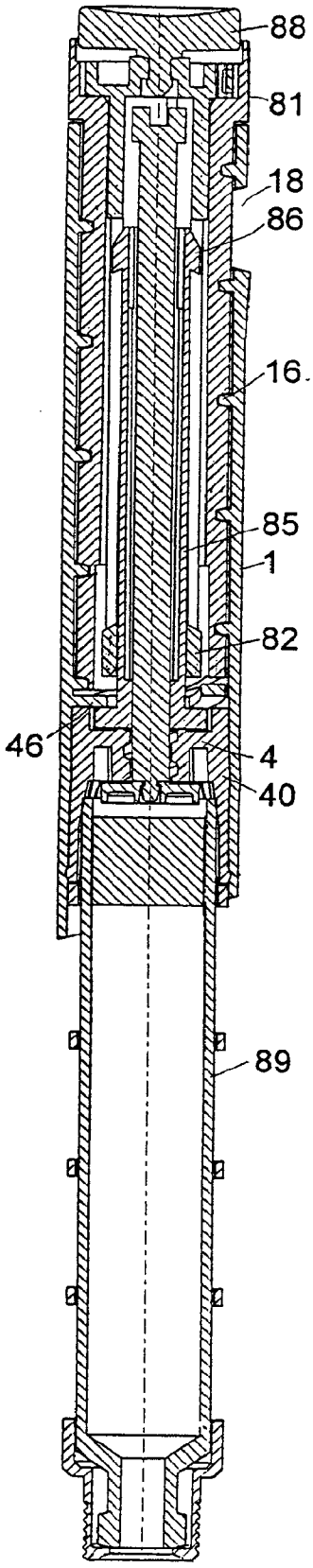

Fig. 15

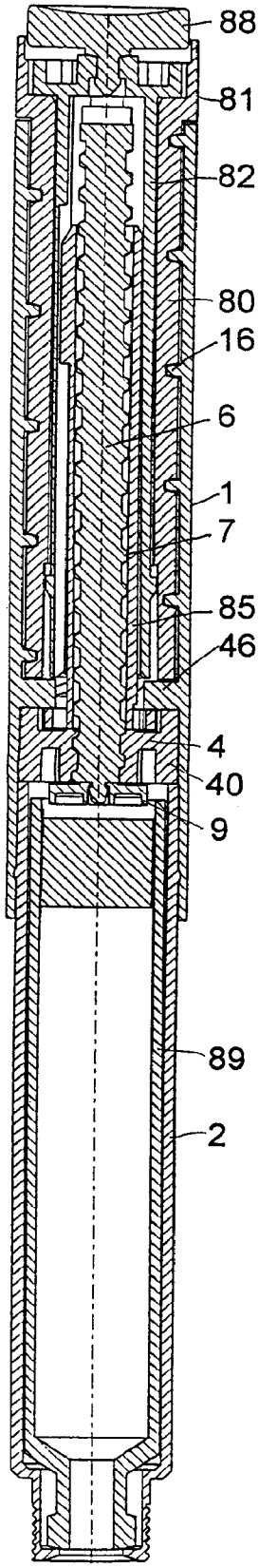

Fig.16

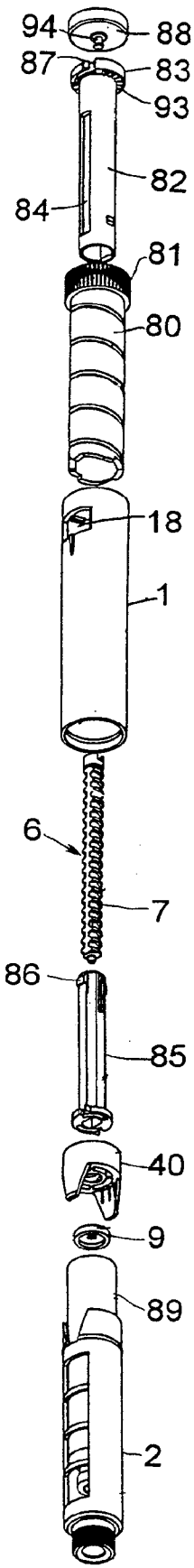

Fig. 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 99/00042

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 5/315, A61M 5/24
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)

IPC6: A61M

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

SE,DK,FI,NO classes as above

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5674204 A (LAWRENCE H.CHANOCH), 7 October 1997 (07.10.97), column 4, line 26 - column 6, line 29, figure 3, abstract	1-8
A	WO 9307922 A1 (NOVO NORDISK A/S), 29 April 1993 (29.04.93), figures 2-7, abstract	1-8
A	EP 0327910 A2 (D.C.P.AF 1988 A/S), 16 June 1989 (16.06.89), figures 2,3, abstract	1-8
A	EP 0450905 A1 (ELI LILLY AND CO.), 9 October 1991 (09.10.91), column 1, line 19 - column 2, line 36	1-8

☐ 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
"E" erlier 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

Date of the actual completion of the international search	Date of mailing of the international search report
7 July 1999	08 -07- 1999
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Joni Sayeler Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

01/06/99

International application No.
PCT/DK 99/00042

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INTERNATIONAL SEARCH REPORT
Information on patent family members

01/06/99

International application No.
PCT/DK 99/00042

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No.: 10-1188-US-CON3)

Applicant:	Veasey et al.
Appl. No.:	Unassigned, Continuation of 12/944,544
Filed:	June 4, 2013
Title:	Pen-Type Injector
TC/A.U.:	TBD
Confirmation No.:	TBD
Examiner:	TBD

FILED VIA EFS-WEB ON JUNE 4, 2013

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

GENERAL AUTHORIZATIONS UNDER 37 C.F.R. §§ 1.25(b) and 1.136(a)(3)

In this or any related application filed pursuant to 37 C.F.R. § 1.53, for the entire pendency thereof, and with respect to Deposit Account No. 132490, the Commissioner is hereby generally authorized:

(a) under 37 C.F.R. § 1.25(b), subject to the provisions of 37 C.F.R. § 1.311(b), to charge all fees set forth in 37 C.F.R. §§ 1.16 to 1.18; and

(b) under 37 C.F.R. § 1.136(a)(3) to treat any future reply requiring an extension of time as incorporating a request therefor, and specifically to charge any fee that may be due in connection with such a request.

Respectfully submitted,

McDONNELL BOEHNEN HULBERT & BERGHOFF LLP

Date: June 4, 2013

By: /Thomas E. Wettermann/
Thomas E. Wettermann
Reg. No. 41,523

McDONNELL BOEHNEN
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TELEPHONE (312) 913-0001

Electronic Patent Application Fee Transmittal	
Application Number:	
Filing Date:	
Title of Invention:	Pen-Type Injector
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Filer:	Thomas E. Wettermann
Attorney Docket Number:	10-1188-US-CON3

Filed as Large Entity

Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility application filing	1011	1	280	280
Utility Search Fee	1111	1	600	600
Utility Examination Fee	1311	1	720	720
Request for Prioritized Examination	1817	1	4000	4000
Pages:				
Claims:				
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Publ. Fee- Early, Voluntary, or Normal	1504	1	300	300
OTHER PUBLICATION PROCESSING FEE	1808	1	130	130
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**6030**

Electronic Acknowledgement Receipt

EFS ID:	15943131
Application Number:	13909649
International Application Number:	
Confirmation Number:	5079
Title of Invention:	Pen-Type Injector
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Customer Number:	20306
Filer:	Thomas E. Wettermann
Filer Authorized By:	
Attorney Docket Number:	10-1188-US-CON3
Receipt Date:	04-JUN-2013
Filing Date:	
Time Stamp:	16:24:52
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$6030
RAM confirmation Number	3597
Deposit Account	132490
Authorized User	

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Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)					
File Listing:					
Document Number	**Document Description**	**File Name**	**File Size(Bytes)/ Message Digest**	**Multi Part /.zip**	**Pages (if appl.)**
1	Transmittal of New Application	10_1188_US_CON3_Utility_Transmittal_2013_06_04.pdf	276565 43d79d45fd2333362f45ce286f87d3a415a5711d	no	2
Warnings:					
Information:					
2	Application Data Sheet	10_1188_US_CON3_ADS_2013_06_04.pdf	1504241 b94fbec451ff5caacfdb2ba69db5ed2d4b16d304	no	7
Warnings:					
Information:					
3		10_1188_US_CON3_Specification_2013_06_04.pdf	90150 a98c2224566bd65857804c1aba4d5bfd3d29cba1	yes	18
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Specification		1	12	
	Claims		13	17	
	Abstract		18	18	
Warnings:					
Information:					
4	Drawings-only black and white line drawings	10_1188_US_CON3_Figures_2013_06_04.pdf	518549 c6db34382bf78206d35a22f028d202f453cfc52d	no	7
Warnings:					
Information:					
5	Oath or Declaration filed	10_1188_US_CON3_Declaration_2013_06_04.pdf	526046 c512914325491982a2d8c390258568f38960928c	no	4
Warnings:					
Information:					
6	TrackOne Request	10_1188_US_CON3_Track_One_Request_2013_06_04.pdf	189276 5fc4aa1215f9c013df19268c2144313ff3a2ce11	no	2
Warnings:					
Information:					

7	Information Disclosure Statement (IDS) Form (SB08)	10_1188_US_CON3_IDS_2013_06_04.pdf	612816 6f97ee108fc53bff0de572005bcc37b6ef900f25	no	5
Warnings:					
Information:					
8	Foreign Reference	10_1188_US_CON3_Foreign_Ref_1.pdf	405542 b0cfe815dcb1074577065f570fb09b703ec83d1d	no	9
Warnings:					
Information:					
9	Foreign Reference	10_1188_US_CON3_Foreign_Ref_2.pdf	476778 7b6e575c877a1af3b3d72eb19e2873371d18a3d4	no	10
Warnings:					
Information:					
10	Foreign Reference	10_1188_US_CON3_Foreign_Ref_3.pdf	1152694 0b7bc03852b4a4d09b4a0ce72b17a71919883590	no	27
Warnings:					
Information:					
11	Foreign Reference	10_1188_US_CON3_Foreign_Ref_4.pdf	1383952 4f5e1e14ea819caaef4d32befc7411c995bc711d	no	30
Warnings:					
Information:					
12	Authorization for Extension of Time all replies	10_1188_US_CON3_General_Authorization_2013_06_04.pdf	81374 cd0f69ec7851cf7d5568cc795e17e3d16c3cbd68	no	1
Warnings:					
Information:					
13	Fee Worksheet (SB06)	fee-info.pdf	39964 56efea5c62f8b90d8a2dea14a188ea20a31a899a	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	7257947		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

2002/000785
CNT 3 1
CNT 4

Doc Code: Oath
Document Description: Oath or declaration filed

PTO/AIA/08 (06-12)
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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☒ Declaration Submitted With Initial Filing OR ☐ Declaration Submitted After Initial Filing (surcharge (37 CFR 1.16(f)) required)

Attorney Docket Number	10-1188-US-CON3
First Named Inventor	Robert Frederick Veasey
COMPLETE IF KNOWN	
Application Number	
Filing Date	
Art Unit	
Examiner Name	

Pen-Type Injector

(Title of the Invention)

As a below named inventor, I hereby declare that:

This declaration is directed to:

☒ The attached application,

OR

☐ United States Application Number or PCT International application number _____

filed on _____.

The above-identified application was made or authorized to be made by me.

I believe I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

Authorization To Permit Access To Application by Participating Office

☑ If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the above-identified patent application is filed access to the above-identified patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the above-identified patent application is filed to have access to the above-identified patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the above-identified patent application with respect to: 1) the above-identified patent application-as-filed; 2) any foreign application to which the above-identified patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the above-identified patent application; and 3) any U.S. application-as-filed from which benefit is sought in the above-identified patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing the Authorization to Permit Access to Application by Participating Offices.

PTO/AIA/08 (06-12)
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DECLARATION — Utility or Design Patent Application

Direct all correspondence to:	■	The address associated with Customer Number:	20306	OR ☐	Correspondence address below

Name		
Address		
City	State	Zip
Country	Telephone	Email

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Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available. Petitioner/applicant is advised that documents which form the record of a patent application (such as the PTO/SB/01) are placed into the Privacy Act system of records DEPARTMENT OF COMMERCE, COMMERCE-PAT-7, System name: *Patent Application Files* . Documents not retained in an application file (such as the PTO-2038) are placed into the Privacy Act system of COMMERCE/PAT-TM-10, System name: *Deposit Accounts and Electronic Funds Transfer Profiles* .

LEGAL NAME OF SOLE OR FIRST INVENTOR:

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

Robert Frederick Veasey

Inventor's Signature: R. Veasey		Date (Optional): 24/4/2013	
Residence: City: Warwickshire	State:	Country: GB	
Mailing Address: 31 Lonsdale Road Leamington Spa			
City: Warwickshire	State:	Zip: CV32 7EP	Country: GB

■ Additional inventors are being named on the 1 supplemental sheet(s) PTO/AIA/10 attached hereto

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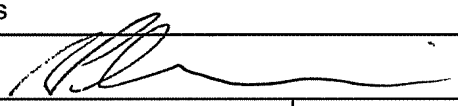
SUPPLEMENTAL SHEET FOR DECLARATION | **ADDITIONAL INVENTOR(S)**
Supplemental Sheet (for PTO/AIA/08,09) Page 1 of 1

Legal Name of Additional Joint Inventor, if any:

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

Robert Perkins

Inventor's Signature  Date (Optional) 24 APRIL 2013

Residence: City Oxfordshire | State | Country GB

Mailing Address 6 Printers Court Abingdon

City Oxfordshire | State | Zip OX14 5BZ ~~OX14 5BZ~~ | Country GB

*R-P 24-APR-2013

Legal Name of Additional Joint Inventor, if any:

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

David Aubrey Plumptre

Inventor's Signature | Date (Optional)

Residence: City Worcestershire | State | Country GB

Mailing Address 36 Shire Way Droitwich

City Worcestershire | State | Zip WR9 7RQ | Country GB

Legal Name of Additional Joint Inventor, if any:

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

Inventor's Signature | Date (Optional)

Residence: City | State | Country

Mailing Address

City | State | Zip | Country

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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SUPPLEMENTAL SHEET FOR DECLARATION | **ADDITIONAL INVENTOR(S)**
Supplemental Sheet (for PTO/AIA/08,09) Page 1 of 1

Legal Name of Additional Joint Inventor, if any:

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

Robert Perkins

Inventor's Signature	Date (Optional)

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Oxfordshire		GB

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Legal Name of Additional Joint Inventor, if any:

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

David Aubrey Plumptre

Inventor's Signature	Date (Optional)
[signature]	24/4/13

Residence: City	State	Country
Worcestershire		GB

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Worcestershire		WR9 7RQ	GB

Legal Name of Additional Joint Inventor, if any:

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

Inventor's Signature	Date (Optional)

Residence: City	State	Country

Mailing Address

City	State	Zip	Country

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/909,649	06/04/2013	3767	1900	10-1188-US-CON3	20	2

CONFIRMATION NO. 5079

20306
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

FILING RECEIPT

OC000000062316536

Date Mailed: 07/09/2013

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Robert Frederick Veasey, Warwickshire, UNITED KINGDOM;
Robert Perkins, Oxfordshire, UNITED KINGDOM;
David Aubrey Plumptre, Worcestershire, UNITED KINGDOM;

Applicant(s)

Robert Frederick Veasey, Warwickshire, UNITED KINGDOM;
Robert Perkins, Oxfordshire, UNITED KINGDOM;
David Aubrey Plumptre, Worcestershire, UNITED KINGDOM;

Assignment For Published Patent Application

DCA DESIGN INTERNATIONAL LTD, Warwick, UNITED KINGDOM

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 12/944,544 11/11/2010
which is a CON of 11/483,546 07/11/2006 PAT 7918833
and is a CON of 10/790,225 03/02/2004 ABN

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.)
UNITED KINGDOM 0304822.0 03/03/2003 No Access Code Provided

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If Required, Foreign Filing License Granted: 07/01/2013

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/909,649**

Projected Publication Date: 10/17/2013

Non-Publication Request: No

Early Publication Request: No

Title

Pen-Type Injector

Preliminary Class

604

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/909,649

APPLICATION AS FILED - PART I

	(Column 1)	(Column 2)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE($)	FEE($)		RATE($)	FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	280
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	720
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*			OR	x 80 =	0.00
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*				x 420 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1600

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1)		(Column 2)	(Column 3)					
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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CHICAGO IL 60606

Doc Code: TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.: 13/909,649

1. THE REQUEST FILED June 4, 2013 IS **GRANTED**.

The above-identified application has met the requirements for prioritized examination

A. ☒ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination.** The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;
B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims**, or a multiple dependent claim;
C. filing a **request for continued examination**;
D. filing a notice of appeal;
E. filing a request for suspension of action;
F. mailing of a notice of allowance;
G. mailing of a final Office action;
H. completion of examination as defined in 37 CFR 41.102; or
I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to Irvin Dingle at (571)272-3210, Office of Petitions.

Irvin Dingle
/Irvin Dingle/
[*Signature*]

Petitions Examiner
(Title)

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/909,649	06/04/2013	Robert Frederick Veasey	10-1188-US-CON3	5079

20306 7590 08/28/2013

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER	
MENDEZ, MANUEL A	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
08/28/2013	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 13/909,649	Applicant(s) VEASEY ET AL.	
	Examiner MANUEL MENDEZ	Art Unit 3763	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-20* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-20* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *06/04/2013* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some * c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/05/2013*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(a):
(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), first paragraph:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention.

In relation to claims 1-10, the specification does not describe a “dose knob”. There is no mention in the specification of a “dose knob” disposed near a proximal end of the dose dial sleeve. Accordingly, the phrase “dose knob” disclosed in line 9 of claim 1 appears to have no support in the specification.

The specification fails to disclose the term “driver” referring to the "driver extending along a portion of the piston rod" disclosed in line 12 of claim 1.

The specification fails to disclose the phrase “container housing” referring to the "container housing operatively coupled to the main housing” disclosed in line 18 of claim 1.

Finally, the specification fails to disclose the term "plunger" disclose in line 22 of claim 1. Clarification concerning the support of the structural elements “dose knob”, “driver”, “container housing”, and “plunger” is respectfully requested.

