PTO/SB/05 (08-08)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UTILITY PATENT APPLICATION TRANSMITTAL

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

Attorney Docket No.	10-1188-US-CON1
First 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** (e.g., PTO/SB/17)
2. ☐ **Applicant claims small entity status.** See 37 CFR 1.27.
3. ☒ **Specification** [*Total Pages* 14]
   Both the claims and abstract must start on a new page
   (For information on the preferred arrangement, see MPEP 608.01(a))
4. ☒ **Drawing(s)** (35 U.S. C. *113*) [*Total Sheets* 7]
5. **Oath or Declaration** [*Total Sheets* _____]
   a. ☐ Newly executed (original or copy)
   b. ☐ A copy from a prior application (37 CFR 1.63(d))
   (for continuation/divisional with Box 18 completed)
   i. ☐ DELETION OF INVENTOR(s)
   Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☒ **Application Data Sheet.** See 37 CFR 1.76
7. ☐ **CD-ROM or CD-R** in duplicate, large table or Computer Program *(Appendix)*
   ☐ Landscape Table on CD
8. **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 PARTS

9. ☐ **Assignment Papers** (cover sheet & document(s))
   Name of Assignee _____
10. ☐ **37 CFR 3.73(b) Statement** *(when there is an assignee)* ☐ **Power of Attorney**
11. ☐ **English Translation Document** *(if applicable)*
12. ☐ **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    ☐ Copies of citations attached
13. ☒ **Preliminary Amendment**
14. ☐ **Return Receipt Postcard** (MPEP 503)
    (Should be specifically itemized)
15. ☐ **Certified Copy of Priority Document(s)**
    (if foreign priority is claimed)
16. ☐ **Nonpublication Request** under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
17. ☒ Other: Submission of Substitute Specification, Substitute Specification, Submission of Replacement Drawings; 7 Pages of Replacement Drawings and General Authorization

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*

☒ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: 11/483,546

Prior application information: *Examiner* Mendez, Manuel A. *Art Unit:* 3763

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	November 11, 2010
Name (Print/Type)	Thomas E. Wettermann	Registration No. (Attorney/Agent)	41,523

PTO/SB/17 (10-08)
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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2009

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($)3,222.00

Complete If Known	
Application Number	Unassigned
Filing Date	Unassigned
First Named Inventor	Robert Frederick Veasey
Examiner Name	Unassigned
Art Unit	Unassigned
Attorney Docket No.	10-1188-US-CON1

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 13-2490 Deposit Account Name: MBHB

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below
☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17
☐ Charge fee(s) indicated below, **except for the filing fee**
☒ Credit any overpayments

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fees Paid ($)
Utility	330	165	540	270	220	110	1,090.00
Design	220	110	100	50	140	70	
Plant	220	110	330	165	170	85	
Reissue	330	165	540	270	650	325	
Provisional	220	110	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	52	26
Each independent claim over 3 (including Reissues)	220	110
Multiple dependent claims	390	195

Total Claims		Extra Claims		Fee ($)		Fees Paid ($)
61	- 20 or HP =	41	x	52	=	2,132.00

HP = highest number of total claims paid for, if greater than 20

Indep. Claims		Extra Claims		Fee ($)		Fees Paid ($)
3	- 3 or HP =	0	x	0	=	0

HP = highest number of independent claims paid for, if greater than 3

Multiple Dependent Claims Fee ($)	Fee Paid ($)

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $270 ($135 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).

Total Sheets		Extra Sheets		Number of each additional 50 or fraction thereof		Fee ($)		Fee Paid ($)
14	- 100 =	0	/50=	0	(round **up** to a whole number) x		=	

4. OTHER FEE(S)

	Fee Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): _____	

SUBMITTED BY

Signature	/Thomas E. Wettermann/	Registration No. 41,523 (Attorney/Agent)	Telephone 312 913 2138
Name (Print/Type)	Thomas E. Wettermann		Date November 11, 2010

PTO/SB/14 (11-08)
Approved for use through 09/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON1
	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.)

Applicant Information:

Applicant 1 Remove

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

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]	UK

Citizenship under 37 CFR 1.41(b) [i] UK

Mailing Address of Applicant:

Address 1	35 Hitchman Road		
Address 2	Leamington Spa		
City	Warwickshire	State/Province	
Postal Code	CV31 3	Country[i]	UK

Applicant 2 Remove

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Robert		Perkins	

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

City	Warwickshire	Country Of Residence[i]	UK

Citizenship under 37 CFR 1.41(b) [i] UK

Mailing Address of Applicant:

Address 1	67 Erica Drive		
Address 2	Leamington Spa		
City	Warwickshire	State/Province	
Postal Code	CV31 2RW	Country[i]	UK

Applicant 3 Remove

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

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]	UK

PTO/SB/14 (11-08)
Approved for use through 09/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON1
	Application Number	
Title of Invention	Pen-Type Injector	

Citizenship under 37 CFR 1.41(b) [i]	UK		
Mailing Address of Applicant:			
Address 1	36 Shire Way		
Address 2	Droitwich		
City	Worcestershire	**State/Province**	
Postal Code	WR9 7	**Country**[i]	UK

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-CON1	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		**Sub Class (if any)**	
Suggested Technology Center (if any)			
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:

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).
Enter either 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.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)

PTO/SB/14 (11-08)
Approved for use through 09/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON1
	Application Number	
Title of Invention	Pen-Type Injector	

Customer Number	20306

Domestic Benefit/National Stage Information:

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(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	11483546	2006-07-11
Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	10790225	2004-03-02

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. 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(a).

Remove

Application Number	Country [i]	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
0304822.0	GB	2003-03-03	(•) Yes ( ) No

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.

Assignee 1 Remove

If the Assignee is an Organization check here.	☒		
Organization Name	DCA Design International LTD		
Mailing Address Information:			
Address 1	19 Church Street		
Address 2			
City	Warwick	**State/Province**	
Country [i]	UK	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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON1
	Application Number	
Title of Invention	Pen-Type Injector	

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.					
Signature	/Thomas E. Wettermann/			Date (YYYY-MM-DD)	2010-11-11
First Name	Thomas E.	Last Name	Wettermann	Registration Number	41523

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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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:

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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.

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.

P96042

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).

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;
characterised 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.

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.

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. Preferably 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

1 A pen-type injector comprising 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;
characterised in that the first lead of the helical thread and the second lead of the helical groove are the same.

2 A pen-type injector according to claim 1, characterised in that 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.

3 A pen-type injector according to claim 1 or claim 2, in which 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.

4 A pen-type injector according to claim 3, in which 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.

5 A pen-type injector according to claim 4, in which a first radial stop is provided on a second face of the nut and a second radial stop is provided on a first face of the second flange.

6 A pen-type injector according to any of claims 2 to 5, in which the first thread of the piston rod is oppositely disposed to the second thread of the piston rod.

7 A pen-type injector according to any of claims 2 to 6, in which 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.

8 A pen-type injector according to any of claims 2 to 7, in which the pen-type injector further includes clicker means disposed between the clutch means and spline means provided on the housing.

9 A pen-type injector according to claim 8, in which 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.

10 A pen-type injector according to claim 8, in which 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.

11 A pen-type injector according to any previous claim, in which 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.

12 A pen-type injector according to claim 11, in which 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.

13 A pen-type injector according to claim 11, in which at least one of the maximum dose stops comprises a part of a raised window portion provided at a second end of the housing.

14 A pen-type injector according to any previous claim, in which 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.

1/7

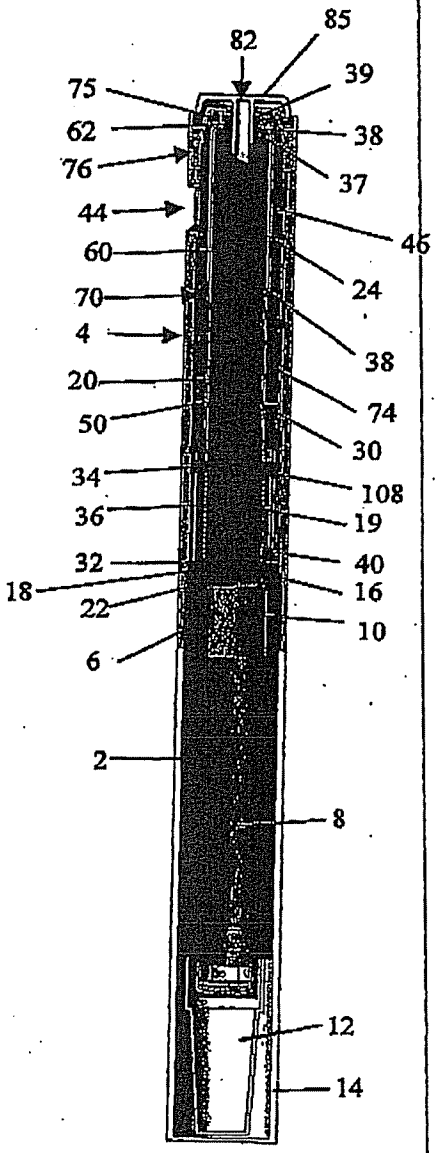

Fig 1

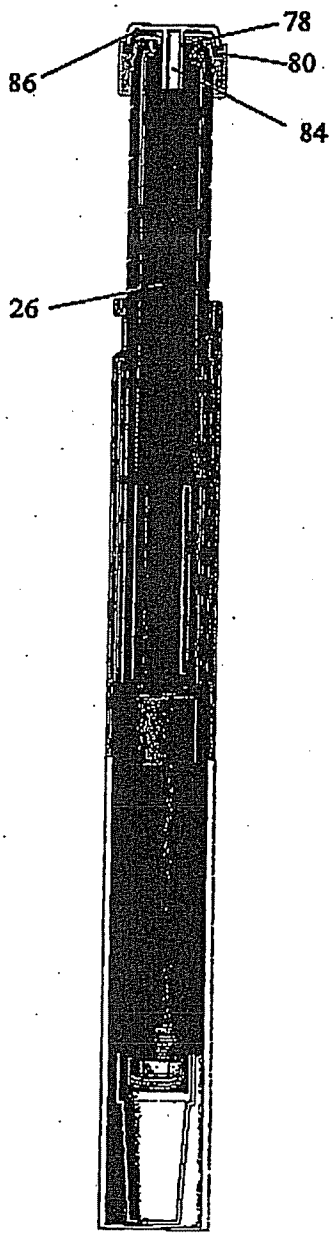

Fig 2

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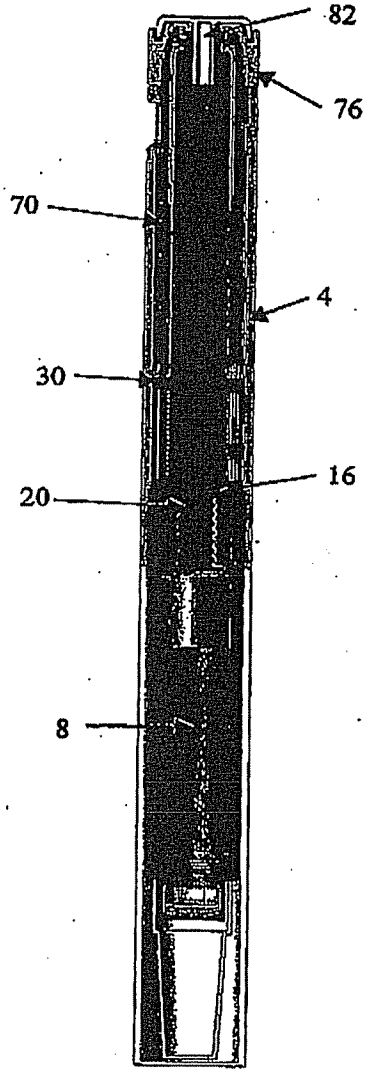