In relation to claims 11-20, the specification does not describe a “dose knob”. There is no mention in the specification of a “dose knob” disposed near a proximal end of the dose dial sleeve. Accordingly, the phrase “dose knob” disclosed in line 8 of claim 11 appears to have no support in the specification. Moreover, the specification fails to disclose the term “driver” referring to the "driver extending along a portion of the piston rod" disclosed in line 11 of claim 11. Clarification concerning the support of the phrases “dose knob” and “driver” is respectfully requested.

In view of the 35 U.S.C. 112 (first paragraph) problems disclosed above, the examiner of record cannot determine the exact scope of the pending claims, and therefore, presents the following Section 103 rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Walters et al. (EP 0937471A2; hereinafter “Walters”).

The Walters publication discloses a housing, a dose dial sleeve, a piston rod, and a drive sleeve. Since it appears that, *inter-alia*, the "dose knob" and the "driver" elements have no support in the specification and the “tubular clutch" is located at the distal end of the “dose knob", it is impossible to properly discern the exact function of the “tubular clutch” in the pending claims. Therefore, for a person of ordinary skill in the art, designing a dispensing apparatus having a housing, a dose dial sleeve, a piston rod, and a drive sleeve would have been considered an obvious design choice.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-20 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 7,918. Although the claims at issue are not identical, they are not patentably distinct from each other because both sets of claims identified above disclose similar structural elements with minor variations that a person of ordinary skill in the art would have considered as obvious design choices.

Claims 1-20 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 15, 17, and 19 of copending Application No. 12/944,544. Although the claims at issue are not identical, they are not patentably distinct from each other because both sets of claims identified above disclose similar

structural elements with minor variations that a person of ordinary skill in the art would have considered as obvious design choices.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MANUEL MENDEZ whose telephone number is (571)272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully submitted,

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Notice of References Cited	Application/Control No. 13/909,649	Applicant(s)/Patent Under Reexamination VEASEY ET AL.	
	Examiner MANUEL MENDEZ	Art Unit 3763	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-7,918,833	04-2011	Veasey et al.	604/209
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	EP 0937471A2, Walters et al., date of publication: 08/25/1999.
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	
	Filing Date	
	First Named Inventor	Robert Frederick Veasey
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	10-1188-US-CON3

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5626566	A	1997-05-06	Petersen et al.	
	2	6083197	A	2000-07-04	Umbaugh	
	3	6221046	B1	2001-04-24	Burroughs et al.	
	4	6899698	B2	2005-05-31	Sams	
	5	5688251	A	1997-11-18	Chanoch	
	6	5674204	A	1997-10-07	Chanoch	
	7	5304152	A	1994-04-19	Sams	
If you wish to add additional U.S. Patent citation information please click the Add button.						Add
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.M./

Receipt date: 06/04/2013	Application Number	13909649 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	
	First Named Inventor	Robert Frederick Veasey
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	10-1188-US-CON3

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020052578	A1	2002-05-02	Moller	
	2	20040059299	A1	2004-03-25	Moller et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	0937476	EP	A2	1999-08-25	Becton, Dickinson and Company		☐
	2	0937471	EP	A2	1999-08-25	Becton, Dickinson and Company		☐
	3	91/14467	WO	A1	1991-10-03	SAMS BERNARD		☐
	4	99/38554	WO	A1	1999-08-05	NOVO NORDISK AS		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.M./

Receipt date: 06/04/2013	Application Number	13909649 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	
	First Named Inventor	Robert Frederick Veasey
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	10-1188-US-CON3

	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Manuel Mendez/	Date Considered	08/25/2013

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.M./

Receipt date: 06/04/2013	Application Number	13909649 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	
	First Named Inventor	Robert Frederick Veasey
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	10-1188-US-CON3

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Thomas E. Wettermann/	Date (YYYY-MM-DD)	2013-06-04
Name/Print	Thomas E. Wettermann	Registration Number	41,523

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.M./

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.M./

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 937 471 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
25.08.1999 Bulletin 1999/34

(51) Int. Cl.[6]: **A61M 5/00**

(21) Application number: **99102372.2**

(22) Date of filing: **08.02.1999**

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **20.02.1998 US 26938**

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(54) Medication delivery pen

(57) A medication delivery pen having a repeat-dose feature that limits motion of the dose control mechanism using an adjustable repeat-dose stop on the dose knob. In addition, the medication delivery pen also provides the user a simple mechanism for setting and correcting the dose and a drive mechanism that makes the dispensing operation as easy as possible requiring as little force as necessary.

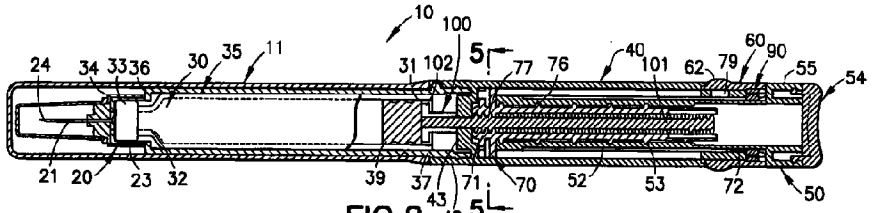

FIG.2

EP 0 937 471 A2

Description

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

[0001] The present invention relates to a medication delivery pen having a variety of features and, more particularly, a medication delivery pen that provides a mechanical advantage that uses less force to delivery the selected dose than would be needed to push directly on a plunger within a vial, a re-settable and/or repeatable dosing feature, and a self-priming feature all within the device using relatively few components.

2. DESCRIPTION OF RELATED ART

[0002] Hypodermic syringes are used to deliver selected doses of medication to patients. The prior art hypodermic syringe includes a syringe barrel having opposed proximal and distal ends. A cylindrical chamber wall extends between the ends and defines a fluid receiving chamber. The proximal end of the prior art syringe barrel is substantially open and receives a plunger in sliding fluid tight engagement. The distal end of the prior art syringe barrel includes a passage communicating with the chamber. A needle cannula may be mounted to the distal end of the prior art syringe barrel, such that the lumen of the needle cannula communicates with the passage and the chamber of the syringe barrel. Movement of the plunger in a proximal direction draws fluid through the lumen of the needle cannula and into the chamber. Movement of the plunger in a proximal-to-distal direction urges fluid from the chamber and through the lumen of the needle cannula.

[0003] Medication to be injected with the prior art hypodermic syringe often is stored in a vial having a pierceable elastomeric seal. Medication in the prior art vial is accessed by piercing the elastomeric seal with the needle cannula. A selected dose of the medication may be drawn into the chamber of the syringe barrel by moving the plunger a selected distance in a proximal direction. The needle cannula may be withdrawn from the vial, and the medication may be injected into a patient by moving the plunger in a distal direction.

[0004] Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the course of the day. The required dose of insulin will vary from patient to patient, and for each patient may vary during the course of the day and from day to day. Each diabetes patient will establish a regimen that is appropriate for his or her own medical condition and for his or her lifestyle. The regimen typically includes some combination of a slow or medium acting insulin and a faster acting insulin. Each of these regimens may require the diabetes patient to periodically self-administer insulin in public locations, such as places of employment or restaurants. The required manipulation of the standard prior art hypodermic syringe and vial can be inconvenient and embarrassing in these public environments.

[0005] Medication delivery pens have been developed to facilitate the self-administration of medication. One prior art medication delivery pen includes a vial holder into which a vial of insulin or other medication may be received. The vial holder is an elongate generally tubular structure with proximal and distal ends. The distal end of the prior art vial holder includes mounting means for engaging a double-ended needle cannula. The proximal end also includes mounting means for engaging a driver and dose setting apparatus as explained further below. A disposable vial for use with the prior art vial holder includes a distal end having a pierceable elastomeric seal that can be pierced by one end of a double-ended needle cannula. The proximal end of this prior art vial includes a plunger slidably disposed in fluid tight engagement with the cylindrical wall of the vial. This prior art medication delivery pen is used by inserting the vial of medication into the vial holder. A prior art pen body then is connected to the proximal end of the vial holder. The pen body includes a dose setting apparatus for designating a dose of medication to be delivered by the pen and a driving apparatus for urging the plunger of the vial distally for a distance corresponding to the selected dose.

[0006] The user of the pen mounts a prior art double-ended needle cannula to the distal end of the vial holder such that the proximal point of the needle cannula pierces the elastomeric seal on the vial. The patient then selects a dose and operates the pen to urge the plunger distally to deliver the selected dose. The dose selecting apparatus returns to zero upon injection of the selected dose with this prior art medication delivery pen. The patient then removes and discards the needle cannula, and keeps the prior art medication delivery pen in a convenient location for the next required medication administration. The medication in the vial will become exhausted after several such administrations of medication. The patient then separates the vial holder from the pen body. The empty vial may then be removed and discarded. A new vial can be inserted into the vial holder, and the vial holder and pen body can be reassembled and used as explained above.

[0007] The above described medication delivery pen is effective and much more convenient for self-administration of medication than the hypodermic syringes that use separate medication vials. However, the above-described medication delivery pens require the user to continually set or reset the desired dose before each injection. As a result, users with impaired vision and fine motor skills have found it difficult to readily set the dose on such pens especially when using a medication delivery pen having a wide range of dosage settings available. Since it is particularly common among patients with diabetes to have complications of the disease causing impaired vision and fine motor skills even more of a

need has been found to address this problem. Hence, it is necessary to provide a medication delivery pen having a simple mechanism for setting the desired dose, repeating the dose when necessary, and priming the medication delivery pen prior to use. It is also important to provide a medication delivery pen that makes the dispensing operation as easy as possible requiring as little force as necessary.

SUMMARY OF THE INVENTION

[0008] The present invention relates to a medication delivery pen that addresses the above-identified problems. The medication delivery pen has a repeat-dose feature that limits motion of the dose control mechanism using an adjustable repeat-dose stop on the dose knob. In addition, the medication delivery pen also provides the user a simple mechanism for setting and correcting the dose and a drive mechanism that makes the dispensing operation as easy as possible requiring as little force as necessary.

[0009] Another feature of the present invention is that the medication delivery pen provides a simple means for retracting the plunger when reloading the medication delivery pen with a new vial.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010]

Fig. 1 is an exploded perspective view of a medication delivery pen according to the present invention.

Fig. 2 is a cross-sectional view of the medication delivery pen shown in Fig. 1 fully assembled and in a ready for use condition.

Fig. 3 is a cross-sectional view of the medication delivery pen shown in Fig. 2 in a set dose condition and ready for dispense of medication.

Fig. 4 is a cross-sectional view of the rod barrel tube shown in Fig. 1.

Fig. 5 is a cross-sectional view of the medication delivery pen shown in Fig. 2 along line A-A.

Fig. 6 is a cross-sectional view of a portion of an alternative medication delivery pen that has a feature that it allows it to be reloadable.

Fig. 7 is a cross-sectional view of yet another medication delivery according to the present invention having means for setting a desired dose and repeating delivery of that desired dose in consecutive injections.

DETAILED DESCRIPTION OF THE INVENTION

[0011] A multi-feature medication delivery pen 10 according to the present invention is shown in Fig. 1. Medication delivery pen 10 includes a cap 11 removably attached to a body 40 so to cover a vial retainer 35 containing a vial 30. As shown in Fig. 2 vial 30 includes a proximal end 31 and a distal end 32 having a vial cap 33 that securely holds a vial septum 34 on distal end 32. Vial 30 also includes a vial piston 39 therein to form a sterile sliding seal within vial 30 to hold medication therein. As shown in Fig. 2 a pen-needle assembly 20 is releasably engaged to a distal end 36 of vial retainer 35. Pen-needle assembly 20 includes a double-ended needle cannula 21 having a distal point 24 and a proximal point (not shown). Double-ended needle cannula 21 is mounted on a hub 23 including means for attaching hub 23 to distal end 36 of vial retainer 35. A proximal end 37 of vial retainer 35 is snap-fit onto a distal end 42 of body 40 or can be mounted thereto by other means, e.g., threads.

[0012] As shown in Figs. 1-3, medication delivery pen 10 includes a rod barrel tube 70, a clicker 90, a lens and ring assembly 60, and a dose knob 50. Rod barrel tube 70 includes a distal end 71 and a proximal end 72, with an outer barrel 73 extending from distal end 71 and surround a rod barrel 74. As shown in Fig. 1 outer barrel 73 may have a pair of openings 75 through its outer surface. Rod barrel 74 includes a set of external threads 76 that mate with a set of internal threads 53 within dose knob 50, described below, and a set of internal threads 77 that mate with a threaded shaft 101 on a plunger 100 having a distal face 102 and a proximal end 105. Plunger 100 also includes a pair of keyways 104 extending from distal face 102 to a keyway stop 103 near proximal end 105. Rod barrel tube 70 also include a plurality of ratchet pawls 78 at distal end 71 that are received within body 40 and engage with ratchet 41 located within body 40 near its distal end 42. Distal end 42 of body 40 also includes a pair of keys 43, shown in Fig. 2, that extend into body 40 to engage with the pair of keyways 104 on plunger shaft 101 of plunger screw 100. Rod barrel tube 70 also includes a window 79 located near its proximal end 72 through which a plurality of dosage numerals 51 printed on dose knob 50 are visible to a user for setting of the desired dose. Dose knob 50 also includes a dose knob cap 54 that is permanently attached to a proximal end 55 of dose knob 50. Dose knob 50 also includes internal threads 53 that engage rod barrel outer diameter threads 76 on rod barrel 74 so that dose knob 50 is threaded out of rod barrel tube 70 as a dose is being set, as shown in Fig. 3. During the dose setting operation rod barrel tube 70 is prevented from rotating within body 40 by interaction of ratchet pawl 78 on rod barrel tube 70 and ratchet 41 within body 40.

[0013] Dose knob 50 also includes a plurality of key slots 52 arranged axially on the outer surface of dose

knob 50 so to receive a matched plurality of keys 91 on the inside of clicker 90 as clicker 90 is mounted onto dose knob 50. Clicker 90 also includes a plurality of clicker fingers 92 on its outer circumference that interacts with a plurality of slots 61 within lens and ring assembly 60. Interaction between clicker fingers 92 and slots 61 occur during the dose setting operation to provide the user with audible and/or tactile feedback during this operation. Lens and ring assembly 60 provide a feature of magnifying the dosage numeral 51 on the outside surface of dose knob 50 to aide the user in setting the dose during the setting operation using lens 62 integrated thereto.

[0014] Dose knob 50 has an enlarged proximal end 55 onto which dose knob cap 54 has been attached and may have a textured surface and/or an indentation to provide easy operator manipulation of dose knob 50 during dose setting of medication delivery pen 10. In addition, it should be appreciated that dose knob cap 54 could be integrally molded at proximal end 55 of dose knob 50.

[0015] Fig. 5 is a cross-sectional view of medication delivery pen 10 shown in Fig. 2 along lines A-A and more clearly show the interaction between the ratchet 41 within body 40 and ratchet pawl 78 at distal end 71 of rod barrel tube 70. Fig. 5 also shows that ratchet pawl 78 at ratchet surface 41 only prevent rotation in one direction so that after a dose has been set as shown in Fig. 3 and pressure is applied to dose knob cap 54 rod barrel tube 70 is free to rotate within body 40. As rod barrel tube 70, rotates interaction between rod barrel internal threads 77 and threaded shaft 101 of plunger screw 100 occurs to move plunger screw 100 in the distal direction a distance corresponding to the desired dose that was set. Plunger screw 100 moves in the distal direction because it is prevented from rotation by interaction of keys 43 in body 40 and keyways 104 on plunger screw 100.

[0016] Fig. 6 is a cross-sectional view of a section of an alternative medication delivery pen that provides the pen with the ability to be reloaded when vial has been filly used and must be replaced. This embodiment is substantially similar to the earlier embodiment except that key 43 within body 40 has been replaced with a plunger screw key 200 that is free to rotate when vial retainer 235 is removed from body 240, but when vial retainer 235 is filly threaded to pen body 240 plunger screw key 200 is prevented from rotating. Plunger screw key 200 includes a proximal face 201 having a plurality of teeth that engage with matching plurality of teeth 244 within body 240. Plunger screw key 200 also includes a shoulder 202 around the circumference that is received in a circumferencial internal diameter clearance slot 245 within body 240 to retain plunger screw key 200 within body 240. Plunger screw 200 also includes a pair of keys 203 that engage keyway 104 and plunger screw 100, discussed above. Interaction between key 203 and keyway 104 prevent plunger screw 100 from rotating when plunger screw key 200 is prevented from rotating because of the interaction between key 204 on plunger screw key 200 and key 244 within body 240 when a proximal end 237 of vial retainer 235 applies sufficient pressure on shoulder 202.

[0017] Fig. 7 is yet another embodiment of a medication delivery pen according to the present invention and, more particularly, shows a feature that allows the user to set a desired dose for repeated delivery. As shown in Fig. 7 this feature is provided by the incorporation into the first embodiment of a dose knob having a distal end 301 and a proximal end 302, wherein proximal end 302 includes a well about its outer surface and a plurality of stop adjuster rotation detents 304 are located within proximal end 302 of dose knob 300. A stop adjuster 310 includes a distal end 311 and a proximal end 312 with distal end 311 being inserted into circumferencial well 303 in dose knob 300. Stop adjuster 310 also includes a set of external threads 313 and a plurality of stop adjuster rotational detents 314 within an inner surface that engage with corresponding stop adjuster rotational detents 304 on dose knob 300. Stop adjuster rotation detents 304 and 314 provide the user with tactile feedback during the operation of setting the repeat dose.

[0018] A dose stop 320 includes a plurality of dose stop keys 321 extending radially from dose stop 320 and a set of internal threads 322 that engage with outer threads 313 on stop adjuster 310. A dose knob cap 330 is attached to dose knob 300 after stop adjuster 310 has been mounted on dose knob 300 to retain stop adjuster 310 thereon. In addition, dose knob cap 330 can provide a textured surface and/or indentations for use during dose setting, as described above.

[0019] After a dose has been set by the user, the user would rotate stop adjuster 310 to move dose stop 320 in a proximal direction until a proximal face 323 of dose stop 320 comes into contact with a distal face 393 on a clicker 390. Of course, clicker 390 provides the same features and functions as clicker 90 in the earlier embodiment. Rotation of stop adjuster 310 cause dose stop 320 to move because of interaction between internal threads 322 and stop adjuster outer diameter thread 313 and interaction between dose stop key 321 and a dose knob keyway 305 on dose knob 300. When dose stop is in the position desired by the user further proximal movement of the dose knob is prevented beyond the set desired dose. Dose stop 320 remains in the position it has been set to until change at a later point by the user via stop adjuster 310.

[0020] While the present invention has been described with respect to a preferred and a number of alternative embodiments, it is apparent that various changes can be made without departing from the scope of the invention as defined by the appended claims.

Claims

1. A medication delivery pen comprising:

a pen-needle assembly;

a vial retainer including a vial containing a medication to be delivered and having said pen-needle removably attached to a distal end;

a housing having said vial retainer mounted to a distal end and including;

a dose control mechanism for setting a desired dose to be delivered from the vial;

a drive mechanism for dispensing the desired dose from the; and

a rod barrel tube for interfacing said dose control mechanism with said drive mechanism.

2. A medication delivery pen according to Claim 1, wherein said rod barrel tube includes an outer thread for engaging said dose control mechanism and an inner thread for engaging said drive mechanism.

3. A medication delivery pen according to Claim 1, further comprising means for preventing rotation of said rod barrel tube and said drive mechanism when said dose control mechanism is being used to set the desired dose.

4. A medication delivery pen according to Claim 3, wherein said means for preventing rotation of said rod barrel tube and said drive mechanism includes a ratchet mechanism between said housing and said rod barrel tube to prevent rotation of said rod barrel tube and said drive mechanism within said housing when said dose control mechanism is being used to set the desired dose.

5. A medication delivery pen according to Claim 1, further comprising a means on said rod barrel tube for displaying the dose set by said dose control mechanism.

6. A medication delivery pen according to Claim 5, wherein said means for displaying the dose includes a window within said rod barrel tube.

7. A medication delivery pen according to Claim 1, further comprising means within said housing for resetting said drive mechanism when a new vial is loaded into said vial retainer.

8. A medication delivery pen according to Claim 1, further comprising means for repeating the desired dose.

9. A medication delivery pen according to Claim 8, wherein said means for repeating the desired dose includes an adjustable repeat dose stop in said dose control mechanism that limits axial motion of said dose control mechanism when setting the desired dose.

10. A medication delivery pen according to Claim 9,

wherein said dose control mechanism includes a dose knob, and

wherein said adjustable repeat dose stop is mounted in said dose knob to limit motion of said dose knob when repeating the desired dose.

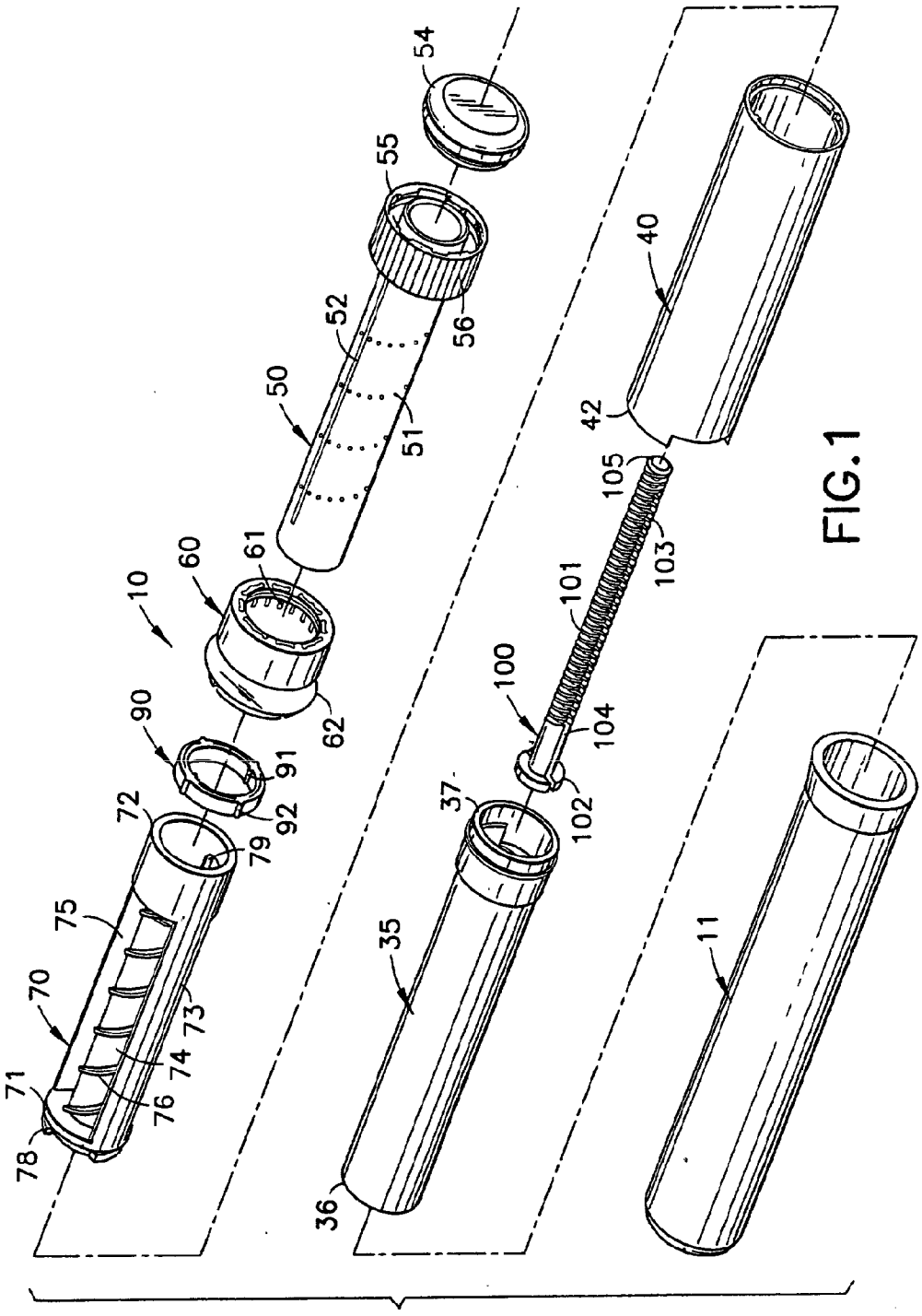

FIG.1

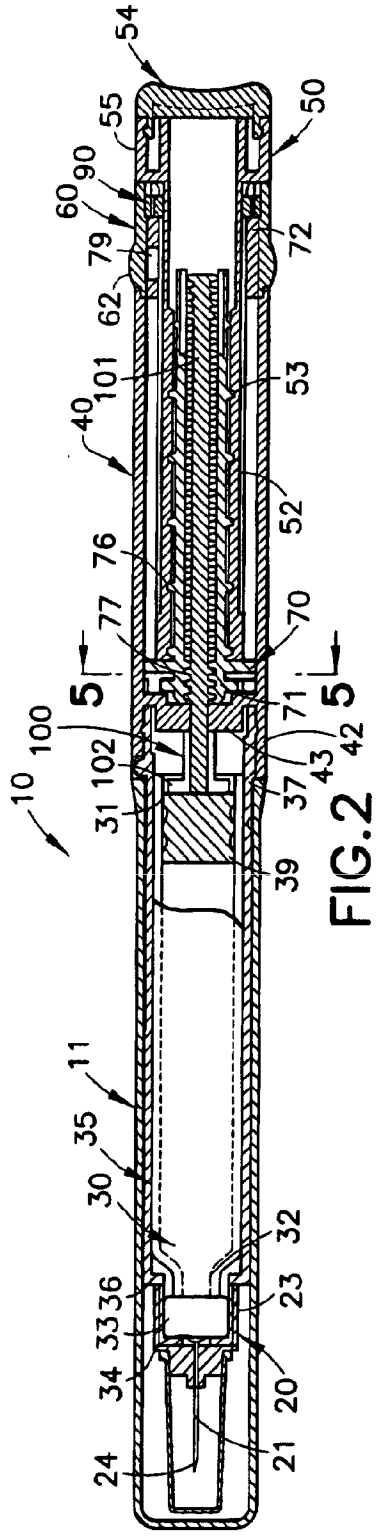

FIG.2

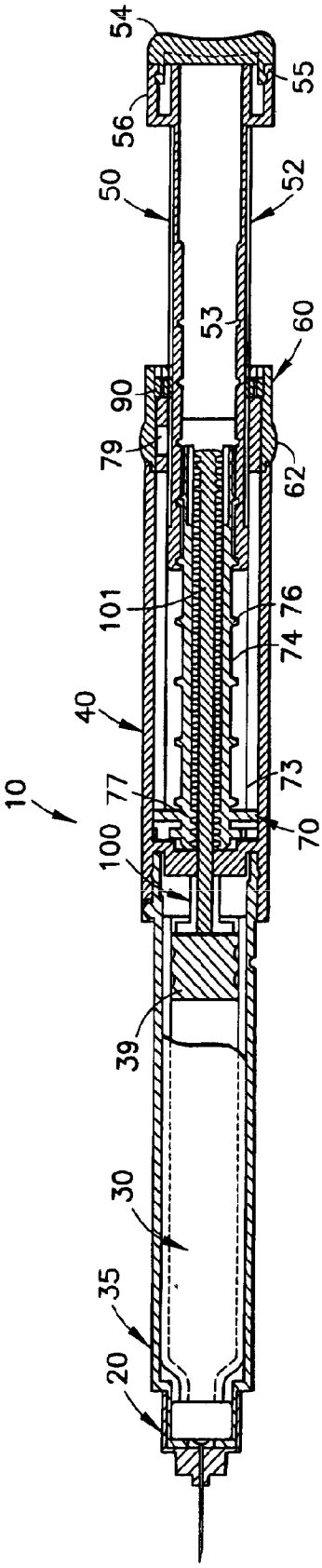

FIG.3

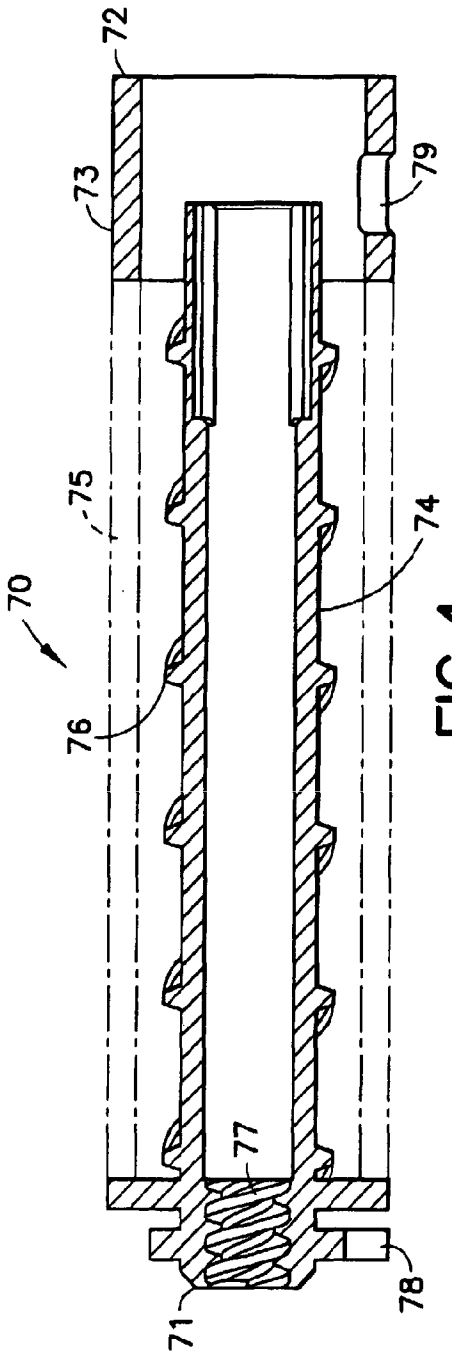

FIG.4

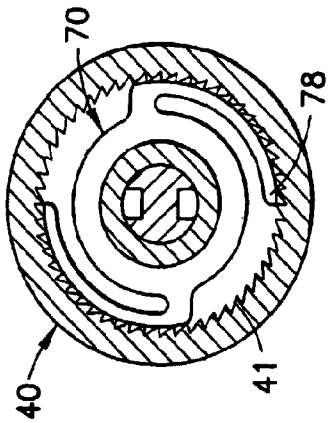

FIG.5

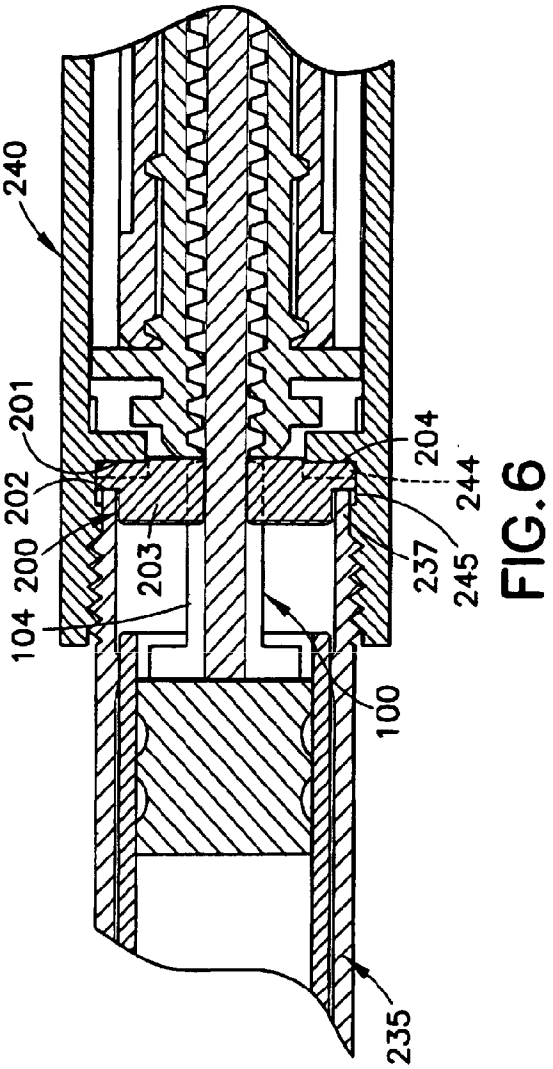

FIG.6

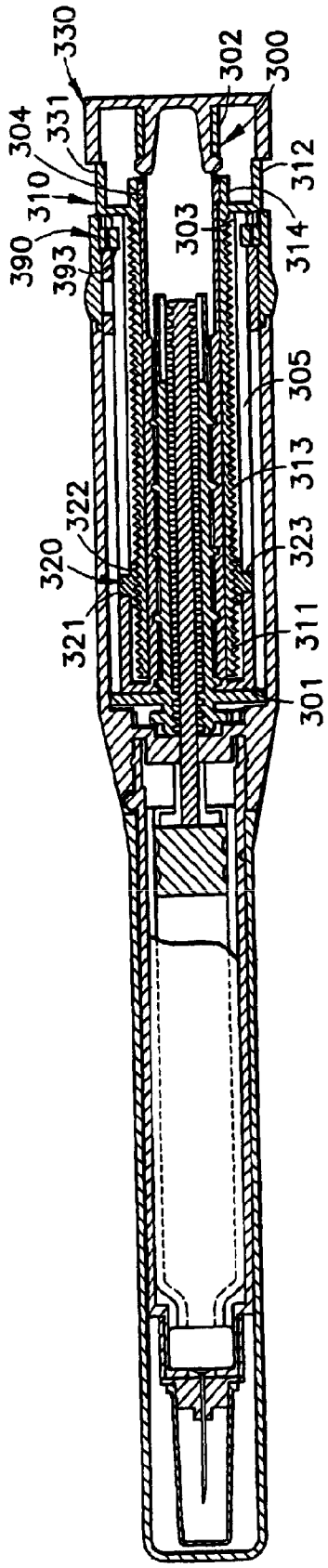

FIG.7

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13909649	VEASEY ET AL.
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	MANUEL MENDEZ	3763

CPC- SEARCHED		
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604	187, 207-211, 218, 221, 224, 232	8/25/2013	mm

SEARCH NOTES		
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(Not for submission under 37 CFR 1.99)

Application Number	13909649
Filing Date	2013-06-04
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	Mendez, Manuel A.
Attorney Docket Number	10-1188-US-CON3

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	4	5505704		1996-04-09	Pawelka et al.	
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	Filing Date	2013-06-04
	First Named Inventor	Robert Frederick Veasey
	Art Unit	3763
	Examiner Name	Mendez, Manuel A.
	Attorney Docket Number	10-1188-US-CON3

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Signature	/Thomas E. Wettermann/	Date (YYYY-MM-DD)	2013-08-30
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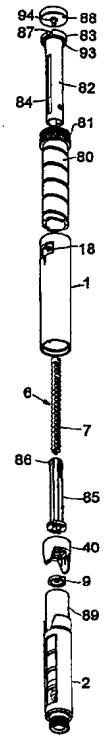
(57) Abstract

In an injection syringe comprising a housing (1), a piston rod (6) with a not circular cross section and an outer thread (7), a piston rod drive comprising a piston rod guide (85) mating the cross section of the piston rod (6) and a nut (4) which is not axially displaceable and mates the thread (7) of the piston rod (6) to form a self locking thread connection, and a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element (81) is screwed out to project from the housing (1) and which thread connection by axial returning of the injection button (88) transforms this axial movement into a rotation of one of the piston drive elements (85) relative to the other one (4). A unidirectional coupling between the nut member (4) and the piston rod guide (85) allows rotation in one direction by which the piston rod (6) is transported in a distal direction. The coupling has an initial reluctance to be overcome before rotation takes place said reluctance being large enough to resist torques exerted during the dose setting.



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An injection syringe

The invention relates to injection syringes of the kind apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses.

Such syringes are mainly made for users who have to inject themselves frequently, e. g. diabetics. A number of demands are set to such syringes. The setting of a dose must be easy an unambiguous and it must be easy to read the set dose. It must be possible with a minimum of trouble to cancel or change a wrongly set dose and when the dose is injected the dose setting must return to zero. When a disposable syringe is in question, i.e. a syringe which is disposed of when the cartridge is empty, the syringe must further be cheap and made of materials suited for recycling or burning without producing noxious gases. For these purposes the number of parts from which the syringe is constructed and the number of different kinds of materials used in the syringe should be kept at a minimum.