Fig 3

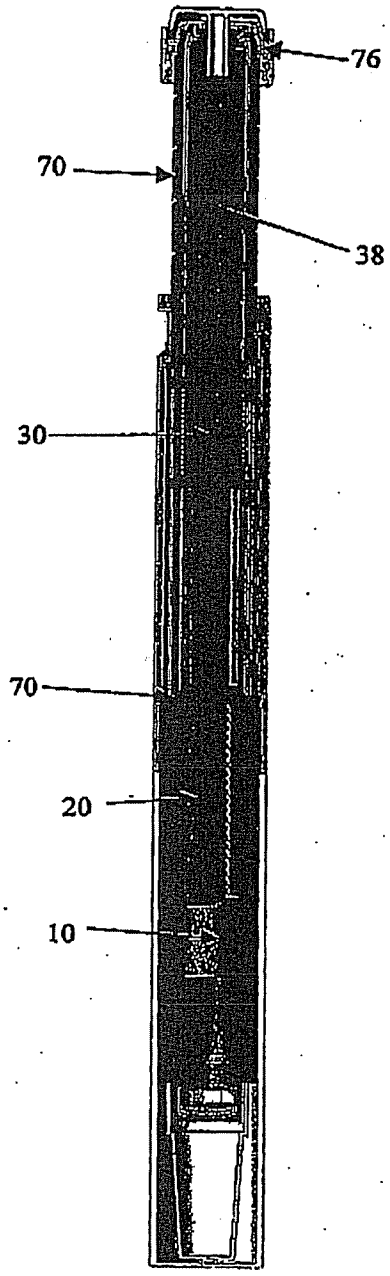

Fig 4

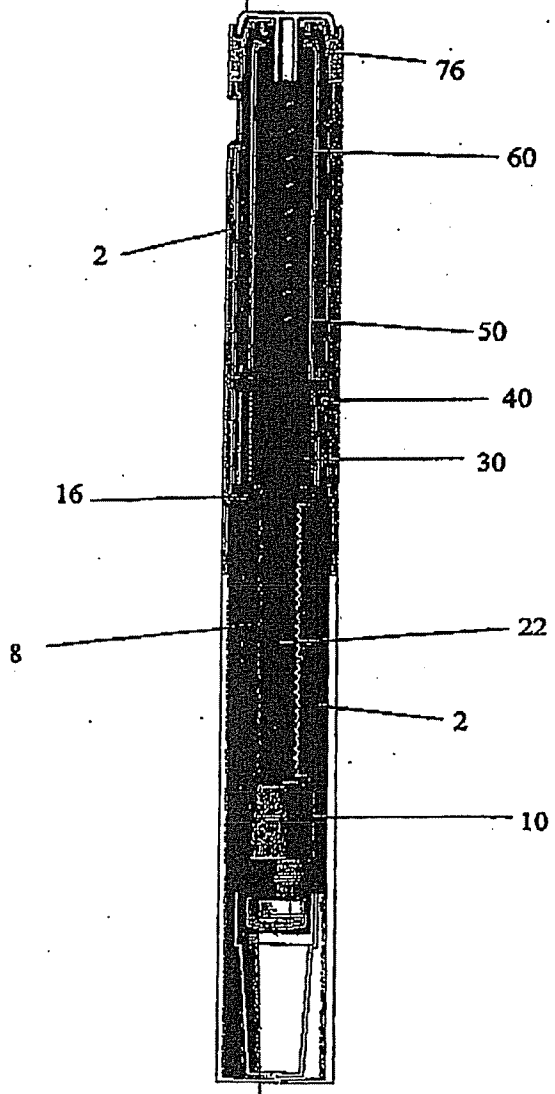

Fig 5

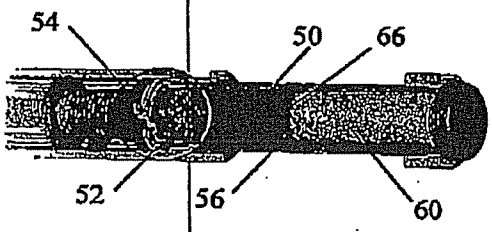

Fig 6

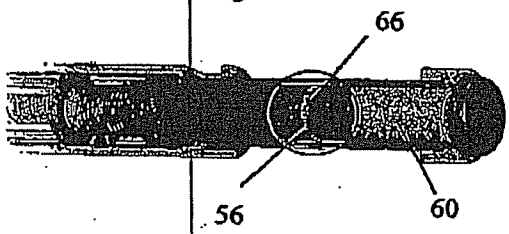

Fig 7

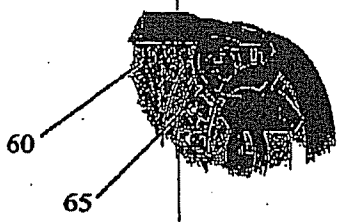

Fig 8

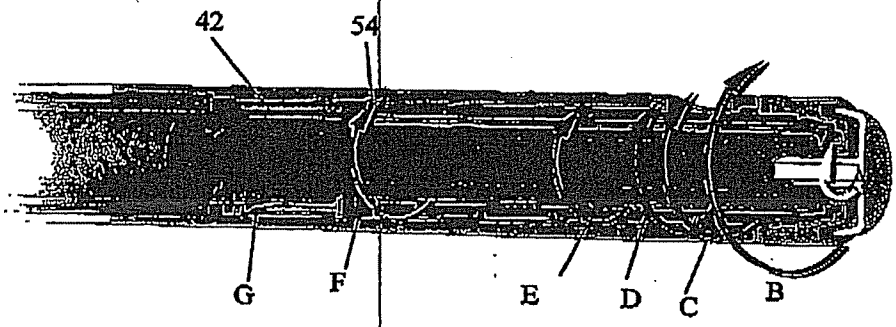

Fig 9

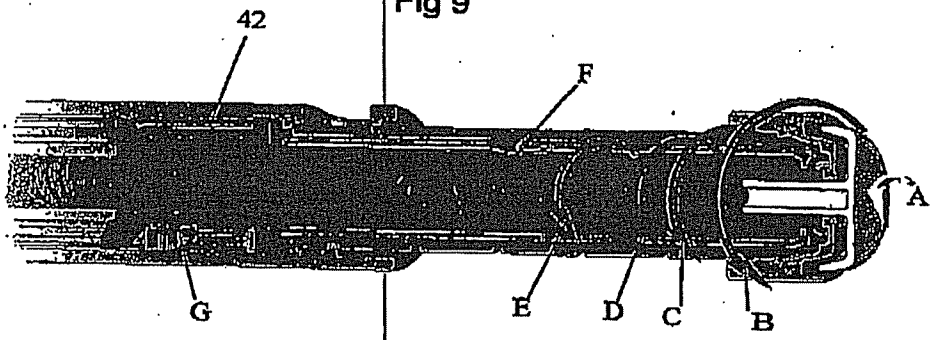

Fig 10

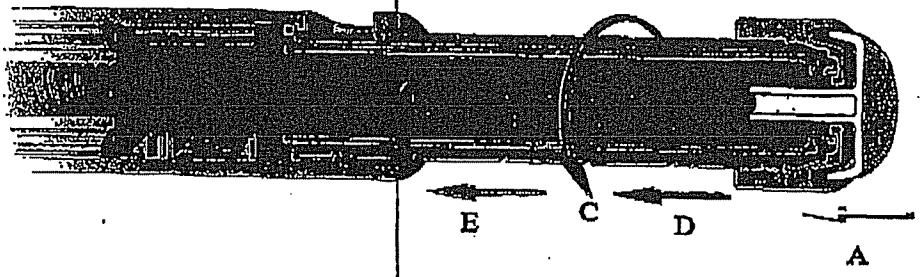

Fig 11

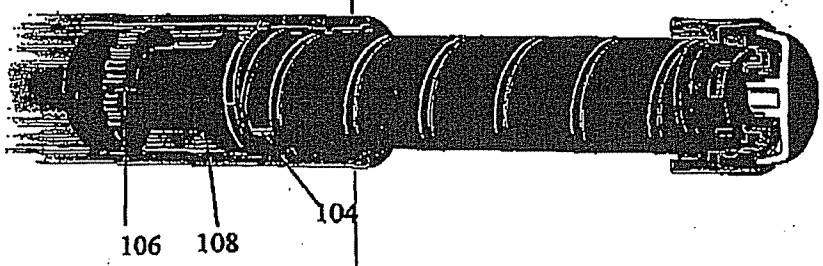

Fig 12

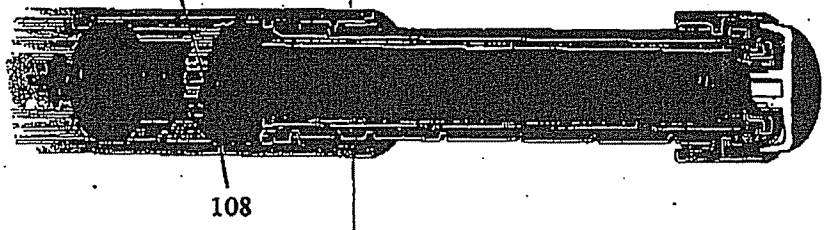

Fig 13

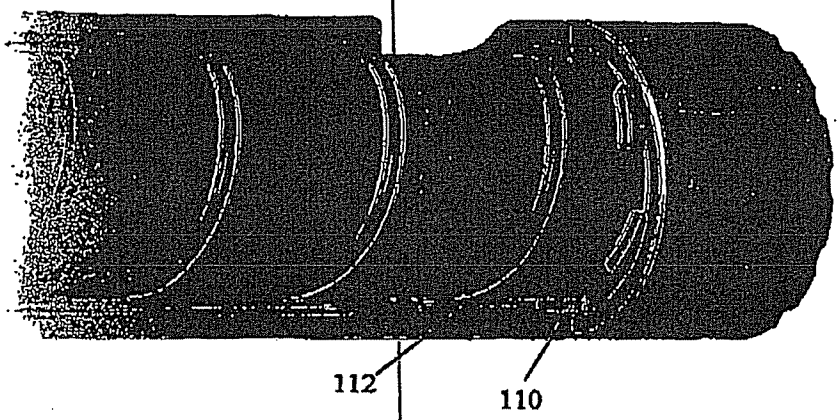

Fig 14

7/7

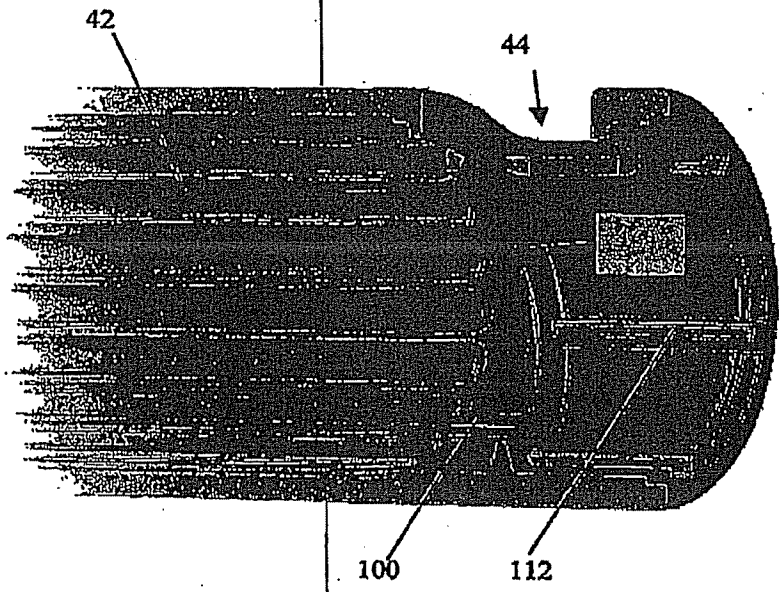

Fig 15

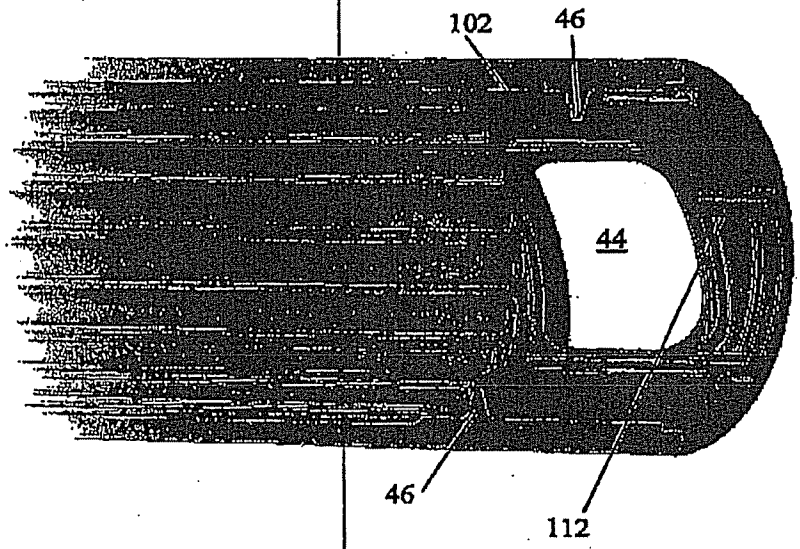

Fig 16

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 10-1188-US-CON1)

In the Application of:	)	
	)	
Robert Frederick Veasey et al.	)	Examiner: Unassigned
	)	
Serial No. Unassigned	)	Group Art Unit: Unassigned
	)	
Filed: Unassigned	)	Confirmation No.: Unassigned
	)	
For: Pen-Type Injector	)	Customer No.: 20306

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

PRELIMINARY AMENDMENT

Dear Sir:

Applicant submits the following preliminary amendment, and respectfully requests that it be entered prior to examination of this application.