Most dose setting devices work with a threaded piston rod co-operating with a nut where the nut and the piston rod may be rotated relative to each other. The dose setting may be obtained by screwing the nut away from a stop to which it is returned during the injection by pressing the piston rod until the nut member abuts the stop. By other dose setting devices one of the elements, the nut or the piston rod, is kept inrotatable and the other is allowed to rotate a set angle depending on the set dose, whereby the piston rod is screwed a distance through the nut.

In most syringes for apportioning set doses it is preferred that the piston rod is backing up the piston upon which it works during the injection. To obtain this precaution is taken to prevent the piston rod from moving in a proximal direction.

The syringe according to EP 327 910 is of the type wherein a nut is screwed away from a stop. During the setting of the dose the screwing may be performed in both direction so that a too large set dose may be lowered just by rotating the nut in an opposite direction. Means are provided preventing that negative doses are set. The mutual rotation of the piston rod and the nut is obtained by rotating a cap relative to the pen housing and a set dose may be

read on a scale and a pointer provided at adjacent edges of the housing and the cap, these edges being so shaped that the cap can only be mounted firmly on the housing when the pointer points zero on the scale. It may be seen as a weak point that doses larger than the one obtained by rotating the parts 360° must be calculated by adding the number pointed at on the scale and a number printed on the side of a tubular extension of the nut which is moved out from the proximal end of the housing proportionally with the dose set and which tubular extension is closed at its proximal end to form an injection button.

In EP 450 905 the above drawback is overcome by writing the numbers along a helical line on a tubular extension of the nut so that these number may successively be seen in a window in a housing element enclosing said tubular extension. Hereby the size of the dose is indicated unambiguously but the user have to remember to set the dose setting device on zero before the next setting of a dose is performed. If this is forgotten a wrong dose may be set and the number may not be seen clearly in the window.

In EP 608 343 is described a pen having a dose setting mechanism wherein the dose is set by rotating a button relative to a housing to set a dose. By the rotation the button is screwed up from the end of the housing in a thread having a pitch so large that the thread connection is not self blocking, i. e. when the button is presses back to the end of the housing it will rotate back in the thread. The button is through a ratchet coupled to a driver, the ratchet forming a unidirectional coupling which during the rotation of the button in one direction to set a dose rides or clicks over the teeth of the ratchet. The cylindrical side of the button carries numbers which shows the size of the set dose in a window when the button is screwed outward. When the button is screwed back the unidirectional coupling will transmit the rotation to the driver which has a nut co-operating with a threaded piston rod which is made inrotatable in a housing . This thread connection has a pitch which makes the nut self locking on the piston rod. A set dose may be cancelled by drawing the engaging parts of the ratchet out of engagement against the force of a spring so that the rotation of the button is not transmitted to the driver and then press the button back to the housing . This pen fulfils all the objects mentioned only the dose cancelling procedure is a little troublesome as the dose set button cannot as it will come most naturally just be screwed back if a too large dose is set. Concomitantly forcing the coupling parts apart against the force of the spring and pressing or screwing the button back may be a little difficult and the demand for a spring necessitates use of metal parts in the syringe.

It is an object of the invention to provide a syringe which has the mentioned advantageous features without having the drawbacks known from existing syringes.

This is obtained by an injection syringes for apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses, comprising

a housing

a piston rod having a not circular cross-section and an outer thread

a piston rod drive comprising two elements

a) a piston rod guide in relation to which the piston rod is axially displaceable but not rotatable, and

b) a nut member which is rotatable but not axially displaceable in the housing and which has an inner thread mating the thread of the piston rod to form a self locking thread connection,

a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element relative to said housing is screwed out from the proximal end of the housing to project from this proximal end a distance determined by the angle of said rotation and which thread connection by axial returning of the injection button transforms this axial movement to a rotation of one of the piston drive elements relative to the other,

which syringe according to the invention is characterised in that

a unidirectional coupling is provided between the nut member and the piston rod guide allowing rotation of these parts relative to each other in one direction but not in the opposite direction, the allowed rotation being one by which the piston rod is transported in a distal di-

rection in the syringe, the coupling being so designed that a set initial reluctance has to be overcome before the rotation takes place.

During the setting of a dose a torque is exerted on the unidirectional coupling in the direction in which this coupling allows rotation after a set initial reluctance has been overcome. As this torque is a weak one resulting when the male and the female part of a not self locking thread connection is rotated relative to each other the initial reluctance can be made large enough to allow this rotation without causing any relative rotation of the parts in the coupling.

When the injection button is pressed the movement of this button is transformed into a rotation of the piston rod (or the nut member) relative to the nut member (or the piston rod). When the button is pressed hard enough the initial reluctans is overcome so that the two elements, the piston rod and the nut member, are rotated relative to each other.

According to the invention a click coupling providing an moderate resistance against rotation is established between the housing and the element rotated relative to the housing to set a dose. Hereby it is ensured that the position corresponding to a set dose is maintained and is not inadvertently altered. The clicks may be taken as an audible signal indicating the size of the set dose.

The unidirectional coupling may be a coupling comprising a pawl sliding over a pawl wheel with teeth having a steep front edge and a ramp shaped trailing edge, and the initial reluctance may be obtained by the fact that the trailing edges of the pawl wheel teeth has a depression engaged by a mating protrusion on the pawl.

A dose scale drum which has in its surface a helical track engaged by a helical rib on the inner side of the housing to form a not self locking thread connection between the housing and the drum may be coupled to the injection button to be moved axially with this button. This way the dose scale drum will be rotated relative to the housing when it is axially displaced with the injection button in said housing.

The thread connection by which the injection button is screwed out from the housing by setting a dose may be the thread connection between the dose scale drum and the housing. In this case the dose scale drum must be coupled to a driver rotating the piston rod (or the nut member) relative to the nut member (or the piston rod) when the injection button is pressed.

A dose is set by rotating an element relative to the housing, and this element may be an element carrying the nut member and the unidirectional coupling so that the rotation is transmitted through said unidirectional coupling to the dose setting drum. The rotation transmitted is in the direction in which the coupling can run free when an initial reluctance is overcome. However, the force needed to screw the dose scale drum up along its thread is not large enough to overcome said reluctance and consequently the rotation is transmitted through the coupling.

In one embodiment of the syringe according to the invention the element rotated relative to the housing may be a part carrying the nut member and the unidirectional coupling through which the rotation is transmitted to the dose setting drum.

In another embodiment of the syringe according to the invention the element rotated relative to the housing may be the injection button and the not self locking thread connection which determines the lifting of the injection button may be an inner thread in a bore in the injection butt on engaging an outer thread on an enlargement of the piston rod. When the injection button is screwed up along the piston rod to project from the housing a torque is exerted on the piston rod trying to rotate this piston rod in a direction which will move it in a distal direction in the syringe. Such a rotation is just the rotation which is allowed by the uniderectional coupling which blocks rotation in the opposite direction. Due to the initial reluctance against rotation of the coupling parts relative to each other the piston rod will not be rotated when the injection button is screwed up along it in a proximal direction in the syringe. If the injection button is screwed in the opposite direction the unidirectional coupling will definitively block a relative rotation of the piston rod and the nut member in the direction which would draw the piston rod in a proximal direction.

In the last mentioned embodiment of the injection syringe the dose scale drum may be mounted rotateable but not axially displaceable on the injection button. When the dose scale drum is moved with the injection button in the axial direction of the syringe the drum will be rotated due to the not self locking thread connection between said drum and the housing so that a number on the drum corresponding to the set dose is visible in a window provided in the wall of the housing. In this embodiment the pitch of the dose drum thread need not be identical with the pitch of the thread along which the injection button is screwed to set a

dose, only both thread connections must have a pitch large enough to make the thread connection the not self locking type, i.e. of the type by which an axial movement can be transformed into a rotation.

In an appropriate embodiment of the syringe according to the invention the dose scale drum is mounted rotatable but not axially displaceable on the injection button.

During the injection the injection button must be kept inrotatable but axially displaceable relative to the housing in the angular position to which the injection button is rotated during the setting of a dose. This may be obtained by letting the click coupling between the housing and the injection button comprise protrusions on one part engaging axial grooves in the other. When the injection button is pressed home into the housing the internal thread in the bore of this button will act on the engaging outer thread on the enlargement at the end of the piston rod and convert the axial movement of the injection button to a rotational movement of the piston rod in a direction by which the piston rod is screwed through the nut member in a distal direction in the syringe. The piston rod guide which is connected to one part of the unidirectional coupling is allowed to rotate when the initial reluctance against rotation in the direction else allowed by the coupling is overcome. Also a rotational movement of the dose scale drum is induced by the axial movement of the injection button so that the scale is returned to its zero position when the button is pressed home. When rotation of the dose scale drum and the piston rod is induced by the axial movement of the injection button this button is reacted upon by a torque which must be taken up by the click connection between the injection button and the housing which connection must consequently be strong enough to absorb this force without rotating.

In the following the invention is described in further details with references to the drawing, wherein

Figure 1 shows a front view of an embodiment of an injection syringe according to the invention,

Figure 2 shows a sectional view along the line II-II in figure 1,

Figure 3 shows in a reduced scale an exploded view of the syringe in figure 1,

Figure 4 shows a sectional view along the line IV-IV in figure 1,

Figure 5 shows a sectional view along the line V-V in figure 1,

Figure 6 shows a front view of another embodiment of an syringe according to the invention,

Figure 7 shows a sectional view along the line VII-VII in figure 6,

Figure 8 shows in a reduced scale an exploded view of the syringe in figure 6,

Figure 9 shows a sectional view along the line IX-IX in figure 6,

Figure 10 shows a sectional view along the line X-X in figure 6.

Figure 11 shows a sectional side view of another embodiment of a syringe according to the invention,

Figure 12 shows a sectional side view perpendicular to the view in figure 11,

Figure 13 shows in a reduced scale an exploded view of the syringe in figure 11 and 12,

Figure 14 shows a sectional side view of the dose setting part of another embodiment of a syringe according to the invention,

Figure 15 shows a sectional side view of still another embodiment of a syringe according to the invention,

Figure 16 shows a sectional side view perpendicular to the view in figure 15,

Figure 17 shows in a reduced scale an exploded view of the syringe in figure 15 and 16,

Initially it may be convenient to define that in this application directions of rotation are always seen from the proximal end of the pen and designed as clockwise or anticlockwise seen in this direction.

Figure 1 shows an injection syringe of the kind by which a liquid from an ampoule can be apportioned in a number of individually set does. Figure 3 shows an exploded view of this syringe and the figures 2, 4 and 5 sectional views taken along different lines in figure 1.

The syringe comprise a tubular housing 1 which is by a partition 15 divided into a first and a second division into the first one of which an ampoule holder 2 is snapped by a snap lock comprising a ring shaped bead 3 on the ampoule holder 2 which bead is snapped into a corresponding circumferantial grove in the inner wall of the housing 1 near an open end thereof. By this snap connection the ampoule holder 2 is secured in the housing 1 so that it can be rotated but not axially displaced relative to this housing.

In the syringe ready for use an ampoule is mounted in the ampoule holder which is then at its distal end closed by an end wall provided with a needle hub receiving part onto which a needle hub can be mounted having a needle with one end communicating with the content of the ampoule and the other end free to be inserted into a patient. In the shown syringe, however, neither ampoule, end wall nor needle hub are shown.

The end of the ampoule holder 2 inserted in the housing 1 is closed by a wall 4 having a central bore with an internal thread 5. A piston rod 6 having an external thread 7 mating the thread 5 of said bore extends through said bore. The threads are so designed that a clockwise rotation of the piston rod will drive this rod into an ampoule accommodating compartment 8 in the first division of the housing 1. At its end projecting into the compartment 8 the piston rod 6 is provided with a pressure foot 9 designed to abut a piston closing the rear end of an ampoule accommodated in the ampoule holder 2.

In the proximal side of the end wall 4 the bore is enlarged and the internal side of the enlargement is provided with pawl wheel teeth 10 having a steep front edge 11 facing the clockwise direction and a ramp shaped rear edge 12 facing the anticlockwise direction. At

least one pawl 13 mounted on a piston rod guide 14 co-operates with the pawl teeth 10 so that said piston rod guide can only be rotated clockwise in the ampoule holder 2.

On the inner wall of the second division of the housing 1 a helical protruding rib 16 is provided defining an inner thread with a high pitch. A dose scale drum 17 is in its outer wall provided with a helical grove defining a corresponding external thread mating the inner thread just mentioned. The pitch angle of the threads exceeds the angle of friction for the materials forming the parts of the thread connection and consequently the thread connection is of the not self locking type which induce a relative rotation of the parts of the connection when these part are moved axially relative to each other.

Numbers indicating set doses are printed on the outer wall of the dose drum 17 and the number corresponding to a set dose is shown in a window 18 provided in the side wall of the housing 1.

The dose scale drum 17 is provide with a tubular extension 21 having an end near the proximal end of the syringe. Said end of the extension is closed by an end wall 19 having a central outer protrusion 20. In a part of the wall adjacent to the end wall 19 the extension 21 is provided with slots 22. The said end of the extension is covered by a cup shaped cap 23 forming an injection button. Internal hooks 24 at the open end of this cap snaps over an external circumferential bead 25 on the extension 21 and the protrusion 20 on the end wall 19 abuts the inner side of the bottom of the cap 23 to form a journal about which the injection button can rotate relative to the extension 21 whereas it cannot be axially displaced relative to this extension.

A driver tube 26 integral with the piston rod guide 14 extends from this piston rod guide to the end wall 19 of the dose scale drum extension 21 and is at its proximal end divided into tongues 27 terminated by external hooks 28 engaging the slots 22 in the extension 21. This way the dose scale drum 17 is bound to rotate with the driver tube 26 but is axially displaceable relative to this tube.

To set a dose the ampoule holder 2 is rotated anticlockwise in the first division of the housing 1. This rotation is performed against a resistance presented due to the fact that a protrusion 30 on the outer wall of the ampoule holder rests in one of a number of depressions 31

circumferentially provided in the inner wall of said first division of the housing as shown in the cross-sectional view in figure 3. The angular spacing of the depressions are appropriately made so that a dose of one unit is set when the protrusion is moved from one depression to the neighbouring depression so that the number of clicks heard and felt during the dose setting rotation corresponds to the size of the set dose.

The rotation of the ampoule holder is due to the friction in the engaging threads 5 and 7 transmitted to the piston rod 6 and further through the unidirectional coupling to the piston rod guide 14 although the torque is transmitted in a such a direction that the pawl will intend to click over the pawl wheel teeth 10. However, before this click function is performed a reluctance have to be overcome. This reluctance is obtained by providing the pawl 13 with a protrusion 29 at its end engaging the pawl wheel teeth 10 and by providing depressions 32 in the ramp shaped edges 12 of the pawl wheel teeth into which depressions the protrusion 29 on the pawl 13 will rest. Before the clicking release of the coupling is obtained a torque sufficient to lift up the protrusion 29 of the pawl 13 from the depression 32 in the ramp shaped edge 12 must be provided. Altogether a moderate torque can be transmitted from the rotated ampoule holder 2 to the driver tube 26. As the hooks 28 at the proximal end of the driver tube 26 engage the slots 22 in the dose scale drum extension 21 the dose scale drum will be rotated and be screwed upwards in the second division of the housing 1 and the injection button 23 will be lifted to protrude from the proximal end of the housing 1. As only a small torque is needed to screw up the dose scale drum this is obtained without releasing the unidirectional coupling to its clicking release function mode. The size of the set dose can currently be seen on the part of the dose scale drum which is presented in the window 18. If a too large dose has been set the ampoule holder can be rotated in a clockwise direction until the number corresponding to the size of the wanted doe is presented in the window 18.

To inject the set dose the injection button 23 is pressed home into the housing 1. Thereby the dose scale drum 17 is pressed in the distal direction and due to the thread connection between said drum and the housing 1 a torque is exerted on the drum rotating this drum in a clockwise direction. Said torque is via the slots 22 in the drum extension 21 and the hooks 28 at the end of the driver tube 26 and this tube itself transmitted to the piston rod guide 14. The pawls 13 on the piston rod guide are allowed to rotate in the clockwise direction when the torque is strong enough to overcome the reluctance provided by the protrusions 29 on the pawls engaging the depressions 32 in the ramp shaped edges of the pawl wheel teeth.

Such a strong torque is provided if only the inject button 23 is pressed hard enough. The piston rod guide 14 will now rotate clockwise with the unidirectional coupling working in its clicking released mode and the piston rod will be rotated clockwise too and will thereby be screwed through the wall 4 further into the ampoule accommodating compartment 8. The unidirectional coupling will never allow an anticlockwise rotation of the piston rod guide and the piston and this way it is ensured that the pressure foot 9 will never be drawn out of abutment with the piston in a not shown ampoule in the compartment 8.

In the shown embodiment the end wall 4 with its threaded bore forms a nut member relative to which the piston rod is rotated by the piston rod guide 14 and the driver tube 26. Embodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the invention.

Another embodiment is described with reference to the figures 6-10. Elements corresponding to elements in the embodiment described with references to the figures 1-5 are provided with the same reference numbers. Different from the embodiment in figure 1-5 is the fact that the injection button 23 and not the dose scale drum 17 is provided with an extension 33, and that the driver tube 26 is omitted. Further the injection button 23 is provided with a flange 32 which abuts the end of the housing when the injection button is pressed home. The extension 33 serves as a journal for the dose scale drum 17 which is free to rotate on this journal but bound to follow axial movements of the injection button 23 due to hooks 34 at the end of the extension 33. A longitudinal bore 35 in the injection button and its extension 33 is provided with an internal helical rib 36 engaging a corresponding helical groove in an enlargement 37 at the proximal end of the piston rod to form a thread connection between said button 23 and said piston rod 6. The pitch of this thread connection is so that a not self locking thread connection is formed.

To set a dose the injection button 23 is manually rotated in a clockwise direction Thereby this button is screwed outwards from the housing 1 as the piston rod 6 will through the piston rod guide 14 and the unidirectional coupling be kept inrotatable although said unidirectional coupling in influenced by a torque in its release direction, however, due to the provided initial reluctance the piston rod guide 14 will not immediately be rotatable. In its movement outwards the injection button 23 will draw the dose scale drum 17 with it. When this drum is

moved axially in the housing it will be rotated due to the not self locking thread connection between said drum 17 and the housing 1.

By this construction the thread along which the injection button is screwed outwards and the tread along which the dose scale drum is rotated in the housing may be different.

A click connection corresponding to the one established between the cartridge holder 2 and the housing 1 in the embodiment according to figure 1 is in the embodiment according to figure 6 appropriately provided between the injection button 23 and the housing 1 where one or more protrusions 38 provided on the inner wall of the housing engages grooves 39in a cylindrical outer wall of the button 23. Thereby axial movement of the injection button is allowed in all its possible angular positions.

When the injection button is pressed to inject a set dose said button will be maintained inrotatable during its axial movement as the locking between the above mentioned protrusions on the inner wall of the housing and grooves on the outer wall of the button is strong enough to absorb the torque exerted on the injection button when it drives the piston rod to rotation in a clockwise direction after having overcome the reluctance against rotation in the release direction of the unidirectional coupling.

The embodiment shown in figure 11, 12 and 13 has the housing 1 with the window 18. The end wall 4 with the internal thread 5 is provided in a separate member 40 which is mounted in an end of the housing, the member 40 having protrusions 41 engaging slots 42 in the housing to lock the member 40 to the housing 1. Further the member 40 has at its periphery longitudinal recesses 43 which are engaged by not shown internal ribs in the housing to lock the member 40 against rotation relative to the housing 1. Further protrusions 44 on the ampoule holder 2 engage the slots 42 to lock the ampoule holder 2 to the housing 1.

The piston rod 6 engages by its external thread 7 the internal thread of the end wall 4 and is at its end in the ampoule holder terminated by a pressure foot 9 relative to which the piston rod 6 is rotatable. A driver tube 45 is at one end provided with the pawl 13 which engages pawl wheel teeth in the member 40 and is held between a ring shaped wall 46 in the housing and the end wall 4 in the member 40 to keep the driver tube 45 from axial movement but allowing it to rotate. On its inner wall the driver tube 45 has a key engaging a longitudinal re-

cess in the piston rod 6. Thereby rotation of the driver tube is transmitted to the piston rod 6 whereas the piston rod can move freely in the axial direction of the driver tube 45. On its outer wall the driver tube 45 has an outer thread 47 which engages an inner thread 50 in a nut member 48 which has at its distal end a flange 49 and is at its proximal end provided with a part 51 with reduced diameter to which part one end of a tubular part 52 which at its other end carries a button 23 is secured.

In the proximal end of the housing 1 a bushing 53 is secured to be non rotatable an non displaceable relative to said housing 1 the rotational locking being obtained by lugs 54 at the proximal end of the housing engaging recesses 55 at the periphery of the bushing 53. A guide member 56 is longitudinally displaceable in the bushing 53 but inrotatable relative to said bushing and consequently relative to the housing 1. The guide member has at its distal end an annular end wall 57. The part 51 of the nut member 48 is passed through the opening of said end wall 57 and has a bead 58 gripping into a circuferential inner recess in the wall of annular opening through said end wall to keep the bushing 53 secured to said part 51 so that this part can be rotated but not axially displaced in relation to the bushing 53. The scale drum 17 is journalled on the nut member 48 and is held on this nut member by having a flange 90 held between the end wall 57 of the guide member 56 and the shoulder formed where the part 51 connects to the nut member 48.

The button 23 is held rotatably on the guide member 56 which has a ring bead 59 engaging a circumferential recess 60 in the inner wall of the button 23 which recess 60 is somewhat broader than than the bead 59 so that the button in excess of being rotatable on said bushing 53 can be axially displaced a distance defined by the width of the recess 60 relative to the width of the bead 59. The button 23 is coupled to the nut member 48 by internal ribs 61 in the tubular part 52 engaging slots 62 in the proximal part of the part 51 of the nut member 48. This coupling forces the button 23 and the nut member 48 to follow each other in rotational movements but allow a minor relative axial displacement.

The proximal end surface of the guide member 56 has one or more axially directed protrusions 63 which can co-operate with radial recesses 64 in the bottom of the button 23, but mainly a biasing keeps these recesses and protrusions out of engagement. Further the guide member has at its proximal end at least one radial protrusion 65 which is biased to engage axial recesses 66 in an inner wall of the button to produced a click sound each time the

button is rotated relative to the bushing so that the protrusion jump from one recess to the neighbour recess.

To set a dose the button 23 is rotated in a clockwise direction. This rotation is due to the coupling between the ribs 61 and the slots 62 transmitted to the nut member 48 which is then screwed in distal direction along the driver tube 45 which is held inrotatably in the housing due to the reluctans of the pawl 13 to move along the pawl teeth in the member 40. The movement of the nut member 48 in proximal direction makes the scale drum 17, the guide member 56, and the tubular part 52 with the button move in proximal direction so that the button is elevated over the end proximal end of the housing 1. A to high set dose can be reduced by rotating the button in an anti clockwise direction.

During the rotation of the button the radial protrusion 65 of the guide member 56 clicks from one axial recess 66 to the other. The distance between can appropriately be chosen so that a click corresponds to a changing of the set dose by one international unit up or down. Due to engagement between the helical grove on the cylinder wall of the scale drum and a helical rib on the inner wall of the housing the movement of the dose scale drum 17 will rotate and displace said drum so that the set dose is shown in the window 18.

When the dose scale drum is displaced outwardly in the housing a steep front side of a saw tooth 91 at the proximal end of the dose scale drum 18 will abut a steep front side of a similar tooth 92 on the bushing whereby the rotation of the dose scale drum is stopped to indicate that a maximum dose has been set.

To inject the set dose the button 23 is pressed. Thereby the bias keeping the protrusions 63 and the recesses 64 out of engagement is overcome and the said engagement is established. The button 23 is now locked relative to the guide element 56 which is again locked against rotation relative to the bushing 53 and consequently relative to the housing 1. The coupling between the tubular part 52 and the nut member 48 makes this nut member inrotatable relative to the housing so an axial movement of said nut member in a distal direction will due to the not self locking thread coupling between this nut element and the driver tube 45 make this driver tube 45 rotate in a clockwise direction and due to the key/groove coupling between the driver tube 45 and the piston rod 6 said piston rod will be screwed through the end wall 4 further into the ampoule holder compartment. The locking of the button 23

against rotation during the injection ensures that the set dose is not inadvertently changed during the injection.

In the embodiment shown in figure 14 separate buttons are provided for the dose setting and the injection. Corresponding to previously described embodiments this one has a housing 1 and a driver tube 67 which is rotatable in only one direction due to a pawl which engage pawl wheel teeth in a part secured in the distal end of the housing. Trapping of the pawl between the member 40 and a ring shaped wall 46 in the housing fixes the driver tube against axial movement. On the outer wall of the driver tube 67 an axial rib 68 is provided which rib engages an axial recess 69 in a tubular injection element 70 to transmit rotation of said injection element to the driver tube 67.

At the proximal end of the housing 1 a dose setting button 71 is mounted so that this button can be rotated but not axially displaced relative to the housing 1. This is obtained by the fact that the dose setting button 71 on a part fitting into the housing has a ring shaped bead 72 which engages a mating circuferential recess 73 in the inner wall of the housing. Outside the housing the dose setting button has a part having a diameter corresponding to or being larger than the diameter of said housing which part can be provided with axial ribs 74 to ensure a good grip by the setting of a dose. The dose setting button 71 has a central bore the inner wall of which has a helical recess 75 engaging a helical rib 76 provided on the outer wall of the proximal part of the injection element 70 which element passes through the bore of the dose setting button 71. The outer wall of the distal part of the injection element 70 forms a journal for the scale drum 17 which through an outer helical recess engaged by an internal helical rib 16 in the housing is rotated to show the set dose in the window 18 when the scale drum is displaced axially in the housing. The proximal end of the injection member is terminated by an end wall 77 which carries an injection button 78 which is by a pivot pin 79 journaled in a central bore in said end wall 77.

To set a dose the dose setting button 71 is rotated in a clockwise direction. As the injection member is kept non rotatable by its coupling to the driver tube 67 the collaboration between the helical recess 75 in the inner wall of the dose setting button 71 and the helical rib 76 on the outer wall of the injection element 70 will screw the injection element out through the dose setting button so that the injection button 78 is lifted up from the proximal end of the housing. Although the driver tube 67 with its pawl can be rotated in the clockwise direction

an initial torque is needed which is larger than the torque transmitted from the dose setting button to the injection element.

To inject a set dose the injection button 78 is pressed and the injection element is moved back into the housing. The co-operation of the helical recess 75 in the inner wall of the dose setting button 71 and the helical rib 76 on the outer wall of the injection element 70 will now make the injection element rotate in a clockwise direction and if only the injection button is pressed hard enough a torque is produced large enough to overcome the initial reluctance of the pawl mechanism against rotation in said clockwise direction.

The separation of the dose setting button 71 and the injection button 78 makes it less likely that the dose setting button is inadvertently operated during the injection.

Figure15, 16 and 17 illustrates still another embodiment. To maintain a clockwise rotation of a dose setting button for increasing the set dose the pawl mechanism working between the driver tube and the housing is turned so that it bars clockwise rotation and reluctantly allows anticlockwise rotation of the driver tube. Further the thread of the piston rod and the thread in the end wall of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment. The piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section. This way rotation is transmitted whereas the piston rod is allowed to move longitudinally through the driver tube.

A scale drum 80 is in its outer wall provided with a helical track which is engaged by a helical rib16 along the inner wall of the housing 1. At its proximal end the scale drum 80 has a diameter exceeding the inner diameter of the housing to form a dose setting button 81 which on its cylindrical outer wall is knurled to ensure a good finger grip.

A bushing 82 having a flange 83 at its proximal end and having a pair of opposite longitudinal slots 84 through its side walls fits into the scale drum 80 and over the driver tube 85 which tube has on its outer wall hooks 86 engaging the slots 84 of the bushing 82 whereby the bushing 82 and the driver tube 85 is coupled to each other so that rotation but not longitudinal displacement is transmitted between said two elements.

In the dose setting button a compartment is provided having a cylindrical side wall circumferentially provided with longitudinal recesses and a bottom with a rosette of teeth having a triangular cross-section. The flange 83 of the bushing 82 is adopted in said compartment and has at its periphery a radial protrusion 87 which is biased toward the side wall of the compartment. At its distal side the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment.

The bushing 82 is mounted in the scale drum 80 with protrusion on the outer wall of the bushing 82 engaging recesses in the inner wall of the scale drum 80 so that a limited movement of the bushing in the scale drum is allowed so that the bushing can be moved axially relative to the scale drum to make or not make the teeth of said rosettes engage each other. An injection button 88 is rotatably mounted with a pivot pin 94 journaled in an end wall of the bushing 82.

When a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing and the dose setting button is lifted away from the proximal end of the housing. The bushing is kept non rotated due to its coupling to the driver tube which is locked against clockwise rotation and if a set dose is reduced by rotating the dose setting button 81 in an anticlockwise direction the pawl mechanism working between the driver tube and the housing is sufficient reluctant to rotate in its not blocking direction to prevent the bushing 82 from following this anticlockwise rotation. Therefore by the rotation of the dose setting button 81 in any direction the radial protrusion 87 on the flange 83 of the bushing 82 will click from one of the axial recess in the inner wall of the dose setting button 81 to the next one, the recesses being so spaced that one click corresponds to a chosen change of the set dose, e. g. one unit or a half unit. During the setting the rosette in the dose setting button forces the rosette 93 on the flange 83 of the bushing 82 out of engagement.

When the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81 which is induced by the thread engagement between the helical track of the scale drum 80 and the rib 16 in the housing when the scale drum 80 is pressed back into said housing. The bushing will rotate the driver tube 85 in an anticlockwise direction which

the pawl mechanism reluctantly allows an the piston rod is thereby screwed further into an ampoule 89 in the ampoule holder 2.

By this device the risk for inadvertent operation of the dose setting button 81 during the injection is eliminated. Further the device consist of a minimum of parts whereby the manufacturing is made easy.

CLAIMS

An injection syringes for apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses, comprising

a housing

a piston rod having a not circular cross-section and an outer thread

a piston rod drive comprising two elements

a) a piston rod guide mating the not circular cross-section of the piston rod to allow axially displacement but not rotatation of the piston rod in relation to said piston rod guide, and

b) a nut member which is not axially displaceable in the housing and which has an inner thread mating the thread of the piston rod to form a self locking thread connection,

a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element relative to said housing is screwed out from the proximal end of the housing to project from this proximal end a distance determined by the angle of said rotation and which thread connection by axial returning of the injection button transforms this axial movement to a rotation of one of the piston drive elements relative to the other,

characterised in that

a unidirectional coupling is provided between the nut member and the piston rod guide allowing rotation of these parts relative to each other in one direction but not in the opposite direction, the allowed rotation being one by which the piston rod is transported in a distal direction in the syringe, the coupling being so designed that an initial reluctance set large

enough to resist a torque exerted on the coupling by the dose setting has to be overcome before rotation takes place.

2. An injection syringe according to claim 1, characterised in that a click coupling providing an moderate resistance against rotation in either directions is established between the housing and the element rotated relative to this housing to set a dose.

3. An injection syringe according to claim 1 or 2, characterised in that the unidirectional coupling comprises a pawl sliding over a pawl wheel with teeth having a steep front edge and a ramp shaped trailing edge.

4. An injection syringe according to claim 3, characterised in that the trailing edges of the pawl wheel teeth has a depression engaged by a mating protrusion on the pawl.

5. An injection syringe according to anyone of the preceding claims, characterised in that a dose scale drum has in its surface a helical track engaged by a helical rib on the inner side of the housing to form a not self locking thread connection between the housing, and that the dose scale drum is coupled to the injection button to be moved axially with this button.

6. An injection syringe according to claim 5, characterised in that the thread connection by which the injection button is lifted by setting a dose is the thread connection between the dose scale drum and the housing.

7. An injection syringe according to claim 1, 2, 3, or 4 characterised in that the element rotated relative to the housing is the injection button and that the not self locking thread connection which determines the lifting of the injection button is an inner thread in a bore in the injection button engaging an outer thread on a part with enlarged diameter of the piston rod.

8. An injection syringe according to claim 1, 2, 3 or 4, characterised in that the piston rod guide is mounted in a driver tube in which tube the piston rod is axially displaceable but is rotated with said tube, and that the not self locking thread connection which determines the lifting of the injection button is provided between the driver tube and a part which is axially displaceable with the injection button.