Amendments to the specification begin on page 2.

Amendments to the claims begin on page 3.

Remarks begin of page 15.

Attachment includes an abstract.

General Authorization: Applicant generally authorizes the Office to charge any underpayment or credit any overpayment to Deposit Account No. 13-2490, and to treat any communication that requires an extension of time as incorporating a request for such an extension.

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AMENDMENTS TO THE SPECIFICATION

1. Please insert the following heading and paragraph on page 1, line 2 of the specification:

CROSS REFERENCE TO RELATED APPLICATIONS

The present application is a continuation application of US Patent Application No. 11/483,546, filed July 11, 2006, currently pending, which is a continuation application of US 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.

2. Please use the abstract on the attached page as the abstract for this application.

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AMENDMENTS TO THE CLAIMS

1-14. (cancelled)

15. (new) 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.

16. (new) The housing part of claim 15, wherein said tubular clutch is directly coupled to said dose knob.

17. (new) The housing part of claim 15, further comprising

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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.

18. (new) The housing part of claim 17, wherein during a dose setting step, said dose knob is rotated and moves away from said proximal end of said main housing so that a dose of said medicament contained within said medicament filled reservoir can be selected.

19. (new) The housing part of claim 18, wherein said dose knob is operatively configured to said tubular clutch so that, during said dose setting step, said tubular clutch, said dose dial sleeve, and said dose knob rotate out of said proximal end of said main housing.

20. (new) The housing part of claim 15, wherein said dose knob extends circumferentially around at least a portion of said tubular clutch.

21. (new) The housing part of claim 15, 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.

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22. (new) The housing part of claim 21, wherein during said dose dispensing step, said dose dial sleeve and said tubular clutch rotate together.

23. (new) The housing part of claim 17, 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.

24. (new) The housing part of claim 15, wherein said dose setting knob is coupled in part by said clutch to said dose dial sleeve so as to prevent relative movement between said dose setting knob and said dose dial sleeve during a dose setting step.

25. (new) The housing part of claim 15, wherein said dose setting knob is partially secured to said dose dial sleeve so as to allow relative movement between said dose setting knob and said dose dial sleeve during a dose dispensing step.

26. (new) The housing part of claim 15, wherein said driver comprises at least one flange.

27. (new) The housing part of claim 26, wherein said at least one flange is located near a distal portion of said driver.

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28. (new) The housing part of claim 15, further comprising a clicker, said clicker providing at least an audible feedback to a user when said dose knob is rotated.

29. (new) The housing part of claim 28, wherein said clicker provides tactile feedback to a user when said dose knob is rotated.

30. (new) The housing part of claim 28, wherein said clicker provides audible feedback when said dose knob is rotated in a dose increasing direction.

31. (new) The housing part of claim 28, wherein said clicker provides audible feedback when said dose knob is rotated in a dose decreasing direction.

32. (new) The housing part of claim 28, 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.

33. (new) The housing part of claim 28, wherein said clicker is disposed between said clutch and a proximal end of said piston rod.

34. (new) The housing part of claim 28, wherein

said clicker generally comprises a cylindrical shape having a first and a second end, and

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said cylindrical shape is provided at said first end with at least one flexible extending arm.

35. (new) The housing part of claim 15, 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.

36. (new) The housing part of claim 35, wherein said plurality of teeth comprise a plurality of dog teeth.

37. (new) The housing part of claim 15, wherein said piston rod comprises a generally circular cross section.

38. (new) The housing part of claim 15 wherein said external thread of said piston rod comprises a part thread.

39. (new) The housing part of claim 15,

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.

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40. (new) The housing part of claim 15, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing.

41. (new) The housing part of claim 15, 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.

42. (new) The housing part of claim 41, wherein said helical rib extends for at least a single sweep of said inner surface of said main housing.

43. (new) The housing part of claim 41, wherein said helical rib comprises a single start helical rib.

44. (new) The housing part of claim 15, wherein said dose dial sleeve comprises at least one radial stop, said radial stop positioned near an end of said helical groove.

45. (new) The housing part of claim 44, 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.

46. (new) The housing part of claim 44, wherein said radial stop is positioned near a distal end of said helical groove.

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47. (new) The housing part of claim 15, wherein if a user inadvertently dials said dose knob in one direction beyond a desired dose, said dose knob may be rotated in a second direction so as to allow said dialed dose to be reduced.

48. (new) The housing part of claim 15, wherein, to dispense a set dose, said dose knob is activated, and wherein activation of said dose knob disengages said tubular clutch in an axially direction with respect to said dose dial sleeve.

49. (new) The housing part of claim 17, wherein said housing part is configured such that a user is prevented from dialing a dose of medicament greater than said medicament remaining in said fluid container.

50. (new) The housing part of claim 15, wherein said housing part and said container comprises a disposable device.

51. (new) The housing part of claim 15, wherein said housing part and said container comprises a re-usable device.

52. (new) The housing part of claim 15, further comprising an insert, said insert provided at a distal end of the main housing, said insert secured against rotation.

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53. (new) The housing part of claim 15, further comprising an insert, said insert provided at a distal end of the main housing, and said insert secured against longitudinal motion.

54. (new) The housing part of claim 53, wherein said insert comprises an opening extending therethrough, such that said piston rod is configured to extend through said opening.

55. (new) The housing part of claim 54, wherein said opening comprises a threaded opening, and wherein during a dose dispense step, an external thread of said piston rod threadingly engages said threaded opening so that said piston rod rotates during a dose dispense step.

56. (new) The housing part of claim 15, wherein said main housing comprises a window through which at least a portion of an outer surface of said dose dial sleeve may be viewable.

57. (new) The housing part of claim 56, wherein said window is located near a proximal end of said main housing and near a helical rib provided on an inner surface of said outer housing.

58. (new) The housing part of claim 15, 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 the same.

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59. (new) The housing part of claim 15, 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.

60. (new) The housing part of claim 15, wherein said driver comprises a cylindrical shape.

61. (new) A pen type drug delivery device, said device comprising:

an external housing comprising a threading along a portion of an inner surface of said external housing, said external housing extending from a distal end to a proximal end;

a dialing element positioned within said housing, said dialing element comprising an outer surface extending from a distal end to a proximal end of said dialing element,

wherein said outer surface comprises a helical threading that defines a groove configured to engage said threading provided on said inner surface of said external housing;

an actuator disposed about an outer surface of an end of said dialing element near said proximal end of said main housing;

a driver extending along at least a portion of a piston rod, said driver comprising a thread adapted to threadingly engage an external thread of a piston rod; and,

a clutch positioned at least partially within an open proximal end of said dialing element and located adjacent a distal end of said actuator and operatively coupled to said actuator,

wherein said dialing element extends circumferentially around at least a portion of said clutch;

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a tubular barrel retainer operatively coupled to said external housing, said tubular barrel retainer comprising a cartridge containing a medicament, said cartridge comprising a reservoir, a piston, a septum, and a cap;

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

62. (new) The pen type drug delivery device of claim 61, wherein said tubular barrel retainer is permanently coupled to said external housing.

63. (new) The pen type drug delivery device of claim 61, wherein said tubular barrel retainer is removably coupled to said external housing.

64. (new) The pen type drug delivery device of claim 61, wherein said pen type drug delivery device comprises a prefilled, variable dose pen type drug delivery device.

65. (new) The pen type drug delivery device of claim 61, wherein said outer surface of said dialing element further comprises dosage indicator markings.

66. (new) The pen type drug delivery device of claim 61, wherein said external housing further comprises a housing window, and wherein said housing window allows said dosage indicator markings to be visible during use of said pen type drug delivery device.

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67. (new) The pen type drug delivery device of claim 61, wherein said driver comprises a cylindrical, tube-shaped body.

68. (new) The pen type drug delivery device of claim 61, wherein said clutch comprises a cylindrical clutch.

69. (new) A clutch for use within a pen type drug delivery device, said clutch comprising

a tubular body, said tubular body extending from a distal end to a proximal end; and said distal end of said tubular body having a diameter sized such that said distal end of said tubular body may be positioned within a proximal end of a dial member.

70. (new) The clutch of claim 69, wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob.

71. (new) The clutch of claim 69, further comprising a plurality of axially extending teeth formed in an interior of a flange of said clutch.

72. (new) The clutch of claim 69, wherein said clutch is positioned within an open proximal end of said dial member and located adjacent a distal end of said dose knob and operatively coupled to said dose knob, and wherein said dial member extends circumferentially around at least a portion of said clutch.

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73. (new) The clutch of claim 70, wherein when said dose knob is activated to dispense a dose of a medicament contained within said pen type delivery device, said clutch is moved in a distal direction.

74. (new) The clutch of claim 70, wherein said pen type drug delivery device further comprises

a cartridge containing a medicament, said cartridge comprising a reservoir, a stopper, a septum and a ferrule.

75. (new) The clutch of claim 74, wherein said cartridge comprises a multidose cartridge.

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REMARKS

Prior to examination of this application on the merits, entry of the above amendments to the specification and claims are requested.

The specification is amended to include a cross-reference to related applications and an abstract, which is attached to this Preliminary Amendment.

Claims 1-14 are cancelled without prejudice or disclaimer, and new claims 15-75 are added. Support for the new claims is self-evident from the originally-filed disclosure, including the original claims, and therefore no new matter is added.

Also, attached to this Preliminary Amendment is an abstract.

If there are any matters that may be resolved or clarified through a telephone interview, the Examiner is respectfully requested to contact Applicant's undersigned representative at (312) 913-0001.

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff LLP

Date: November 11, 2010

By: /Thomas E. Wettermann/
Thomas E. Wettermann
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Tab A

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.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 10-1188-US-CON1)

In the Application of:	)	
	)	
Robert Frederick Veasey et al.	)	Examiner: Unassigned
	)	
Serial No. Unassigned	)	Group Art Unit: Unassigned
	)	
Filed: Unassigned	)	Confirmation No.: Unassigned
	)	
For: Pen-Type Injector	)	

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

SUBMISSION OF SUBSTITUTE SPECIFICATION

Subject to the approval of the Examiner, please replace the specification in the application filed herewith with the attached Substitute Specification. The Substitute Specification is the same as the originally-filed specification and is provided as a clean copy of the originally-filed specification. If for any reason the Substitute Specification is not in full compliance with the pertinent statutes and regulations, please so advise the undersigned.

If any fees are necessary for the submission of this Substitute Specification, please charge Deposit Account No. 13-2490.

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff LLP

Date: November 11, 2010

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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).

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;
characterised 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.

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.

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. Preferably 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

1 A pen-type injector comprising 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;
characterised in that the first lead of the helical thread and the second lead of the helical groove are the same.

2 A pen-type injector according to claim 1, characterised in that 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.

3 A pen-type injector according to claim 1 or claim 2, in which 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.

4 A pen-type injector according to claim 3, in which 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.

5 A pen-type injector according to claim 4, in which a first radial stop is provided on a second face of the nut and a second radial stop is provided on a first face of the second flange.

6 A pen-type injector according to any of claims 2 to 5, in which the first thread of the piston rod is oppositely disposed to the second thread of the piston rod.

7 A pen-type injector according to any of claims 2 to 6, in which 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.

8 A pen-type injector according to any of claims 2 to 7, in which the pen-type injector further includes clicker means disposed between the clutch means and spline means provided on the housing.

9 A pen-type injector according to claim 8, in which 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.

10 A pen-type injector according to claim 8, in which 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.

11 A pen-type injector according to any previous claim, in which 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.

12 A pen-type injector according to claim 11, in which 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.

13 A pen-type injector according to claim 11, in which at least one of the maximum dose stops comprises a part of a raised window portion provided at a second end of the housing.

14 A pen-type injector according to any previous claim, in which 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.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 10-1188-US-CON1)

In the Application of:	)	
	)	
Robert Frederick Veasey et al.	)	Examiner: Unassigned
	)	
Serial No. Unassigned	)	Group Art Unit: Unassigned
	)	
Filed: Unassigned	)	Confirmation No.: Unassigned
	)	
For: Pen-Type Injector	)	

Commissioner for Patents
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Alexandria, Virginia 22313-1450

SUBMISSION OF REPLACEMENT DRAWINGS

Subject to the approval of the Examiner, please replace the drawings in the application filed herewith with the drawings in the seven (7) attached Replacement Sheets (which include Figures 1-16). These Replacement Sheets include cleaner versions of the originally-filed drawings. If for any reason the Replacement Sheets are not in full compliance with the pertinent statutes and regulations, please so advise the undersigned.