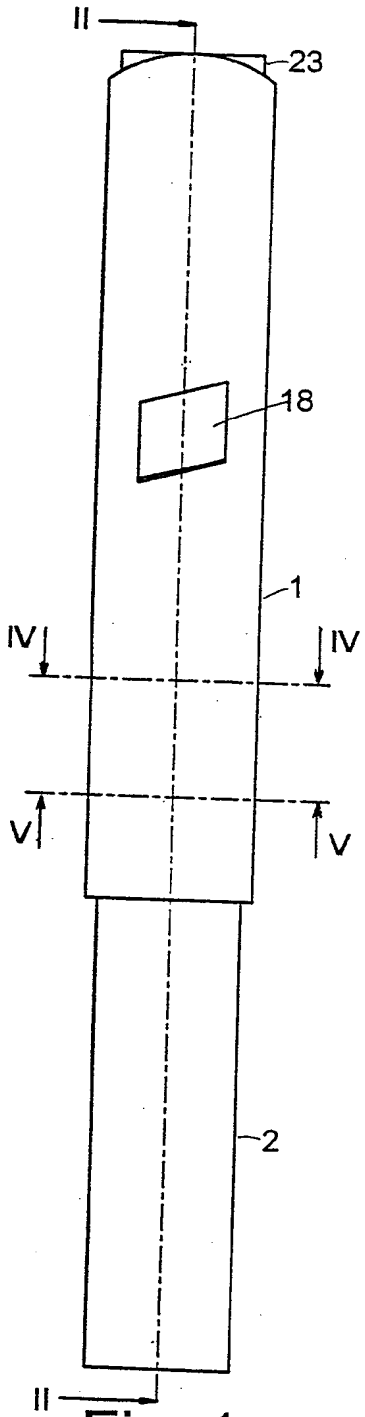

Fig. 1

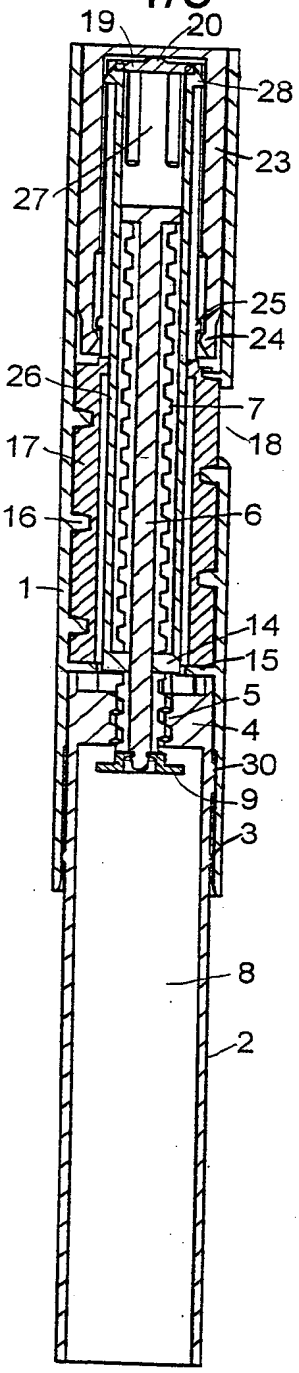

Fig.2

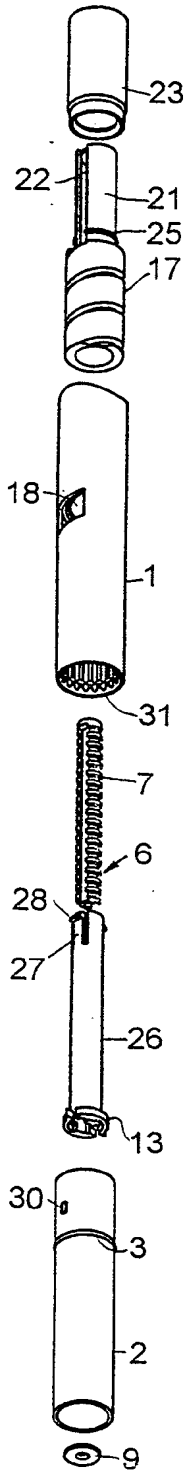

Fig.3

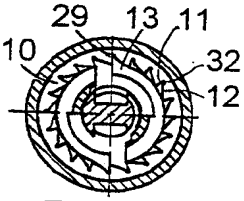

Fig.4

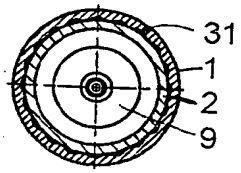

Fig. 5

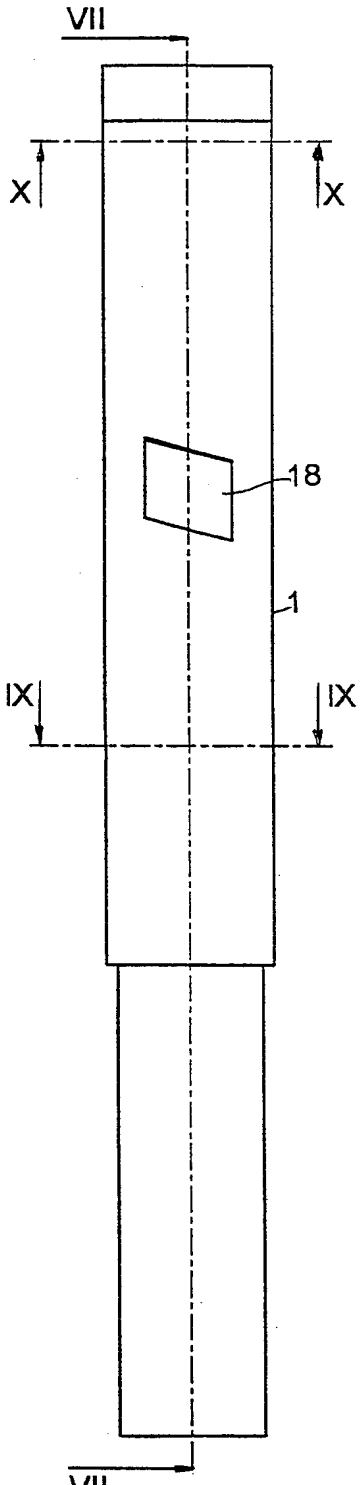

Fig. 6

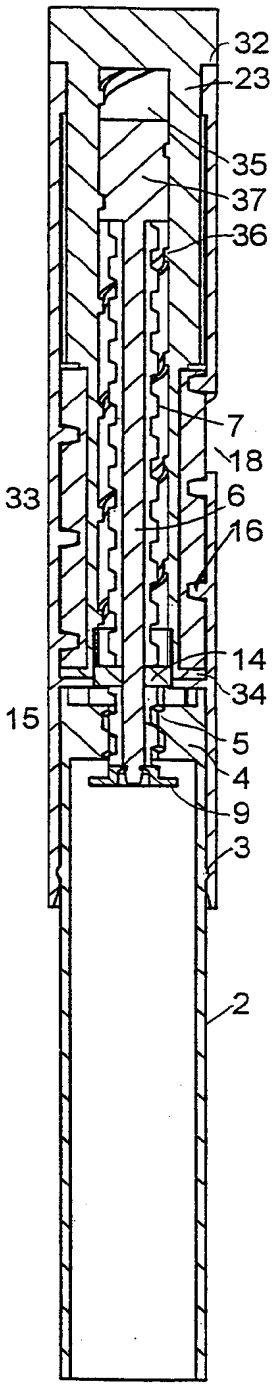

Fig. 7

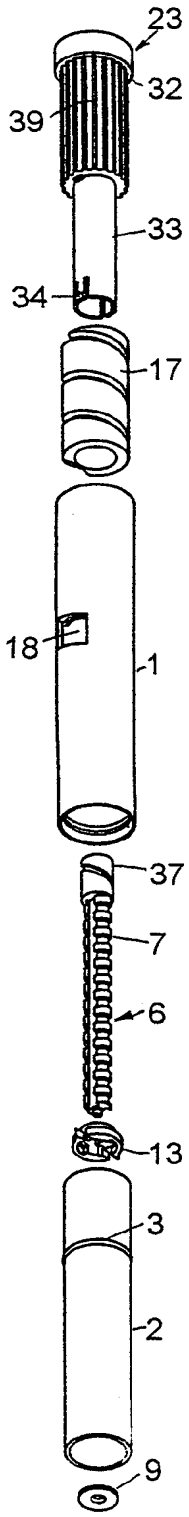

Fig.8

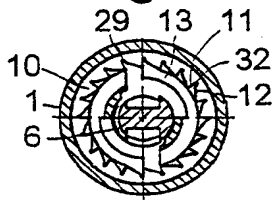

Fig. 9

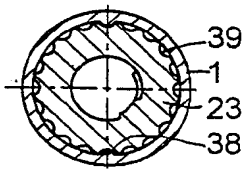

Fig.10

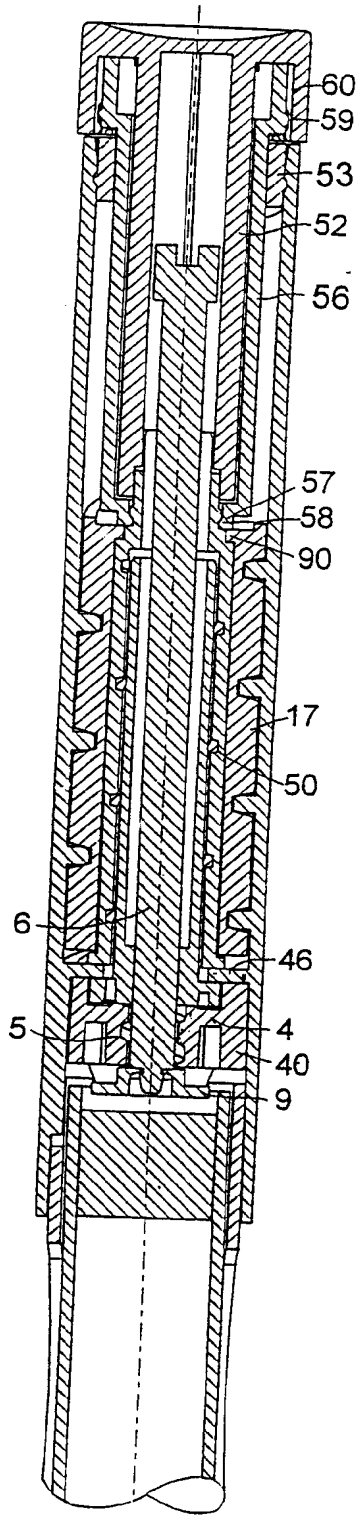

Fig. 11

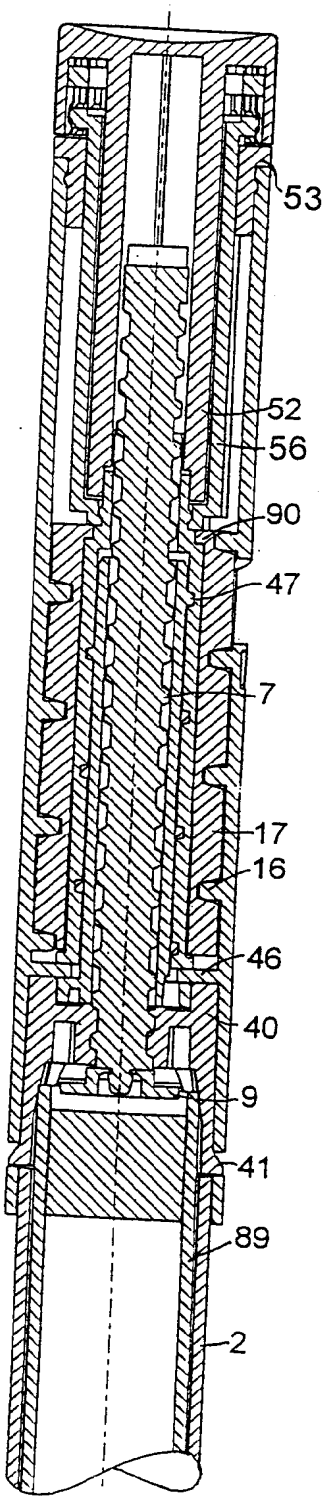

Fig. 12

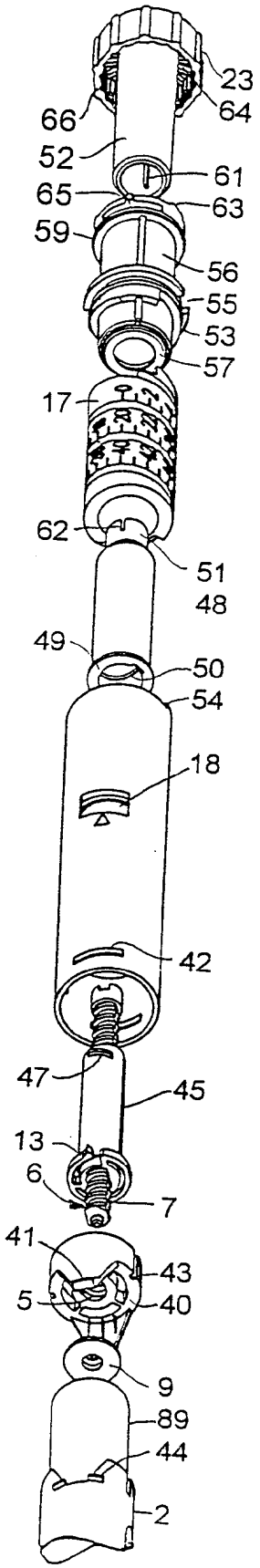

Fig. 13

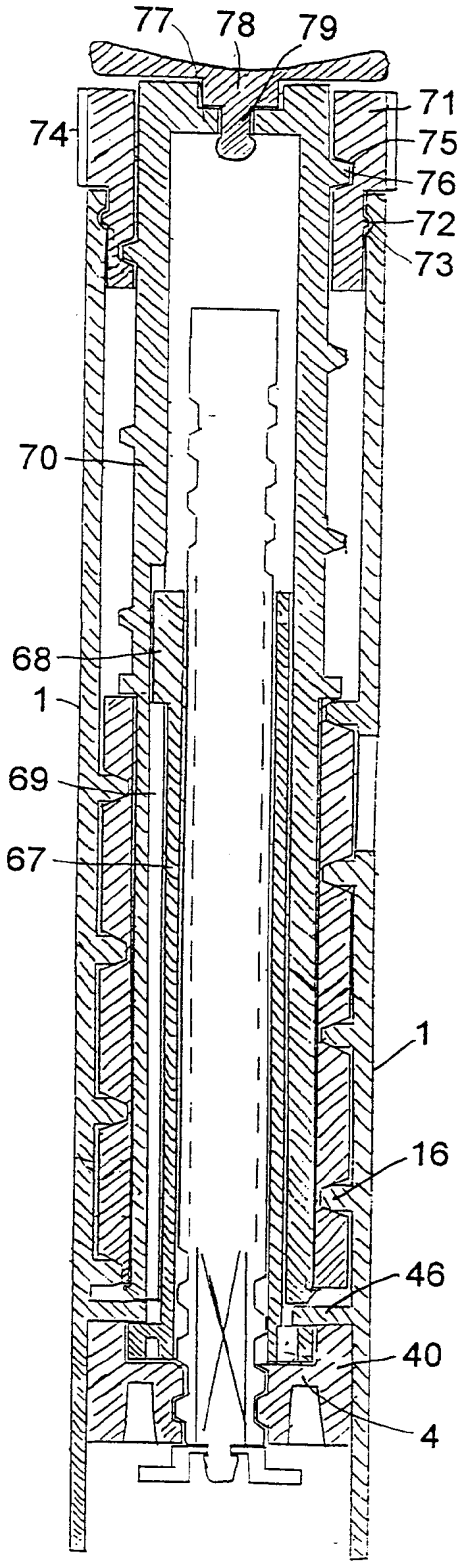

Fig. 14

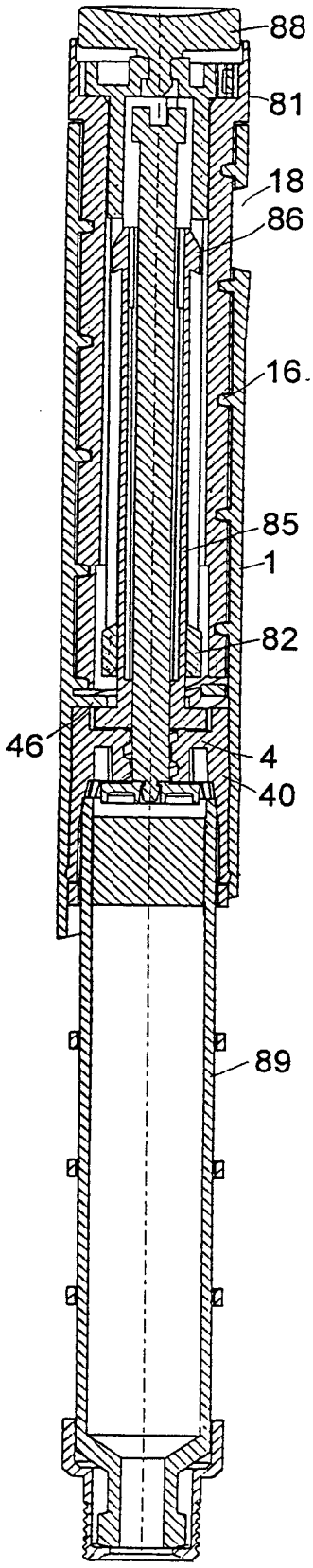

Fig. 15

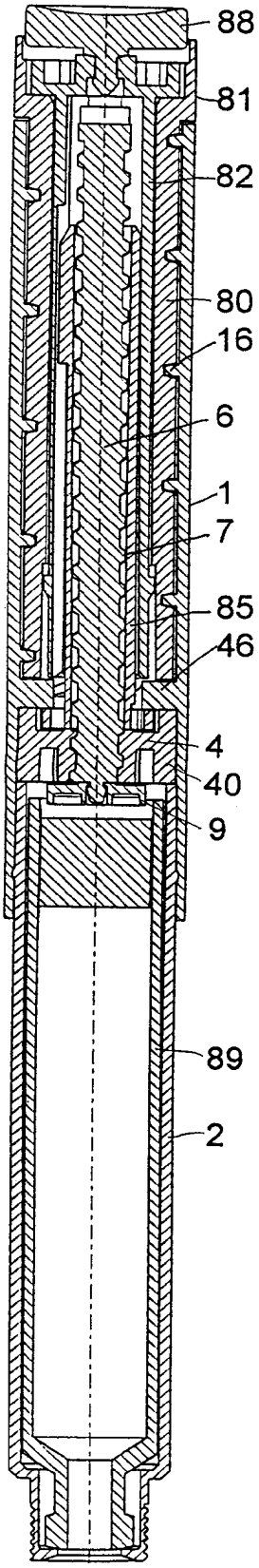

Fig.16

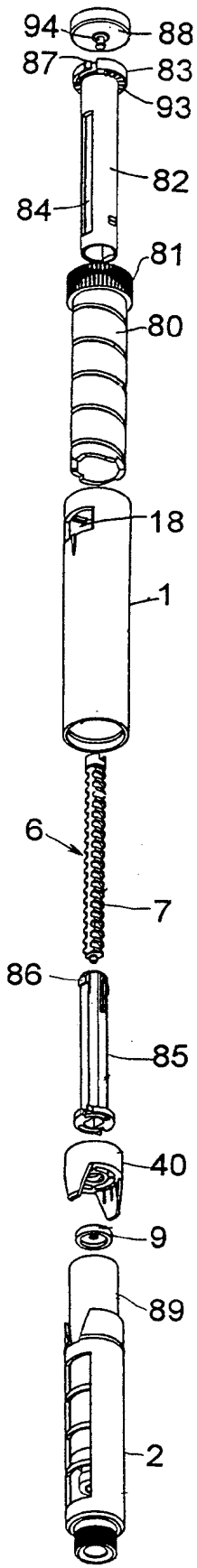

Fig. 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 99/00042

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 5/315, A61M 5/24
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)

IPC6: A61M

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

SE,DK,FI,NO classes as above

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5674204 A (LAWRENCE H.CHANOCH), 7 October 1997 (07.10.97), column 4, line 26 - column 6, line 29, figure 3, abstract --	1-8
A	WO 9307922 A1 (NOVO NORDISK A/S), 29 April 1993 (29.04.93), figures 2-7, abstract --	1-8
A	EP 0327910 A2 (D.C.P.AF 1988 A/S), 16 June 1989 (16.06.89), figures 2,3, abstract --	1-8
A	EP 0450905 A1 (ELI LILLY AND CO.), 9 October 1991 (09.10.91), column 1, line 19 - column 2, line 36 -- --------	1-8

☐ 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
"E" erlier 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

Date of the actual completion of the international search	Date of mailing of the international search report
7 July 1999	08 -07- 1999
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Joni Sayeler Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

01/06/99

International application No.
PCT/DK 99/00042

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INTERNATIONAL SEARCH REPORT
Information on patent family members

01/06/99

International application No.
PCT/DK 99/00042

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		US 5295976 A	22/03/94

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON3)

In re Application of:	)	
	)	
Robert Frederick Veasey et al.	)	
	)	Examiner: Mendez, Manuel A.
Serial No.: 13/909,649	)	
	)	Group Art Unit: 3763
Filed: June 4, 2013	)	
	)	Confirmation No.: 5079
For: Pen-Type Injector	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

GENERAL AUTHORIZATION UNDER 37 C.F.R. § 1.136(a)(3)

Sir:

The Commissioner is hereby generally authorized under 37 C.F.R. § 1.136(a)(3) to treat the present and any future related filings in this or any related application filed pursuant to 37 C.F.R. § 1.53 requiring an extension of time as incorporating a request therefore, and the Commissioner is hereby specifically authorized to charge Deposit Account No. 13-2490 for any fee that may be due in connection with such a request for an extension of time.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff LLP

Date: August 30, 2013

By: /Thomas E. Wettermann/
Thomas E. Wettermann
Reg. No. 41,523

McDonnell Boehnen Hulbert & Berghoff LLP
300 S. Wacker Drive
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312.913.0001

Electronic Patent Application Fee Transmittal

Application Number:	13909649
Filing Date:	04-Jun-2013
Title of Invention:	Pen-Type Injector
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Filer:	Thomas E. Wettermann
Attorney Docket Number:	10-1188-US-CON3

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	16732007
Application Number:	13909649
International Application Number:	
Confirmation Number:	5079
Title of Invention:	Pen-Type Injector
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Customer Number:	20306
Filer:	Thomas E. Wettermann
Filer Authorized By:	
Attorney Docket Number:	10-1188-US-CON3
Receipt Date:	31-AUG-2013
Filing Date:	04-JUN-2013
Time Stamp:	16:25:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	8199
Deposit Account	132490
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)					
File Listing:					
Document Number	**Document Description**	**File Name**	**File Size(Bytes)/ Message Digest**	**Multi Part /.zip**	**Pages (if appl.)**
1	Transmittal Letter	10_1188_US_CON3_Supplemental_IDS_Transmittal_2013_08_30.pdf	140453 86b579acca2dd039f9129b3b153055b7b834b32c	no	1
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	10_1188_US_CON3_Supplemental_IDS_2013_08_30.pdf	612516 ff6d3f49849bc757c1a7c051b47887d527919947	no	4
Warnings:					
Information:					
3	Foreign Reference	10_1188_US_CON3_Foreign_Ref_1.pdf	1419670 691498422127a117ab77bef6fb851672714d7387	no	30
Warnings:					
Information:					
4	Authorization for Extension of Time all replies	10_1188_US_CON3_General_Authorization_2013_08_30.pdf	58577 58cf23f3a2ef9e0367d3d95de3fd3d69a8c8eedb	no	1
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30236 be5de5bd20b915a79d52a7696e54ef74abfee448	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2261452		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/21 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	

Application Number	13/909,649
Filing Date	June 4, 2013
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	Mendez, Manuel A.
Attorney Docket Number	10-1188-US-CON3

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Supplemental Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
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- ☐ Petition
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- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) ___
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please Identify below):
  Copy of Cited Reference and General Authorization

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	McDonnell Boehnen Hulbert & Berghoff LLP		
Signature	/Thomas E. Wettermann/		
Printed name	Thomas E. Wettermann		
Date	August 30, 2013	Reg. No.	41,523

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Signature	/Thomas E. Wettermann/		
Typed or printed name	Thomas E. Wettermann	Date	August 30, 2013

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No.: 10-1188-US-CON3)

In the Application of:	)	
	)	
Robert Frederick Veasey et al.	)	Examiner: Mendez, Manuel A.
	)	
Serial No. 13/909,649	)	Group Art Unit: 3763
	)	
Filed: June 4, 2013	)	Confirmation No.: 5079
	)	
For: Pen-Type Injector	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

RESPONSE TO THE OFFICE ACTION MAILED AUGUST 28, 2013

Dear Sir:

This paper is submitted in response to the Office Action mailed August 28, 2013. Please enter the following remarks and amendments into the record for this application.

Amendments to the Claims are reflected in the listing of claims that begins on page 2 of this paper.

Remarks/Arguments begin on page 9 of this paper.

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AMENDMENTS

IN THE CLAIMS

1. (currently amended) A housing part for a medication dispensing apparatus, said housing part comprising:

a main housing, said main housing extending from a distal end to a proximal end;

a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve;

a ~~dose knob~~ dose dial grip disposed near a proximal end of said dose dial sleeve;

a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;

a ~~driver~~ drive sleeve extending along a portion of said piston rod, said ~~driver~~ drive sleeve comprising an internal threading near a distal portion of said ~~driver~~ drive sleeve, said internal threading adapted to engage an external thread of said piston rod;

a tubular clutch located adjacent a distal end of said ~~dose knob~~ dose dial grip, said tubular clutch operatively coupled to said ~~dose knob~~ dose dial grip, wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch; and

a ~~container housing~~ cartridge retaining part operatively coupled to said main housing, said ~~container housing~~ cartridge retaining part comprising a fluid container,

wherein said fluid container defines a medicament filled reservoir with a movable ~~plunger~~ cartridge piston at a proximal end and an outlet at a distal end,

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said ~~plunger~~ cartridge piston movable by said piston rod to be advanced toward an outlet of said fluid container when said piston rod is moved distally.

2. (currently amended) The housing part of claim 1, wherein during a dose dispensing step, said ~~dose knob~~ dose dial grip is activated in a distal direction and said tubular clutch disengages such that said dose dial sleeve rotates back towards said proximal end of said main housing.

3. (currently amended) The housing part of claim 1, wherein

during a dose dispensing step, said ~~driver~~ drive sleeve advances axially in a distal direction relative to said main housing, and

said ~~driver~~ drive sleeve advances said piston rod in said distal direction so as to dispense said medicament from said outlet at said distal end of said fluid container.

4. (currently amended) The housing part of claim 1, further comprising a clicker, said clicker providing at least an audible feedback to a user when said ~~dose knob~~ dose dial grip is rotated.

5. (currently amended) The housing part of claim 4, wherein said clicker comprises,

at least one flexible arm, said flexible arm comprising at least one tooth member, and

at least one spline,

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wherein when said ~~dose knob~~ dose dial grip is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback.

6. (original) The housing part of claim 1, wherein

said tubular clutch comprises a plurality of teeth formed near an end of said tubular clutch,

said plurality of teeth remaining meshed during a dose setting step, and

said plurality of teeth becoming unmeshed during a dose dispensing step.

7. (original) The housing part of claim 1,

wherein said piston rod comprises a first thread and a second thread, and

wherein at least one of said first or said second thread comprises at least one part threads rather than a complete thread.

8. (original) The housing part of claim 1, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing.

9. (currently amended) The housing part of claim 1, wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along said ~~an~~ outer surface of said dose dial sleeve.

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10. (original) The housing part of claim 1, wherein said dose dial sleeve comprises at least one radial stop, said radial stop positioned near an end of said helical groove, wherein when said dose dial sleeve is rotated to set a maximum dose of said medication dispensing apparatus, said radial stop near said end of said helical groove abuts an end of said threading provided on said inner surface of said main housing and thereby prevents rotation of said dose dial sleeve.

11. (currently amended) A housing part for a medication dispensing apparatus, said housing part comprising:

a main housing, said main housing extending from a distal end to a proximal end;

a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve;

a ~~dose knob~~ dose dial grip disposed near a proximal end of said dose dial sleeve;

a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;

a ~~driver~~ drive sleeve extending along a portion of said piston rod, said ~~driver~~ drive sleeve comprising an internal threading near a distal portion of said ~~driver~~ drive sleeve, said internal threading adapted to engage an external thread of said piston rod; and,

a tubular clutch located adjacent a distal end of said ~~dose knob~~ dose dial grip, said tubular clutch operatively coupled to said ~~dose knob~~ dose dial grip,

wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch, and wherein said helical groove of the dose dial sleeve has a first

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lead and said internal threading of said ~~driver~~ drive sleeve has a second lead, and wherein said first lead and said second lead are different.

12. (currently amended) The housing part of claim 11, wherein during a dose dispensing step, said ~~dose knob~~ dose dial grip is activated in a distal direction and said tubular clutch disengages such that said dose dial sleeve rotates back towards said proximal end of said main housing.

13. (currently amended) The housing part of claim 11, wherein

during a dose dispensing step, said ~~driver~~ drive sleeve advances axially in a distal direction relative to said main housing, and

said ~~driver~~ drive sleeve advances said piston rod in said distal direction so as to dispense ~~said~~ a medicament from said outlet at said distal end of ~~said~~ a fluid container.

14. (currently amended) The housing part of claim 11, further comprising a clicker, said clicker providing at least an audible feedback to a user when said ~~dose knob~~ dose dial grip is rotated.

15. (currently amended) The housing part of claim 14, wherein said clicker comprises,

at least one flexible arm, said flexible arm comprising at least one tooth member, and

at least one spline,

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wherein when said ~~dose knob~~ dose dial grip is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback.

16. (original) The housing part of claim 11, wherein

said tubular clutch comprises a plurality of teeth formed near an end of said tubular clutch,

said plurality of teeth remaining meshed during a dose setting step, and

said plurality of teeth becoming unmeshed during a dose dispensing step.

17. (original) The housing part of claim 11,

wherein said piston rod comprises a first thread and a second thread, and

wherein at least one of said first or said second thread comprises at least one part threads rather than a complete thread.

18. (original) The housing part of claim 11, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing.

19. (original) The housing part of claim 11, wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along ~~an~~ said outer surface of said dose dial sleeve.

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20. (original) The housing part of claim 11, wherein said dose dial sleeve comprises at least one radial stop, said radial stop positioned near an end of said helical groove, wherein when said dose dial sleeve is rotated to set a maximum dose of said medication dispensing apparatus, said radial stop near said end of said helical groove abuts an end of said threading provided on said inner surface of said main housing and thereby prevents rotation of said dose dial sleeve.

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REMARKS

Claims 1-20 are currently pending. In the Office Action mailed August 28, 2013, claims 1-20 stand rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement.

Specifically, with respect to claims 1-10, the Examiner states that the specification does not describe a "dose knob" as there is purportedly "no mention in the specification of a 'dose knob' disposed near a proximal end of the dose dial sleeve." August 28, 2013 Office Action, Pages 2 and 3. Applicants have replaced the term "dose knob" with the term "dose dial grip." Support for this claim term may be found throughout the Application as filed, including Page 9 Lines 10-17. As such, no new matter has been added.

In addition, the Examiner states that the specification as filed fails to disclose the term "driver." August 28, 2013 Office Action, Pages 2 and 3. Applicants have replaced this term "driver" with the term "drive sleeve." Support for this claim term may be found throughout the Application as filed, including Page 6 Line 27 – Page 7 Line 3. As such, no new matter has been added.

The Examiner also states that the specification fails to disclose the phrase "container housing." August 28, 2013 Office Action, Page 3. Applicants have replaced this term with the term "cartridge retaining part." Support for such may be found throughout the Application as filed, including Page 5 Lines 19-30. As such, no new matter has been added.

Finally, the Examiner also states that the specification fails to disclose the phrase "plunger." August 28, 2013 Office Action, Page 3. Applicants have replaced this term with the term "cartridge piston." Support for such a replacement may be found throughout the Application as filed, including Page 5 Lines 28-30. As such, no new matter has been added.

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In addition, claims 1-20 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims of 15, 17, and 10 of copending Application No. 12/944,544. Applicants acknowledge this rejection under the doctrine of obviousness-type double patenting, and elect to address this ground of rejection upon notification that the rejection has been made non-provisional, all conditions for patentability have been met, and the claims are otherwise in condition for allowance.

The present Office Action also states that claims 1-20 stand "rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 7,918. [sic: 7,918,833]." August 28, 2013 Office Action, Page 5.

Applicants note that M.P.E.P. § 2142 states that the Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. The present Office Action summarily concludes that: "[a]lthough the claims at issue are not identical, they are not patently distinct from each other because both sets of claims identified . . . disclose similar structural elements with minor variations that a person of ordinary skill in the art would have considered as obvious design choices." August 28, 2013 Office Action, Page 5. Applicants note that the pending Office Action fails to explicitly articulate a *prima facie* case of obviousness which addresses all of the limitations of Applicants' presently pending claims, primarily independent claims 1 and 11.

For example, as Applicants' discuss in greater detail in the Application as filed, the presently pending claims are generally directed to a housing part for a medication dispensing apparatus comprising a main housing, a dose dial sleeve, a dose dial grip, a piston rod, a drive sleeve, and a tubular clutch. Applicants' presently pending independent claims are generally directed to such aspects of a housing part.

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As just one example, Applicants' presently pending independent claim 1 expressly recites the following:

- a dose dial grip disposed near a proximal end of the dose dial sleeve;

- a piston rod provided within said housing, the piston rod is non-rotatable during a dose setting step relative to the main housing;

- a drive sleeve extending along a portion of the piston rod;

- a drive sleeve comprising an internal threading adapted to engage an external thread of said piston rod;

- a tubular clutch;

- the tubular clutch located adjacent a distal end of the dose knob;

- the tubular clutch located adjacent a distal end of the dose knob, the tubular clutch operatively coupled to the dose knob; and

- a dose dial sleeve that extends circumferentially around at least a portion of the tubular clutch.

Applicants' other remaining independent claim, claim 11, recites similar limitations. As such, Applicants note that pending claims 1 and 11 are neither anticipated nor rendered obvious by any of the claims of the 7,918,833 Patent and that this nonstatutory obviousness-type double patenting rejection should be withdrawn.

With respect to the prior art rejections, the Examiner has rejected claims 1-20 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Walters et al (EP 0937471A2) ("Walters 471").

Applicants note that the present application is generally directed to pen-type injectors, that is to injectors of the kind that provide for administration by injection of medicinal products from a multidose cartridge where a user may set the dose. Applicants' Specification, Page 1 Lines 14-17.

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Applicants traverse the presently pending rejections based in part on the following.

First, with respect to the present rejections in view of Walters 471, Applicants note that Walters 471 does not teach or suggest a "dose dial sleeve . . . comprising a helical groove configured to engage a threading provided by said main housing." The main housing or body 40 in Walters 471 does not provide any type of threading. *See, e.g.*, Walters 471 [0012] Lines 39-43 and Figures 1-3. Naturally, therefore, Walters 471 further fails to teach or suggest a "dose dial sleeve . . . comprising a helical groove configured to engage a threading provided by said main housing."

Second, to further distinguish Walters 471, Applicants have clarified claim 1 as follows: "dose dial sleeve . . . comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve." Independent claim 11 has been clarified in a similar manner. Support for this limitation may be found throughout Applicants' specification as filed, including Page 8, Lines23-25. We would amend dependent claim 9 accordingly.

The dose knob 50 of Walters 471 does not comprise a helical groove along an outer surface of the dose knob but rather appears to teach an internal thread 53 that purports to engage rod barrel outer diameter threads 76 on rod barrel 74. Walters 471 [0012] Lines 48-52. Moreover, in Walters 471, the dose knob 50 comprises dosage numeral 51 and key slots 52. A dose knob cap 54 is described as being permanently attached to a proximal end 55 of the dose knob 50. *See, e.g.*, Walters 471 [0012-0013] and Figure 1. The dose knob 50 does not comprise any type of "helical groove along an outer surface." As such, the dose knob 50 of Walters 471 fails to teach or suggest a "helical groove to engage a threading provided by said main housing."

Third, Walters 471 does not teach or suggest Applicants' presently claimed "clutch."

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Rather, the principal components described in the delivery pen 10 illustrated in Figure 1 of Walters 471 comprises a cap 11; a body 40; a vial retainer 35; a dose knob 50; a lens and ring assembly 60; a rod barrel tube 70; a clicker 90; and a plunger screw 100. As such, Walters 471 also fails to teach or suggest Applicants' presently claimed "tubular clutch" and also does not teach or suggest such a tubular clutch "located adjacent a distal end of said dose dial grip."

Fourth, as can also be seen from Figures 2 and 3 of Walters 471, the dose knob 50 appears to extend "circumferentially" only about portions of the rod barrel tube 70 and the threaded shaft 101. As such, Walters 471 further fails to teach or suggest a dose dial sleeve that "extends circumferentially around at least a portion of said tubular clutch."

Applicants respectfully submit that, in view of the remarks above, the present application, including claims 1-20, is in condition for allowance and solicit action to that end.

If there are any matters that may be resolved or clarified through a telephone interview, the Examiner is respectfully requested to contact Applicants' undersigned representative at (312) 913-0001.