If any fees are necessary for the submission of these Replacement Sheets, please charge Deposit Account No. 13-2490.

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff LLP

Date: November 11, 2010

By: /Thomas E. Wettermann/
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Fig. 1

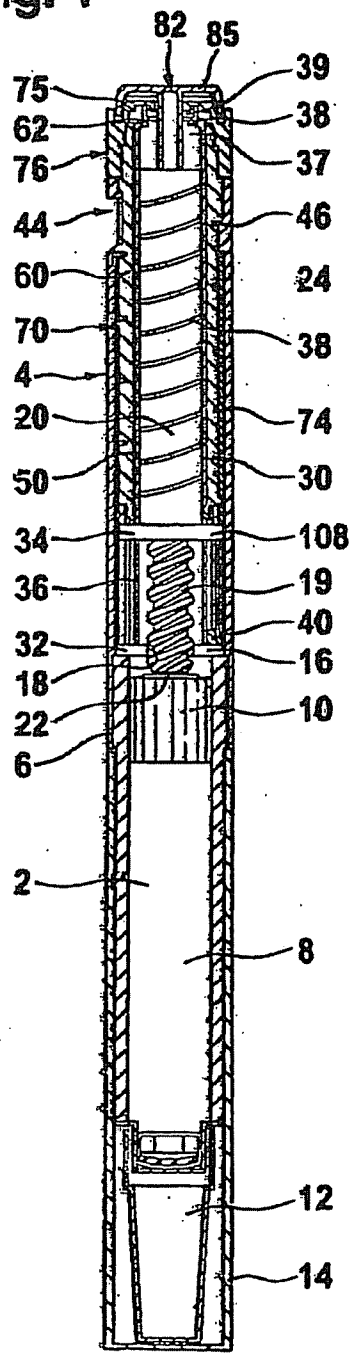


Fig. 2

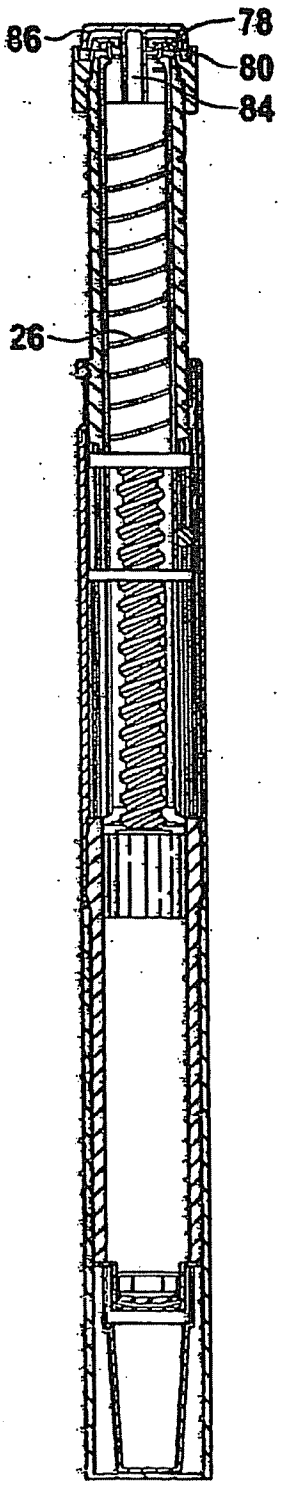


Fig. 3

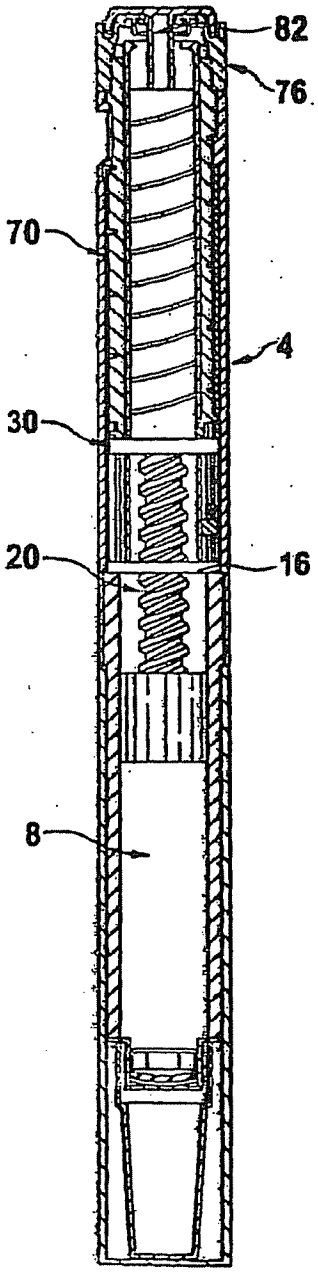


Fig. 4

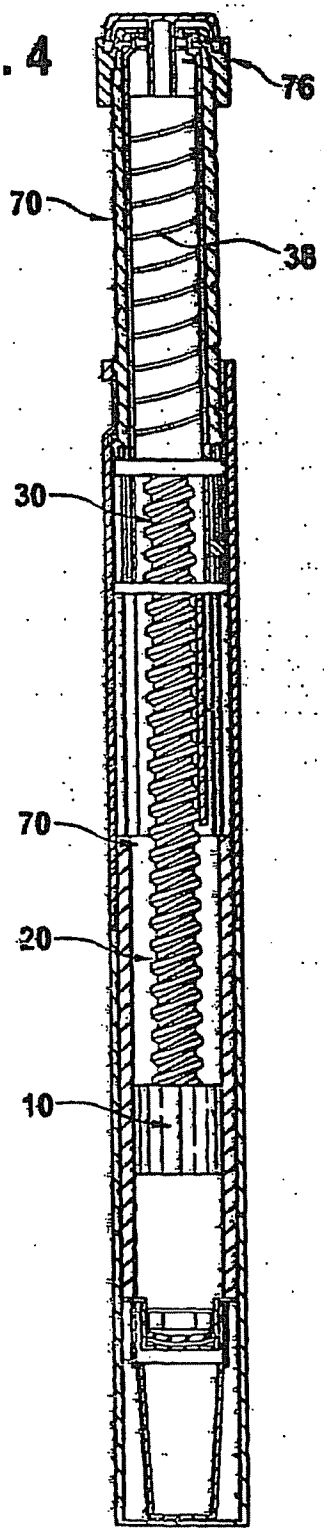


Fig. 5

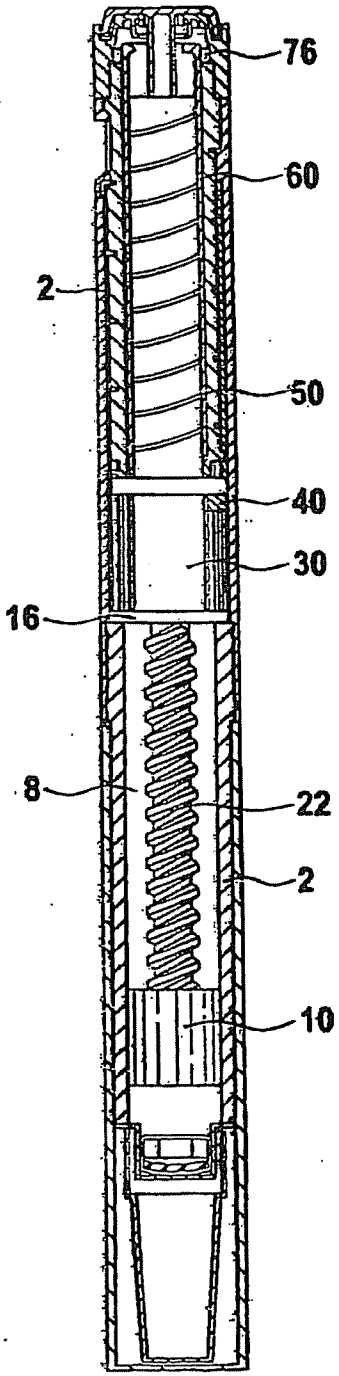


Fig. 6

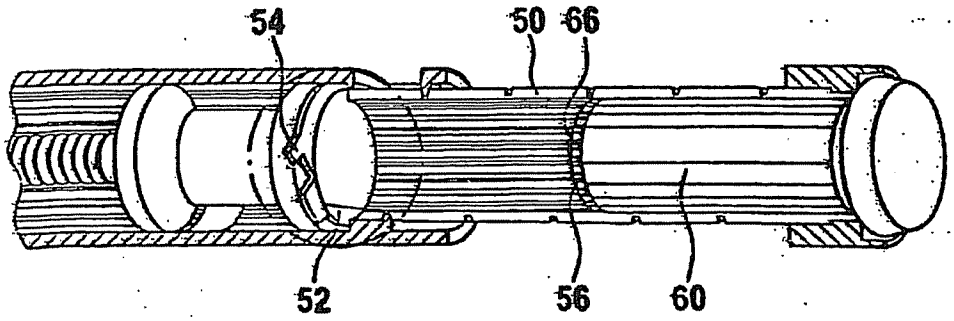


Fig. 7

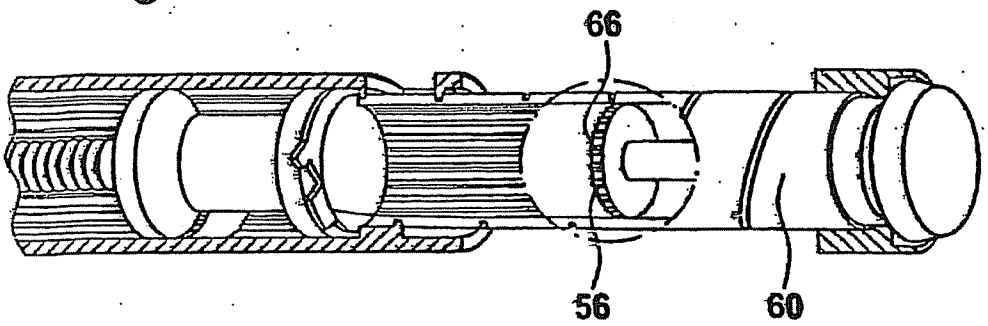


Fig. 8

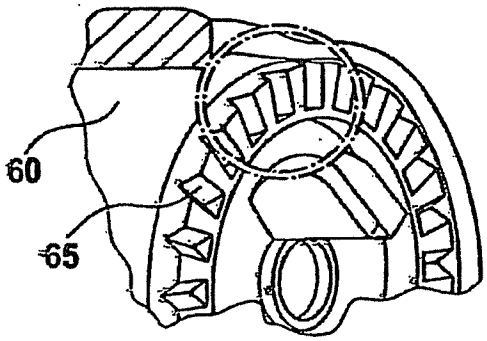


Fig. 9

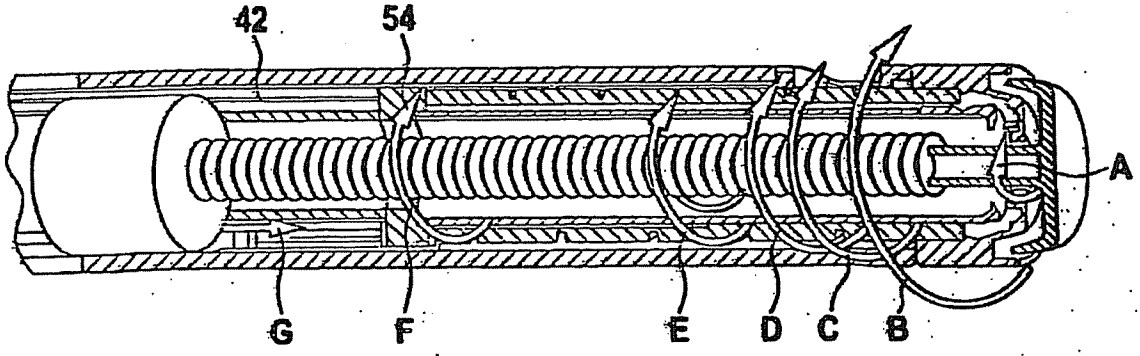


Fig. 10

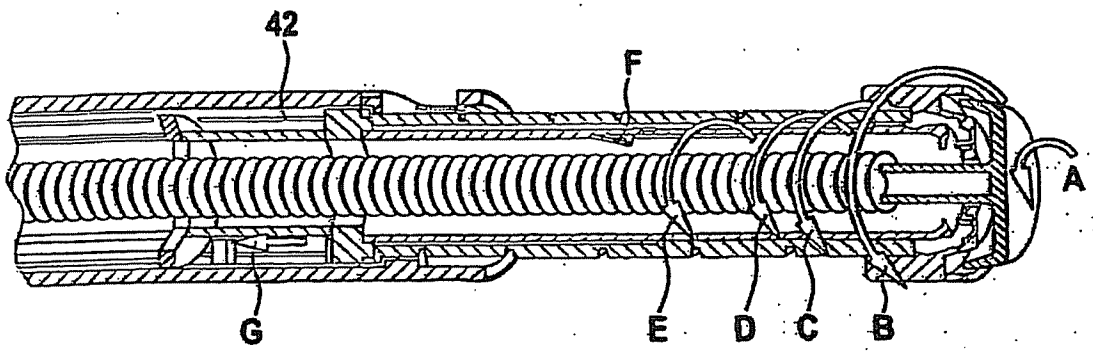


Fig. 11

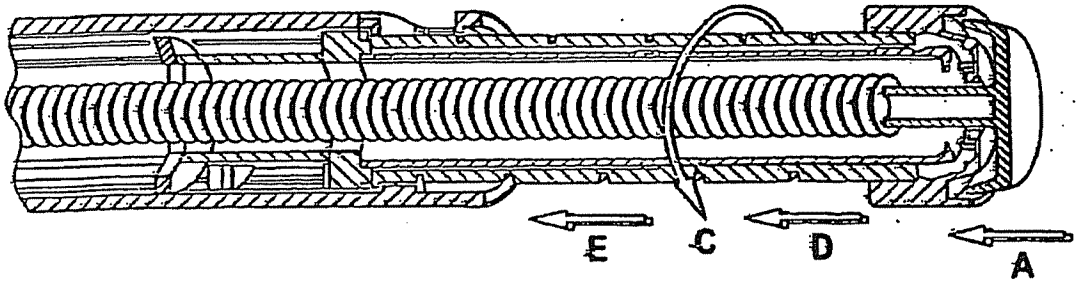


Fig. 12

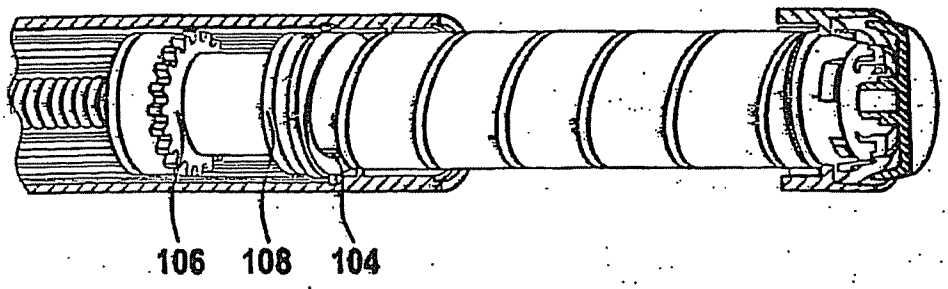


Fig. 13

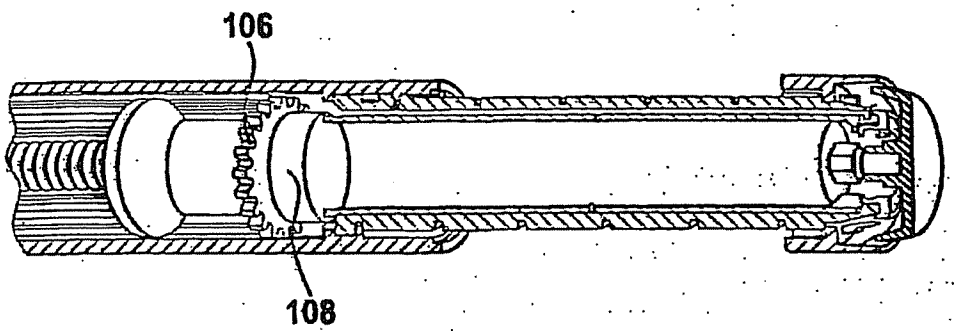


Fig. 14

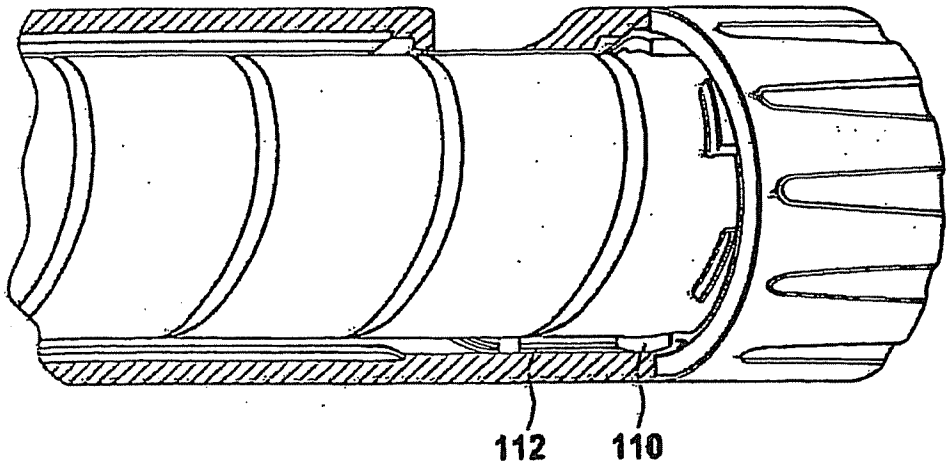


Fig. 15

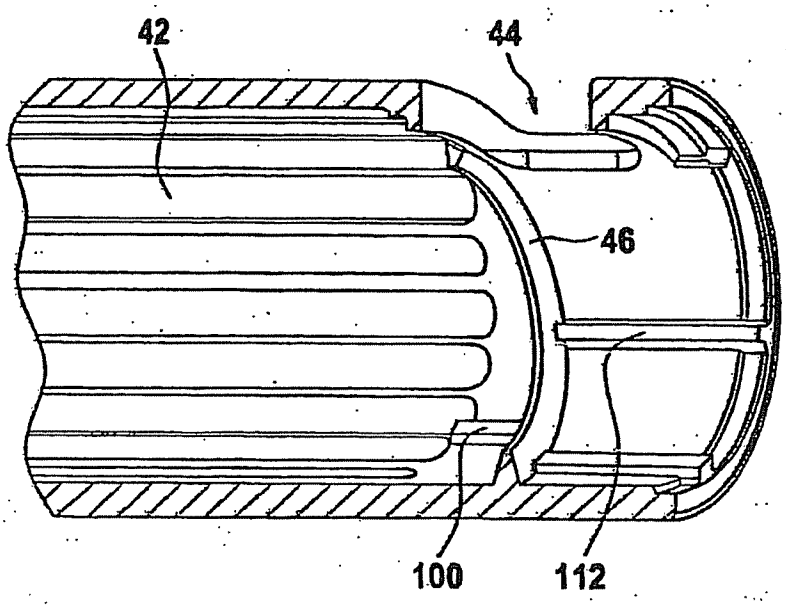
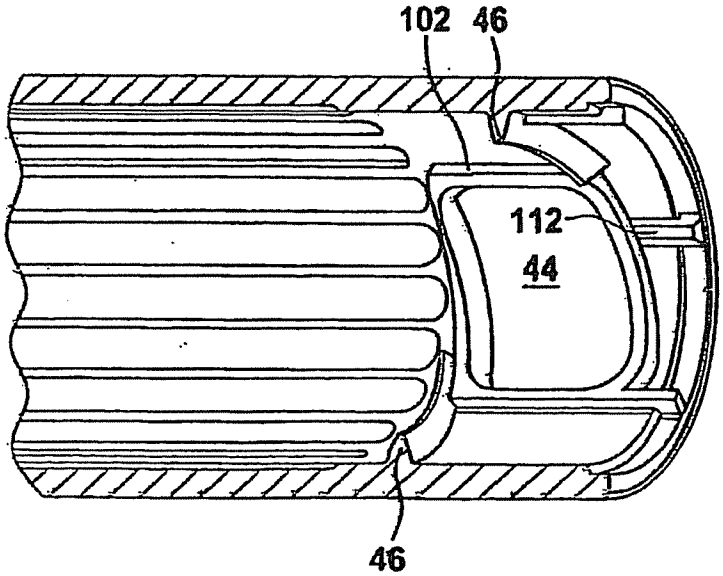


Fig. 16



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON1)

In re Application of:	)	
	)	
Robert Frederick Veasey et al.	)	
	)	Examiner: Unassigned
Serial No.: Unassigned	)	
	)	Group Art Unit: Unassigned
Filed: Unassigned	)	
	)	Confirmation No.: Unassigned
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 any future reply 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 11, 2010 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:	
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-CON1

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility application filing	1011	1	330	330
Utility Search Fee	1111	1	540	540
Utility Examination Fee	1311	1	220	220
Pages:				
Claims:				
Claims in excess of 20	1202	41	52	2132
Miscellaneous-Filing:				
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**3222**

Electronic Acknowledgement Receipt

EFS ID:	8817075
Application Number:	12944544
International Application Number:	
Confirmation Number:	5949
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-CON1
Receipt Date:	11-NOV-2010
Filing Date:	
Time Stamp:	18:03:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$3222
RAM confirmation Number	14579
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 of New Application	10_1188_US_CON1_Utility_Transmittal_2010_11_11.pdf	159799 5a0fab92a83362b83776ad95850d26d465ca30b3	no	1
Warnings:					
Information:					
2	Miscellaneous Incoming Letter	10_1188_US_CON1_Fee_Transmittal_2010_11_11.pdf	141239 a036d828823d5c5ce09069919e3f9622809e0ae8	no	1
Warnings:					
Information:					
3	Application Data Sheet	10_1188_US_CON1_ADS_2010_11_11.pdf	3568688 96a167a16b3c30e27c738cee4a41f11ef2bf3c90	no	5
Warnings:					
Information:					
4		10_1188_US_CON1_Specification_2010_11_11.pdf	1518028 c3a7c2d93887b47e03fd1d18f613bf27d897c381	yes	15
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Specification		1	12	
	Claims		13	15	
Warnings:					
Information:					
5	Drawings-only black and white line drawings	10_1188_US_CON1_Figures_2010_11_11.pdf	986403 df9ea3eb4389d1ede0b183134451080cd77aca24	no	7
Warnings:					
Information:					
6	Preliminary Amendment	10_1188_US_CON1_Preliminary_Amendment_2010_11_11.pdf	1049898 59e691816bdd774fe3443a0505342d35c8443e2e	no	17
Warnings:					
Information:					
7	Miscellaneous Incoming Letter	10_1188_US_CON1_Submission_of_Substitute_Specification_2010_11_11.pdf	80589 eb573cf63426b3896ee989a206e892b1f4dae8de	no	1

Warnings:					
Information:					
8		10_1188_US_CON1_Substitute_Specification_2010_11_11.pdf	1383458 26054764e65c83bee299ba82af8fcfc5fa22826a	yes	14
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Specification		1	11	
	Claims		12	14	
Warnings:					
Information:					
9	Miscellaneous Incoming Letter	10_1188_US_CON1_Submission_of_Replacement_Drawings_2010_11_11.pdf	82031 06b52f55c9ed3ba85d68d23dc9dce0d4bec7e3a0	no	1
Warnings:					
Information:					
10	Drawings-only black and white line drawings	10_1188_US_CON1_Replacement_Drawings_2010_11_11.pdf	591552 27dae9a34063b206f682cd0984f514e57f354a69	no	7
Warnings:					
Information:					
11	Authorization for Extension of Time all replies	10_1188_US_CON1_General_Authorization_2010_11_11.pdf	62253 e36f082293cdd48c545028291345b00b226e7f45	no	1
Warnings:					
Information:					
12	Fee Worksheet (PTO-875)	fee-info.pdf	36001 622e50f743553cfbc97055b1dfcb90c5ba9f9530	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	9659939	

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/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
12/944,544	11/11/2010	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☒ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	330
☒ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	540
☒ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	220
TOTAL CLAIMS (37 CFR 1.16(i))	14 minus 20 =	* 0	X $ =		OR	X $52 =	0
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	* 0	X $ =			X $220 =	0
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 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			TOTAL	1090

APPLICATION AS AMENDED – PART II

AMENDMENT 11/11/2010

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 61	Minus	** 20	= 41	X $ =		OR	X $52=	2132
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $ =		OR	X $220=	0
☐ 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	2132

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
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 number found in the appropriate box in column 1.