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff LLP

Date: October 16, 2013

By: /Thomas E. Wettermann/
Thomas E. Wettermann
Reg. No. 41,523

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON3)

In re Application of:	)	
	)	
Robert Frederick Veasey et al.	)	
	)	Examiner: Mendez, Manuel A.
Serial No.: 13/909,649	)	
	)	Group Art Unit: 3763
Filed: June 4, 2013	)	
	)	Confirmation No.: 5079
For: Pen-Type Injector	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

GENERAL AUTHORIZATION UNDER 37 C.F.R. § 1.136(a)(3)

Sir:

The Commissioner is hereby generally authorized under 37 C.F.R. § 1.136(a)(3) to treat the present and any future related filings in this or any related application filed pursuant to 37 C.F.R. § 1.53 requiring an extension of time as incorporating a request therefore, and the Commissioner is hereby specifically authorized to charge Deposit Account No. 13-2490 for any fee that may be due in connection with such a request for an extension of time.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff LLP

Date: October 16, 2013

By: /Thomas E. Wettermann/
Thomas E. Wettermann
Reg. No. 41,523

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Electronic Acknowledgement Receipt

EFS ID:	17144413
Application Number:	13909649
International Application Number:	
Confirmation Number:	5079
Title of Invention:	Pen-Type Injector
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Customer Number:	20306
Filer:	Thomas E. Wettermann
Filer Authorized By:	
Attorney Docket Number:	10-1188-US-CON3
Receipt Date:	16-OCT-2013
Filing Date:	04-JUN-2013
Time Stamp:	16:39:21
Application Type:	Utility under 35 USC 111(a)

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	10_1188_US_CON3_OA_Transmittal_2013_10_16.pdf	140397 70d1847d459d864b41a736166ab1e07cbb92ec97	no	1

Warnings:	
Information:	

2	Amendment Copy Claims/Response to Suggested Claims	10_1188_US_CON3_OA_Response_2013_10_16.pdf	147966 034677fa6949b56c7411a54bc10f251c26184238	no	13
Warnings:					
Information:					
3	Authorization for Extension of Time all replies	10_1188_US_CON3_General_Authorization_2013_10_16.pdf	58571 0e3193e8ce9cead340c8f56fba5af56e65bbb472	no	1
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Information:					
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TRANSMITTAL FORM

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Total Number of Pages in This Submission	15

Application Number	13/909,649
Filing Date	June 4, 2013
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	Mendez, Manuel A.
Attorney Docket Number	10-1188-US-CON3

ENCLOSURES *(Check all that apply)*

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- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please Identify below):
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Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	McDonnell Boehnen Hulbert & Berghoff LLP		
Signature	/Thomas E. Wettermann/		
Printed name	Thomas E. Wettermann		
Date	October 16, 2013	Reg. No.	41,523

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Signature	/Thomas E. Wettermann/		
Typed or printed name	Thomas E. Wettermann	Date	October 16, 2013

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/909,649	Filing Date 06/04/2013	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)		
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

		(Column 1)		(Column 2)	(Column 3)		
	10/16/2013	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)		
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/POLIN ANG/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/909,649	06/04/2013	Robert Frederick Veasey	10-1188-US-CON3

CONFIRMATION NO. 5079

20306
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

PUBLICATION NOTICE

OC000000064440181

Title: Pen-Type Injector

Publication No.US-2013-0274680-A1
Publication Date:10/17/2013

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

20306 7590 10/24/2013

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER
MENDEZ, MANUEL A

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 10/24/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/909,649	06/04/2013	Robert Frederick Veasey	10-1188-US-CON3	5079

TITLE OF INVENTION: PEN-TYPE INJECTOR

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1780	$0	$0	$1780	01/24/2014

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

20306 7590 10/24/2013
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/909,649	06/04/2013	Robert Frederick Veasey	10-1188-US-CON3	5079

TITLE OF INVENTION: PEN-TYPE INJECTOR

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1780	$0	$0	$1780	01/24/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
MENDEZ, MANUEL A	3763	604-209000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/909,649	06/04/2013	Robert Frederick Veasey	10-1188-US-CON3	5079

20306 7590 10/24/2013

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER	
MENDEZ, MANUEL A	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 10/24/2013

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notices of Allowance and Fee(s) Due mailed between October 1, 2013 and December 31, 2013

(Addendum to PTOL-85)

If the "Notice of Allowance and Fee(s) Due" has a mailing date on or after October 1, 2013 and before January 1, 2014, the following information is applicable to this application.

If the issue fee is being timely paid on or after January 1, 2014, the amount due is the issue fee and publication fee in effect January 1, 2014. On January 1, 2014, the issue fees set forth in 37 CFR 1.18 decrease significantly and the publication fee set forth in 37 CFR 1.18(d)(1) decreases to $0.

If an issue fee or publication fee has been previously paid in this application, applicant is not entitled to a refund of the difference between the amount paid and the amount in effect on January 1, 2014.

Notice of Allowability	Application No. 13/909,649	Applicant(s) VEASEY ET AL.	
	Examiner MANUEL MENDEZ	Art Unit 3763	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *amendment filed on 10/16/2013*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-20*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☒ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☒ Certified copies of the priority documents have been received in Application No. *10/790225* .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 8/31/2013
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Manuel A. Mendez/
Primary Examiner, Art Unit 3763

The present application is being examined under the pre-AIA first to invent provisions.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The examiner of record acknowledges receipt of the amendment filed on 10/16/2013. The examiner agrees with the arguments presented on pages 9-13. In particular, the examiner concurs with the arguments indicating that Walters 471 does not teach or suggest the following claim language: (1) "a dose dial sleeve...comprising a helical groove configured to engage a threading provided by said main housing, (2) "a dose dial sleeve ...comprising a helical groove configured to engage a threading provided by said main housing, said helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve, and (3) a clutch. Based on the above comments, claims 1-20 are considered to be allowable over the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MANUEL MENDEZ whose telephone number is (571)272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully submitted,

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 5079

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/909,649	06/04/2013	604	3763	10-1188-US-CON3

APPLICANTS

Robert Frederick Veasey, Warwickshire, UNITED KINGDOM;
Robert Perkins, Oxfordshire, UNITED KINGDOM;
David Aubrey Plumptre, Worcestershire, UNITED KINGDOM;

**** CONTINUING DATA ***************************

This application is a CON of 12/944,544 11/11/2010
which is a CON of 11/483,546 07/11/2006 PAT 7918833
and is a CON of 10/790,225 03/02/2004 ABN

**** FOREIGN APPLICATIONS ***************************

UNITED KINGDOM 0304822.0 03/03/2003

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

07/01/2013

Foreign Priority claimed	☑ Yes ☐ No	☐ Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
35 USC 119(a-d) conditions met	☑ Yes ☐ No		UNITED KINGDOM	7	20	2
Verified and Acknowledged	/MANUEL A MENDEZ/ Examiner's Signature	Initials				

ADDRESS

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606
UNITED STATES

TITLE

Pen-Type Injector

FILING FEE RECEIVED		
1900	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13909649	VEASEY ET AL.
	Examiner	**Art Unit**
	MANUEL MENDEZ	3763

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	10/20/2013								
	1	=								
	2	=								
	3	=								
	4	=								
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	19	=								
	20	=								

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13909649	VEASEY ET AL.
	Examiner	**Art Unit**
	MANUEL MENDEZ	3763

CPC		
Symbol	**Type**	**Version**

CPC Combination Sets				
Symbol	**Type**	**Set**	**Ranking**	**Version**

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/MANUEL MENDEZ/ Primary Examiner.Art Unit 3763	10/20/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1 and 2

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13909649	VEASEY ET AL.
	Examiner	**Art Unit**
	MANUEL MENDEZ	3763

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
604	209	A	6	1	M	5 / 00 (2006.01.01)						

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/MANUEL MENDEZ/ Primary Examiner.Art Unit 3763	10/20/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1 and 2

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13909649	VEASEY ET AL.
	Examiner	**Art Unit**
	MANUEL MENDEZ	3763

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		17												
	2		18												
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	10														
	11														
	12														
	13														
	14														
	15														
	16														

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 20	
/MANUEL MENDEZ/ Primary Examiner.Art Unit 3763 (Primary Examiner)	10/20/2013 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1 and 2

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	13909649
Filing Date	2013-06-04
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	Mendez, Manuel A.
Attorney Docket Number	10-1188-US-CON3

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5304152		1994-04-19	Sams	
	2	5320609		1994-06-14	Haber et al.	
	3	5480387		1996-01-02	Gabriel et al.	
	4	5505704		1996-04-09	Pawelka et al.	
	5	6193698		2001-02-27	Kirchhofer et al.	
	6	6248095		2001-06-19	Giambattista et al.	
	7	7241278		2007-07-10	Moller	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.M./

Receipt date: 08/31/2013	Application Number	13909649 13909649 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2013-06-04
(Not for submission under 37 CFR 1.99)	First Named Inventor	Robert Frederick Veasey
	Art Unit	3763
	Examiner Name	Mendez, Manuel A.
	Attorney Docket Number	10-1188-US-CON3

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	9938554	WO	A1	1999-08-05	Novo Nordisk A/S		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Manuel Mendez/	Date Considered	10/20/2013

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.M./

Receipt date: 08/31/2013	Application Number	13909649 13909649 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	2013-06-04
	First Named Inventor	Robert Frederick Veasey
	Art Unit	3763
	Examiner Name	Mendez, Manuel A.
	Attorney Docket Number	10-1188-US-CON3

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Thomas E. Wettermann/	Date (YYYY-MM-DD)	2013-08-30
Name/Print	Thomas E. Wettermann	Registration Number	41,523

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.M./

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.M./

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13909649	VEASEY ET AL.
	Examiner	Art Unit
	MANUEL MENDEZ	3763

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
604	187, 207-211, 218, 221, 224, 232	8/25/2013	mm

SEARCH NOTES		
Search Notes	Date	Examiner
inventor search	8/25/2013	mm

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
604	209	10/20/2013	mm

	/Manuel A. Mendez/ Primary Examiner, Art Unit 3763

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

20306 7590 10/24/2013
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

Thomas E. Wettermann	(Depositor's name)
/Thomas E. Wettermann/	(Signature)
November 4, 2013	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/909,649	06/04/2013	Robert Frederick Veasey	10-1188-US-CON3	5079

TITLE OF INVENTION: PEN-TYPE INJECTOR

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1780	$0	$0	$1780	01/24/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
MENDEZ, MANUEL A	3763	604-209000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 McDonnell Boehnen
2 Hulbert & Berghoff LLP
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Sanofi-Aventis Deutschland GmbH

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Frankfurt am Main, Germany

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
- ☒ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ☐ A check is enclosed.
- ☒ Payment by credit card. Form PTO-2038 is attached.
- ☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 13-2490 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature /Thomas E. Wettermann/ Date November 4, 2013

Typed or printed name Thomas E. Wettermann Registration No. 41,523

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON3)

In re Application of:	
Robert Frederick Veasey et al.	
Serial No.: 13/909,649	Group Art Unit: 3763
Filed: June 4, 2013	Examiner: Mendez, Manuel A.
For: Pen-Type Injector	Confirmation No.: 5079

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

Sir:

Responsive to the Notice of Allowance mailed October 24, 2013, the Applicants express appreciation for the allowance of the present application. The Applicants note the Examiner's reasons for allowance, but further comment that the art of record, alone and in combination, fails to show, teach or suggest the entirety of each combination of steps and/or structure recited by each of the allowed claims of the present invention.

The Applicants respectfully submit that the reasons for allowance are only warranted in instances in which the record of the prosecution as a whole does not make clear his or her reasons for allowing a claim or claims. The Applicants do not necessarily agree with each statement in the reasons for allowance. The Applicants believe that the Statements of Reasons for Allowance in this case are improper as it merely copies limitations of the claims

into the reasons for allowance. While the Applicants believe that the claims are allowable, the Applicants do not acquiesce that patentability resides in the features, as explicitly set forth in the claims, nor that each feature is required for patentability.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff LLP

Date: November 4, 2013 By: /Thomas E. Wettermann/
Thomas E. Wettermann
Reg. No. 41,523

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON3)

In re Application of:	)	
	)	
Robert Frederick Veasey et al.	)	
	)	Examiner: Mendez, Manuel A.
Serial No.: 13/909,649	)	
	)	Group Art Unit: 3763
Filed: June 4, 2013	)	
	)	Confirmation No.: 5079
For: Pen-Type Injector	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

GENERAL AUTHORIZATION UNDER 37 C.F.R. § 1.136(a)(3)

Sir:

The Commissioner is hereby generally authorized under 37 C.F.R. § 1.136(a)(3) to treat the present and any future related filings in this or any related application filed pursuant to 37 C.F.R. § 1.53 requiring an extension of time as incorporating a request therefore, and the Commissioner is hereby specifically authorized to charge Deposit Account No. 13-2490 for any fee that may be due in connection with such a request for an extension of time.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff LLP

Date: November 4, 2013 By: /Thomas E. Wettermann/
Thomas E. Wettermann
Reg. No. 41,523

McDonnell Boehnen Hulbert & Berghoff LLP
300 S. Wacker Drive
Chicago, Illinois 60606
312.913.0001

Electronic Patent Application Fee Transmittal

Application Number:	13909649
Filing Date:	04-Jun-2013
Title of Invention:	PEN-TYPE INJECTOR
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Filer:	Thomas E. Wettermann
Attorney Docket Number:	10-1188-US-CON3

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	1501	1	1780	1780
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**1780**

Electronic Acknowledgement Receipt

EFS ID:	17310023
Application Number:	13909649
International Application Number:	
Confirmation Number:	5079
Title of Invention:	PEN-TYPE INJECTOR
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Customer Number:	20306
Filer:	Thomas E. Wettermann
Filer Authorized By:	
Attorney Docket Number:	10-1188-US-CON3
Receipt Date:	04-NOV-2013
Filing Date:	04-JUN-2013
Time Stamp:	18:10:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1780
RAM confirmation Number	6031
Deposit Account	132490
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)					
File Listing:					
Document Number	**Document Description**	**File Name**	**File Size(Bytes)/ Message Digest**	**Multi Part /.zip**	**Pages (if appl.)**
1	Transmittal Letter	10_1188_US_CON3_Issue_Fee_Transmittal_2013_11_04.pdf	140480 d7f9daa74d7b08b49dca577cead39e2729cd81c4	no	1
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	10_1188_US_CON3_Issue_Fee_2013_11_04.pdf	110717 ced0ba1cf379764969f3e3ade3620c319f7de178	no	2
Warnings:					
Information:					
3	Miscellaneous Incoming Letter	10_1188_US_CON3_Comments_Statement_Reasons_Allowance_2013_11_04.pdf	52795 2ed976e722ab2039834f8c6c27c76c7b467457b9	no	2
Warnings:					
Information:					
4	Authorization for Extension of Time all replies	10_1188_US_CON3_General_Authorization_2013_11_04.pdf	58943 1e73c3c3232f29b0d8a634733f1efb0fe2955cdb	no	1
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30286 17e249f938f20e35acd208cb1f9045dc2f359c16	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	393221		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/21 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	

Application Number	13/909,649
Filing Date	June 4, 2014
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	Mendez, Manuel A.
Attorney Docket Number	10-1188-US-CON3

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) ___
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please Identify below): Issue Fee, Comments on Statement of Reasons for Allowance and General Authorization

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	McDonnell Boehnen Hulbert & Berghoff LLP		
Signature	/Thomas E. Wettermann/		
Printed name	Thomas E. Wettermann		
Date	November 4, 2013	Reg. No.	41,523

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being electronically transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	/Thomas E. Wettermann/		
Typed or printed name	Thomas E. Wettermann	Date	November 4, 2013

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/909,649	12/10/2013	8603044	10-1188-US-CON3	5079

20306 7590 11/20/2013

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Robert Frederick Veasey, Warwickshire, UNITED KINGDOM;
Robert Perkins, Oxfordshire, UNITED KINGDOM;
David Aubrey Plumptre, Worcestershire, UNITED KINGDOM;

AO 120 (Rev. 08/10)

TO:	**Mail Stop 8** **Director of the U.S. Patent and Trademark Office** **P.O. Box 1450** **Alexandria, VA 22313-1450**	**REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK**

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court for the District of Delaware on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
	1/30/2014	for the District of Delaware

PLAINTIFF	DEFENDANT
SANOFI-AVENTIS U.S. LLC and SANOFI-AVENTIS DEUTSCHLAND GMBH	ELI LILLY AND COMPANY

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	8,556,864 B2	10/15/2013	Sanofi-Aventis Deutschland GmbH
2	8,603,044 B2	12/10/2013	Sanofi-Aventis Deutschland GmbH
3	7,476,652 B2	1/13/2009	Sanofi-Aventis Deutschland GmbH
4	7,713,930 B2	5/11/2010	Sanofi-Aventis Deutschland GmbH
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
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In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

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AO 120 (Rev. 08/10)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
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DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
14CV884-RGA	7/7/2014	for the District of Delaware

PLAINTIFF	DEFENDANT
SANOFI-AVENTIS U.S. LLC and SANOFI-AVENTIS DEUTSCHLAND GMBH	ELI LILLY AND COMPANY

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1	7,476,652	1/13/2009	Sanofi-Aventis Deutschland GmbH
2	7,713,930	5/11/2010	Sanofi-Aventis Deutschland GmbH
3	7,918,833	4/5/2011	Sanofi-Aventis Deutschland GmbH
4	8,512,297	8/20/2013	Sanofi-Aventis Deutschland GmbH
5	8,556,864	10/15/2013	Sanofi-Aventis Deutschland GmbH

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DECISION/JUDGEMENT
see attached Order

CLERK	(BY) DEPUTY CLERK	DATE
John A. Cerino	N. Schmyer	5/11/15

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AO 120 (Rev. 08/10)

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DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
14CV884-RGA	7/7/2014	for the District of Delaware

PLAINTIFF	DEFENDANT
SANOFI-AVENTIS U.S. LLC and SANOFI-AVENTIS DEUTSCHLAND GMBH	ELI LILLY AND COMPANY

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	8,603,044	12/10/2013	Sanofi-Aventis Deutschland GmbH
2	8,679,069	3/25/2014	Sanofi-Aventis Deutschland GmbH
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In the above—entitled case, the following patent(s)/ trademark(s) have been included:

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In the above—entitled case, the following decision has been rendered or judgement issued:

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See attached Order

CLERK	(BY) DEPUTY CLERK	DATE
John A. Cerino	N. Schmyer	5/11/2015

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AO 120 (Rev. 08/10)

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☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
		FOR THE DISTRICT OF DELAWARE

PLAINTIFF	DEFENDANT
SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS DEUTSCHLAND GMBH, and SANOFI WINTHROP INDUSTRIE	MERCK SHARP & DOHME CORP.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	US 7,918,833	4/5/2011	Sanofi-Aventis Deutschland GmbH
2	US 8,512,297	8/20/2013	Sanofi-Aventis Deutschland GmbH
3	US 8,556,864	10/15/2013	Sanofi-Aventis Deutschland GmbH
4	US 8,603,044	12/10/2013	Sanofi-Aventis Deutschland GmbH
5	US 8,992,486	10/15/2013	Sanofi-Aventis Deutschland GmbH

*Attached is a list of additional patents.

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

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ADDITIONAL PATENTS TO THE COMPLAINT

PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
6. US 8,679,069	3/25/2014	Sanofi-Aventis Deutschland GmbH
7. US 9,011,391	4/21/2015	Sanofi-Aventis Deutschland GmbH
8. US 9,233,211	1/12/2016	Sanofi-Aventis Deutschland GmbH
9. US 7,476,652	1/13/2009	Sanofi-Aventis Deutschland GmbH
10. US 7,713,930	3/11/2010	Sanofi-Aventis Deutschland GmbH

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		FOR THE DISTRICT OF DELAWARE

PLAINTIFF	DEFENDANT
SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS DEUTSCHLAND GMBH, and SANOFI WINTHROP INDUSTRIE	MERCK SHARP & DOHME CORP.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
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8. US 9,233,211	1/12/2016	Sanofi-Aventis Deutschland GmbH
9. US 7,476,652	1/13/2009	Sanofi-Aventis Deutschland GmbH
10. US 7,713,930	3/11/2010	Sanofi-Aventis Deutschland GmbH