Legal Instrument Examiner:
/MARCUS MONROE/

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 12/944,544

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	330
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	540
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	220
TOTAL CLAIMS (37 CFR 1.16(i))	61 minus 20 =	* 41			OR	x 52 =	2132
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*				x 220 =	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 $270 ($135 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	3222

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
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) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) 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.

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
12/944,544	11/11/2010	Robert Frederick Veasey	10-1188-US-CON1

CONFIRMATION NO. 5949

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

FORMALITIES LETTER

OC000000044663932

Date Mailed: 11/26/2010

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is missing.
  A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.
  Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - The drawings must be reasonably free from erasures and must be free from alterations, overwriting, interlineations, folds, and copy marks. See Figure(s) 1-16.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- A surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of $**130** for a non-small entity, must be submitted.

SUMMARY OF FEES DUE:

Total fee(s) required within **TWO MONTHS** from the date of this Notice is $**130** for a non-small entity
- $**130** Surcharge.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/sgorems/

Office of Data Management, 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

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/944,544	11/11/2010	3767	3222	10-1188-US-CON1	61	3

CONFIRMATION NO. 5949

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

FILING RECEIPT

OC000000044663931

Date Mailed: 11/26/2010

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**

Applicant(s)

Robert Frederick Veasey, Warwickshire, UNITED KINGDOM;
Robert Perkins, Warwickshire, 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 11/483,546 07/11/2006
and is a CON of 10/790,225 03/02/2004 ABN

Foreign Applications

UNITED KINGDOM 0304822.0 03/03/2003

Request to Retrieve - This application either claims priority to one or more applications filed in an intellectual property Office that participates in the Priority Document Exchange (PDX) program or contains a proper **Request to Retrieve Electronic Priority Application(s)** (PTO/SB/38 or its equivalent). Consequently, the USPTO will attempt to electronically retrieve these priority documents.

If Required, Foreign Filing License Granted: 11/23/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/944,544**

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No
Title

Pen-Type Injector

Preliminary Class

604

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where

the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

PTO/SB/81 (01-09)
Approved for use through 11/30/2011. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS

Application Number	12/944,544
Filing Date	November 11, 2010
First Named Inventor	Robert Frederick Veasey et al.
Title	Pen-Type Injector
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	10-1188-US-CON1

I hereby revoke all previous powers of attorney given in the above-identified application.

☐ A Power of Attorney is submitted herewith.

OR

☒ I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith: 20306

OR

☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

Practitioner(s) Name	Registration Number

Please recognize or change the correspondence address for the above-identified application to:

☒ The address associated with the above-mentioned Customer Number.

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the:

☒ Applicant/Inventor.

OR

☐ Assignee of record of the entire interest. See 37 CFR 3.71.

Statement under 37 CFR 3.73(b) (Form PTO/SB/96) submitted herewith or filed on _____

SIGNATURE of Applicant or Assignee of Record

Signature	R. Veasey	Date	11/2/2011
Name	Robert Frederick Veasey	Telephone	+44 1926 499461
Title and Company	Inventor		

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 3 forms are submitted.

PTO/SB/81 (01-09)
Approved for use through 11/30/2011. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS

Application Number	12/944,544
Filing Date	November 11, 2010
First Named Inventor	Robert Frederick Veasey et al.
Title	Pen-Type Injector
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	10-1188-US-CON1

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Practitioner(s) Name	Registration Number

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☒ The address associated with the above-mentioned Customer Number.

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the:

☒ Applicant/Inventor.

OR

☐ Assignee of record of the entire interest. See 37 CFR 3.71.

Statement under 37 CFR 3.73(b) (Form PTO/SB/96) submitted herewith or filed on _____

SIGNATURE of Applicant or Assignee of Record

Signature		Date	15-FEB-2011
Name	Robert Perkins	Telephone	
Title and Company	Inventor		

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 3 forms are submitted.

PTO/SB/81 (01-09)
Approved for use through 11/30/2011. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS

Application Number	12/944,544
Filing Date	November 11, 2010
First Named Inventor	Robert Frederick Veasey et al.
Title	Pen-Type Injector
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	10-1188-US-CON1

I hereby revoke all previous powers of attorney given in the above-identified application.

☐ A Power of Attorney is submitted herewith.

OR

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OR

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Practitioner(s) Name	Registration Number

Please recognize or change the correspondence address for the above-identified application to:

☒ The address associated with the above-mentioned Customer Number.

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the:

☒ Applicant/Inventor.

OR

☐ Assignee of record of the entire interest. See 37 CFR 3.71.

Statement under 37 CFR 3.73(b) (Form PTO/SB/96) submitted herewith or filed on _____

SIGNATURE of Applicant or Assignee of Record

Signature	/David Plumptre/	Date	14/2/2011
Name	David Aubrey Plumptre	Telephone	+44 1926 499461
Title and Company	Inventor		

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 3 forms are submitted.

PTO/SB/22 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2009 *(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)*	Docket Number (Optional) 10-1188-US-CON1
Application Number 12/944,544	Filed November 11, 2010
For Pen-Type Injector	
Art Unit 3767	Examiner Unassigned

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

		Fee	Small Entity Fee	
☐	One month (37 CFR 1.17(a)(1))	$130	$65	$
☒	Two months (37 CFR 1.17(a)(2))	$490	$245	$ 490.00
☐	Three months (37 CFR 1.17(a)(3))	$1110	$555	$
☐	Four months (37 CFR 1.17(a)(4))	$1730	$865	$
☐	Five months (37 CFR 1.17(a)(5))	$2350	$1175	$

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☒ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 13-2490.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the ☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☒ attorney or agent of record. Registration Number 41,523

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____.

/Thomas E. Wettermann/	March 21, 2011
Signature	Date
Thomas E. Wettermann	312-913-2138
Typed or printed name	Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). 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 6 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON1)

In re Application of:	)	
	)	
Robert Frederick Veasey et al.	)	
	)	Examiner: Unassigned
Serial No.: 12/944,544	)	
	)	Group Art Unit: 3767
Filed: November 11, 2010	)	
	)	Confirmation No.: 5949
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 any future reply 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: March 21, 2011 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:	12944544
Filing Date:	11-Nov-2010
Title of Invention:	Pen-Type Injector
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Filer:	Thomas E. Wettermann
Attorney Docket Number:	10-1188-US-CON1

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:				
Late filing fee for oath or declaration	1051	1	130	130
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 2 months with $0 paid	1252	1	490	490
Miscellaneous:				
			Total in USD ($)	**620**

Electronic Acknowledgement Receipt

EFS ID:	9703674
Application Number:	12944544
International Application Number:	
Confirmation Number:	5949
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-CON1
Receipt Date:	21-MAR-2011
Filing Date:	11-NOV-2010
Time Stamp:	18:14:03
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$620
RAM confirmation Number	5898
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	Miscellaneous Incoming Letter	10_1188_US_CON1_Missing_Parts_Transmittal_2011_03_21.pdf	140310 592f5b328ebfcfacd0850a194fe8a7011fc290c1	no	1
Warnings:					
Information:					
2	Miscellaneous Incoming Letter	10_1188_US_CON1_Missing_Parts_Response_2011_03_21.pdf	50673 5c9e69f50a09b599328872cef30ecd5b9a033cf9	no	1
Warnings:					
Information:					
3	Oath or Declaration filed	10_1188_US_CON1_Declaration_2011_03_21.pdf	703937 9fe5651e66ba41d5f2b3aef4a260f52aaf4b16d1	no	5
Warnings:					
Information:					
4	Power of Attorney	10_1188_US_CON1_Power_Of_Attorney_2011_03_21.pdf	420245 79c5528a8df5d5a6f497e40a5970244b8f646564	no	3
Warnings:					
Information:					
5	Extension of Time	10_1188_US_CON1_2Mo_Ext_Time_2011_03_21.pdf	128429 8b3761cb40979d8c28175f07b32b9ad2a6824080	no	1
Warnings:					
Information:					
6	Authorization for Extension of Time all replies	10_1188_US_CON1_General_Authorization_2011_03_21.pdf	58750 a4e018ea2ef3c7073faff010b162004f2391c4de	no	1
Warnings:					
Information:					
7	Fee Worksheet (PTO-875)	fee-info.pdf	32070 bf2fe387dae4b60c5e08e067a0bb6fb50f43d8ba	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1534414		

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)

Application Number	12/944,544
Filing Date	November 11, 2010
First Named Inventor	Robert Frederick Veasey et al.
Art Unit	3767
Examiner Name	Unassigned
Total Number of Pages in This Submission: 12	Attorney Docket Number: 10-1188-US-CON1

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):
  Executed Declaration 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	March 21, 2011	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	March 21, 2011

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON1)

In re Application of:	)	
	)	
Robert Frederick Veasey et al.	)	
	)	Examiner: Unassigned
Serial No.: 12/944,544	)	
	)	Group Art Unit: 3767
Filed: November 11, 2010	)	
	)	Confirmation No.: 5949
For: Pen-Type Injector	)	

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

RESPONSE TO NOTICE TO FILE MISSING PARTS OF APPLICATION

In accordance with the Notice to File Missing Parts dated November 26, 2010, we are filing herewith an executed Declaration and Power of Attorney, together with the requisite fees, pursuant to 37 C.F.R. §§ 1.16(e).

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff LLP

Date: March 21, 2011

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

McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, Illinois 60606

PTO/SB/01 (04-09)
Approved for use through 09/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted With Initial Filing OR ☒ Declaration Submitted after Initial Filing (surcharge (37 CFR1.16 (f)) required)

Attorney Docket Number	10-1188-US-CON1
First Named Inventor	Robert Frederick Veasey et al.
COMPLETE IF KNOWN	
Application Number	12/944,544
Filing Date	November 11, 2010
Art Unit	Unassigned
Examiner Name	Unassigned

I hereby declare that: (1) Each inventor's residence, mailing address, and citizenship are as stated below next to their name; and (2) I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Pen-Type Injector

(Title of the Invention)

the application of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) 11/11/2010 as United States Application Number or PCT International

Application Number 12/944,544 and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified application, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Authorization To Permit Access To Application by Participating Offices

☐ 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.

DECLARATION — Utility or Design Patent Application

Claim of Foreign Priority Benefits

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
0304822.0	GB	03/03/2003	☐	☐	☒
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

PTO/SB/01 (04-09)
Approved for use through 09/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION — Utility or Design Patent Application

Direct all correspondence to:	☒ The address associated with Customer Number:	20304	OR	☐ Correspondence address below

Name		
Address		
City	State	ZIP
Country	Telephone	Email

WARNING:

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*.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle [if any]) Robert Frederick	Family Name or Surname Veasey
Inventor's Signature R. Veasey	Date 18/3/11

Residence: City	State	Country	Citizenship
Warwickshire		UK	UK

Mailing Address 31 Lonsdale Road Leamington Spa			
City Warwickshire	State	Zip CV32 7EP	Country UK

☒ Additional Inventors or a legal representative are being named on the 1 supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.

PTO/SB/02A (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION

ADDITIONAL INVENTOR(S)

Supplemental Sheet

Name of Additional Joint Inventor, if any: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))	Family Name or Surname
Robert	Perkins

Inventor's Signature: [signature] Date: 17 MARCH 2011

Residence: City	State	Country	Citizenship
Oxfordshire		UK	UK

Mailing Address: 6 Printers Court, Abingdon

City	State	Zip	Country
Oxfordshire		OX14 SBZ	UK

Name of Additional Joint Inventor, if any: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))	Family Name or Surname
David Aubrey	Plumptre

Inventor's Signature: Date:

Residence: City	State	Country	Citizenship
Worcestershire		UK	UK

Mailing Address: 36 Shire Way, Droitwich

City	State	Zip	Country
Worcestershire		WR9 7	UK

Name of Additional Joint Inventor, if any: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))	Family Name or Surname

Inventor's Signature: Date:

Residence: City	State	Country	Citizenship

Mailing Address:

City	State	Zip	Country

PTO/SB/02A (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION

ADDITIONAL INVENTOR(S)

Supplemental Sheet

Name of Additional Joint Inventor, if any: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))	Family Name or Surname
Robert	Perkins

Inventor's Signature _____ Date _____

Residence: City	State	Country	Citizenship
Warwickshire		UK	UK

67 Erica Drive
Leamington Spa

Mailing Address

City	State	Zip	Country
Warwickshire		CV31 2RW	UK

Name of Additional Joint Inventor, if any: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))	Family Name or Surname
David Aubrey	Plumptre

Inventor's Signature _____ Date 14/2/2011

Residence: City	State	Country	Citizenship
Worcestershire		UK	UK

36 Shire Way
Droitwich

Mailing Address

City	State	Zip	Country
Worcestershire		WR9 7	UK

Name of Additional Joint Inventor, if any: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))	Family Name or Surname

Inventor's Signature _____ Date _____

Residence: City	State	Country	Citizenship

Mailing Address

City	State	Zip	Country

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
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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
12/944,544	11/11/2010	3767	3352	10-1188-US-CON1	61	3

CONFIRMATION NO. 5949

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

FILING RECEIPT

OC000000049232315

Date Mailed: 08/11/2011

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**

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: The patent practitioners associated with Customer Number 20306

Domestic Priority data as claimed by applicant

This application is a CON of 11/483,546 07/11/2006 PAT 7,918,833
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

Request to Retrieve - This application either claims priority to one or more applications filed in an intellectual property Office that participates in the Priority Document Exchange (PDX) program or contains a proper **Request to Retrieve Electronic Priority Application(s)** (PTO/SB/38 or its equivalent). Consequently, the USPTO will attempt to electronically retrieve these priority documents.

If Required, Foreign Filing License Granted: 11/23/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/944,544**

Projected Publication Date: To Be Determined - pending completion of Corrected Papers

Non-Publication Request: No

Early Publication Request: No

Title

Pen-Type Injector

Preliminary Class

604

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

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NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/944,544	11/11/2010	Robert Frederick Veasey	10-1188-US-CON1

CONFIRMATION NO. 5949

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

FORMALITIES LETTER

OC000000049232356

Date Mailed: 08/11/2011

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Filing Date Granted

An application number and filing date have been accorded to this application. The application is informal since it does not comply with the regulations for the reason(s) indicated below. Applicant is given TWO MONTHS from the date of this Notice within which to correct the informalities indicated below. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

The required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - The drawings must be reasonably free from erasures and must be free from alterations, overwriting, interlineations, folds, and copy marks. See Figure(s) 1 to 16.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/ctuazon/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/944,544	11/11/2010	Robert Frederick Veasey	10-1188-US-CON1

CONFIRMATION NO. 5949

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

WITHDRAWAL NOTICE

OC000000049232318

Date Mailed: 08/11/2011

Letter Regarding a New Notice and/or the Status of the Application

If a new notice or Filing Receipt is enclosed, applicant may disregard the previous notice mailed on 11/26/2010. The time period for reply runs from the mail date of the new notice. Within the time period for reply, applicant is required to file a reply in compliance with the requirements set forth in the new notice to avoid abandonment of the application.

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web. https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If the reply is not filed electronically via EFS-Web, the reply must be accompanied by a copy of the new notice.

If the Office previously granted a petition to withdraw the holding of abandonment or a petition to revive under 37 CFR 1.137, the status of the application has been returned to pending status.

/ctuazon/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/944,544

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	330
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	540
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	220
TOTAL CLAIMS (37 CFR 1.16(i))	61 minus 20 =	* 41			OR	x 52 =	2132
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*				x 220 =	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 $270 ($135 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	3222

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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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/944,544	11/11/2010	Robert Frederick Veasey	10-1188-US-CON1

CONFIRMATION NO. 5949

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

POA ACCEPTANCE LETTER

OC000000049231891

Date Mailed: 08/11/2011

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 03/21/2011.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/lchau/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON1)

In re Application of:	)	
	)	
Robert Frederick Veasey et al.	)	
	)	Examiner: Unassigned
Serial No.: 12/944,544	)	
	)	Group Art Unit: 3352
Filed: November 11, 2010	)	
	)	Confirmation No.: 5949
For: Pen-Type Injector	)	

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

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

In accordance with the Notice to file Corrected Application Papers dated August 11, 2011, we are filing herewith Replacement Drawings.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff LLP

Date: December 21, 2011 By: /Thomas E. Wettermann/
Thomas E. Wettermann
Reg. No. 41,523

McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, Illinois 60606

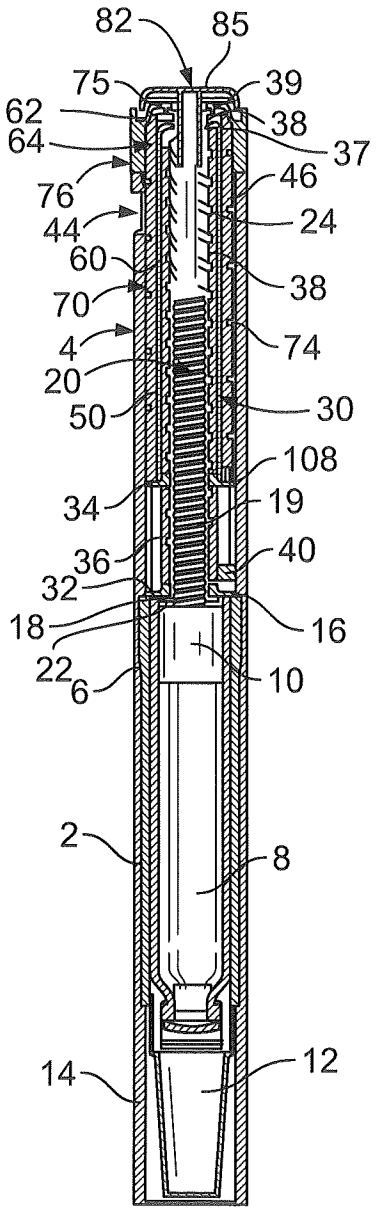

FIG. 1

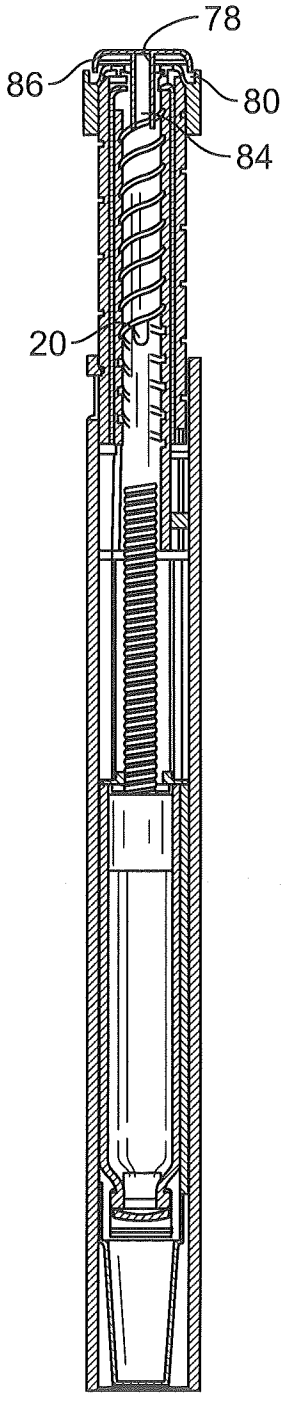

FIG. 2

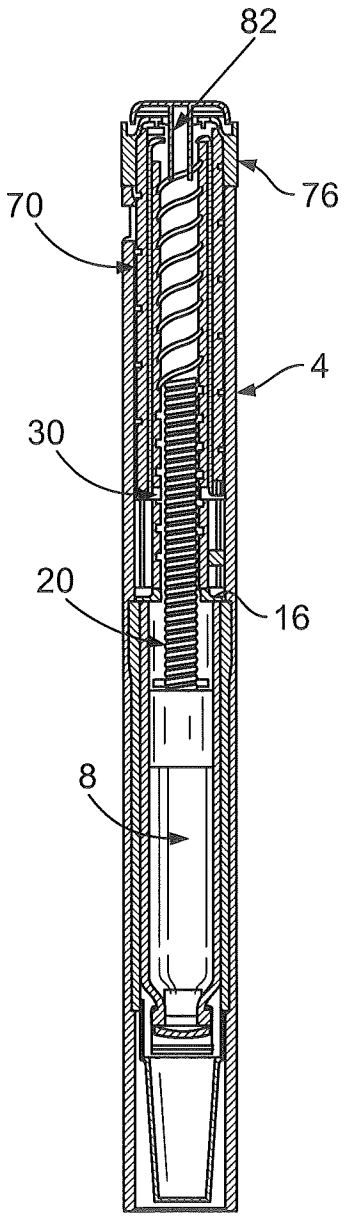

FIG. 3

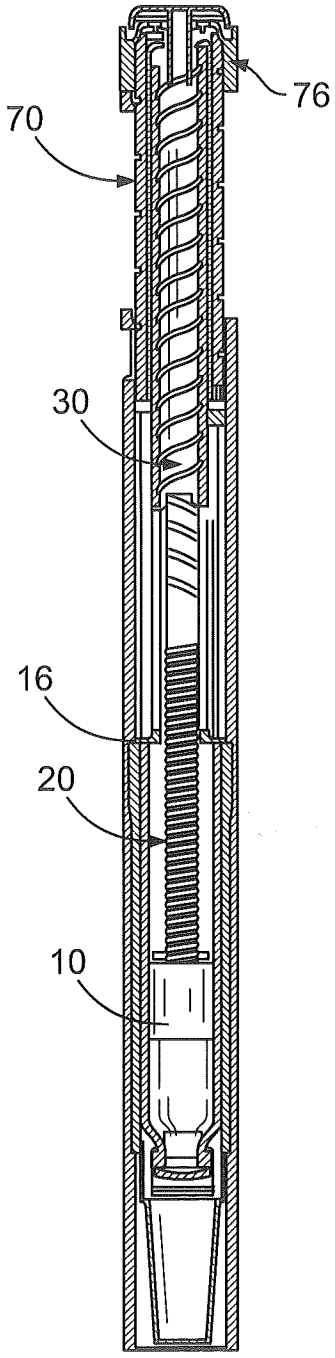

FIG. 4

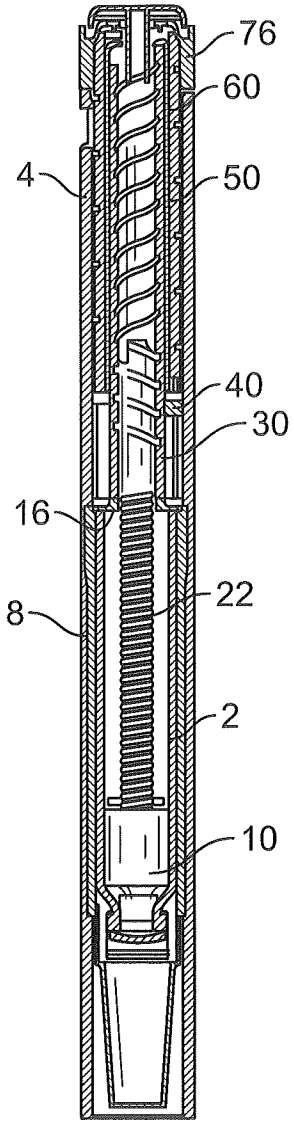

FIG. 5

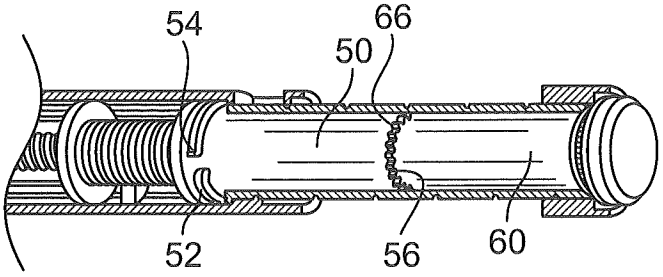

FIG. 6

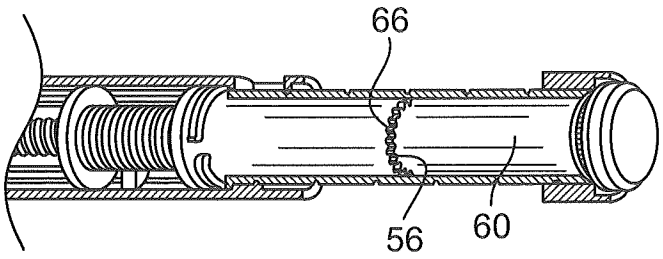

FIG. 7

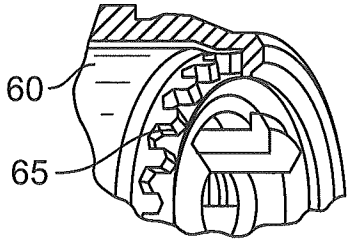

FIG. 8

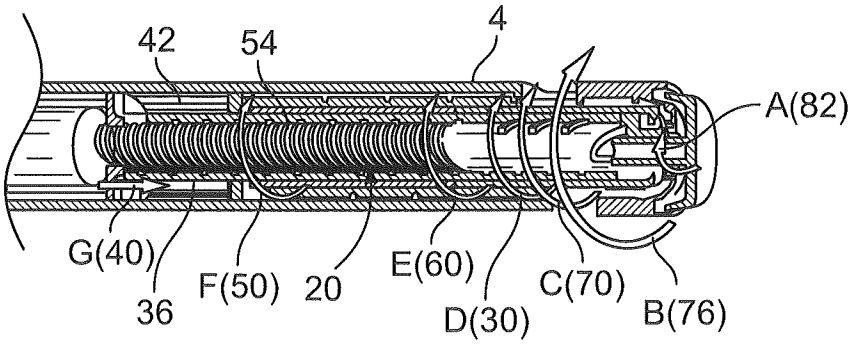

FIG. 9

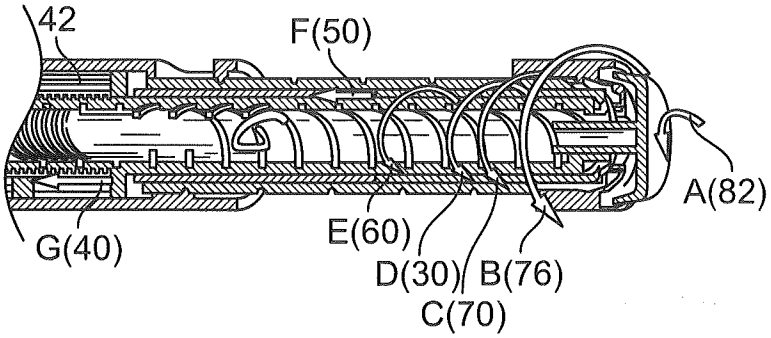

FIG. 10

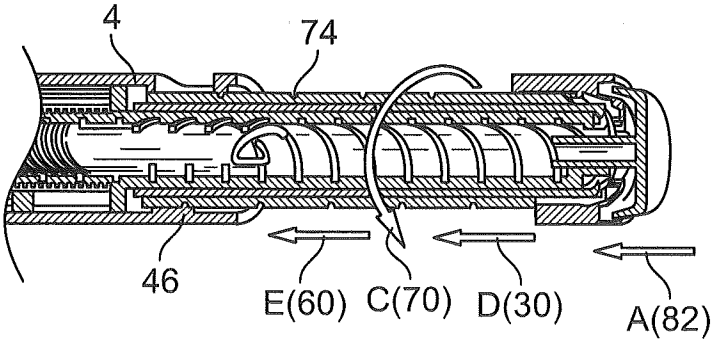

FIG. 11

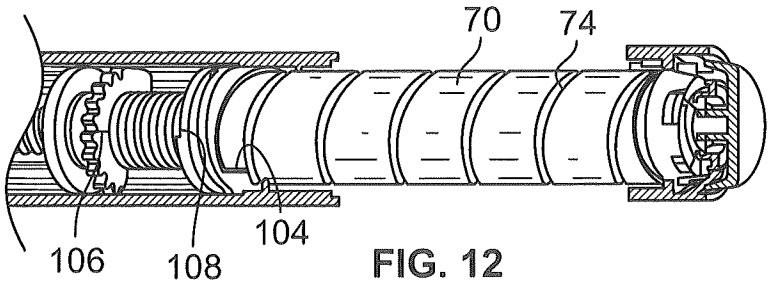

FIG. 12

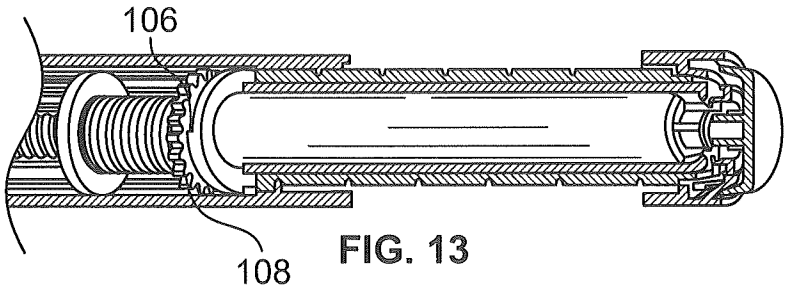

FIG. 13

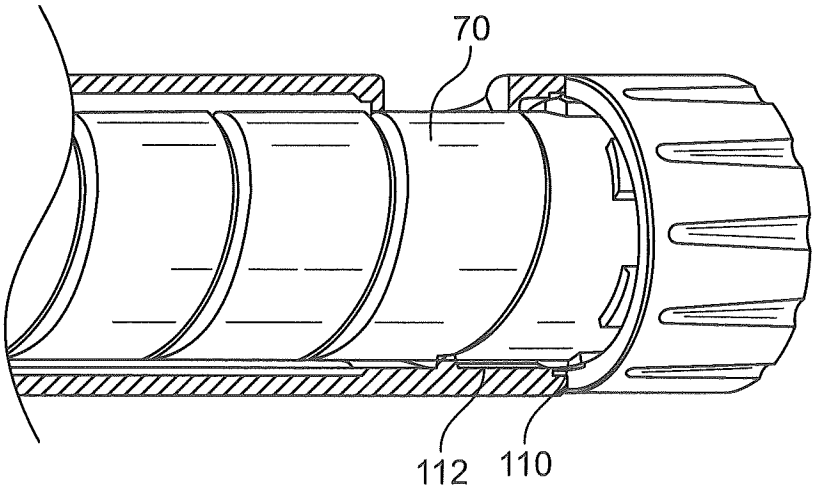

FIG. 14

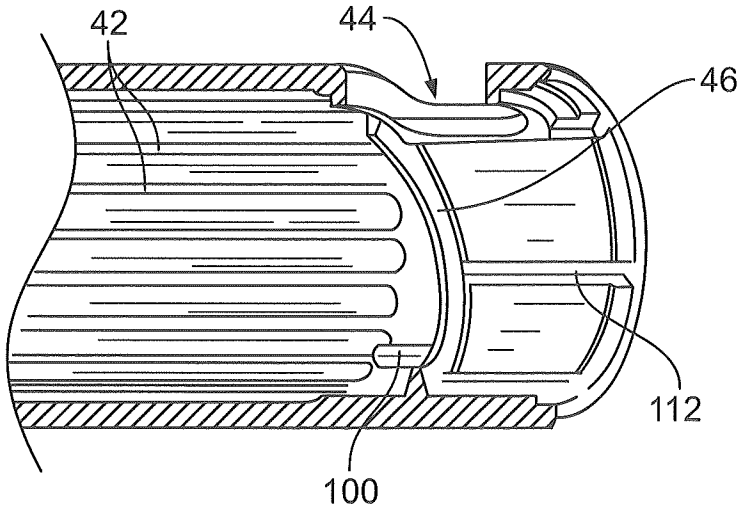

FIG. 15

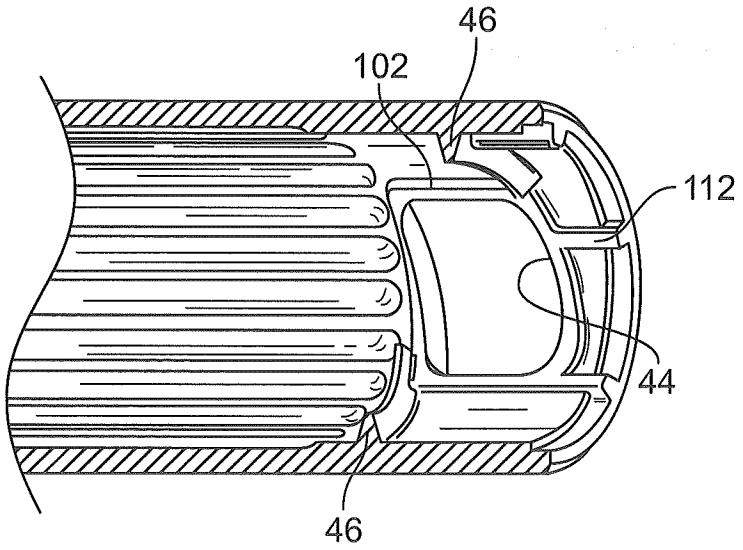

FIG. 16

PTO/SB/22 (09-11)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)	Docket Number (Optional) 10-1188-US-CON1
Application Number 12/944,544	Filed November 11, 2010
For Pen-Type Injector	
Art Unit 3767	Examiner Unassigned

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	$150	$75	$
☐ Two months (37 CFR 1.17(a)(2))	$560	$280	$
☒ Three months (37 CFR 1.17(a)(3))	$1270	$635	$ 1,270.00
☐ Four months (37 CFR 1.17(a)(4))	$1980	$990	$
☐ Five months (37 CFR 1.17(a)(5))	$2690	$1345	$

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☒ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 13-2490.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☒ attorney or agent of record. Registration Number 41,523

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____.

/Thomas E. Wettermann/ — Signature
December 21, 2011 — Date
Thomas E. Wettermann — Typed or printed name
312 913 2138 — Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). 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 6 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON1)

In re Application of:	)	
	)	
Robert Frederick Veasey et al.	)	
	)	Examiner: Unassigned
Serial No.: 12/944,544	)	
	)	Group Art Unit: 3767
Filed: November 11, 2010	)	
	)	Confirmation No.: 5949
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: December 21, 2011 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:	12944544
Filing Date:	11-Nov-2010
Title of Invention:	Pen-Type Injector
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Filer:	Thomas E. Wettermann
Attorney Docket Number:	10-1188-US-CON1

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:				
Extension - 3 months with $0 paid	1253	1	1270	1270

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**1270**

Electronic Acknowledgement Receipt

EFS ID:	11678485
Application Number:	12944544
International Application Number:	
Confirmation Number:	5949
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-CON1
Receipt Date:	21-DEC-2011
Filing Date:	11-NOV-2010
Time Stamp:	18:14:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1270
RAM confirmation Number	7951
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_CON1_Response_Transmittal_2011_12_21.pdf	140358 111498c02c73350e08beed9e1e977351b0258f06	no	1
Warnings:					
Information:					
2	Miscellaneous Incoming Letter	10_1188_US_CON1_Corrected_Papers_Response_2011_12_21.pdf	54494 6517f86eedf1c08baa7cc81388c27936b9a00a8f	no	1
Warnings:					
Information:					
3	Drawings-only black and white line drawings	10_1188_US_CON1_Replacement_Drawings_2011_12_21.pdf	518544 d9f42732e6294dba55d6309a8b5603c66fee577e	no	7
Warnings:					
Information:					
4	Extension of Time	10_1188_US_CON1_3Mo_Ext_Time_2011_12_21.pdf	112298 9745c57364a6bdc5903449b5b600cd4a06cb439a	no	1
Warnings:					
Information:					
5	Authorization for Extension of Time all replies	10_1188_US_CON1_General_Authorization_2011_12_21.pdf	58823 02e5a43202476683fc1937cdf68625b2ece1fa28	no	1
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	30279 da9e5bd7ddaf2f4cd0c20925c04eaa7adad15ce4	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	914796		

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	11

Application Number	12/944,544
Filing Date	November 11, 2010
First Named Inventor	Robert Frederick Veasey et al.
Art Unit	3352
Examiner Name	Unassigned
Attorney Docket Number	10-1188-US-CON1

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):
  Response to Notice to File Corrected Application Papers, Corrected Drawings 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	December 21, 2011	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	December 21, 2011

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 12/944,544

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	380
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	620
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	250
TOTAL CLAIMS (37 CFR 1.16(i))	61 minus 20 =	* 41			OR	x 60 =	2460
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*				x 250 =	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	3710

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
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) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
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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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/944,544	11/11/2010	3767	3352	10-1188-US-CON1	61	3

CONFIRMATION NO. 5949

UPDATED FILING RECEIPT

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

OC00000051711281

Date Mailed: 01/04/2012

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**

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: The patent practitioners associated with Customer Number 20306

Domestic Priority data as claimed by applicant

This application 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

Request to Retrieve - This application either claims priority to one or more applications filed in an intellectual property Office that participates in the Priority Document Exchange (PDX) program or contains a proper **Request to Retrieve Electronic Priority Application(s)** (PTO/SB/38 or its equivalent). Consequently, the USPTO will attempt to electronically retrieve these priority documents.

If Required, Foreign Filing License Granted: 11/23/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/944,544**

Projected Publication Date: 04/12/2012

Non-Publication Request: No

Early Publication Request: No

Title

Pen-Type Injector

Preliminary Class

604

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Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12944544
Filing Date	2010-11-11
First Named Inventor	Robert Frederick Veasey et al.
Art Unit	3763
Examiner Name	
Attorney Docket Number	10-1188-US-CON1

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	5626566		1997-05-06	Petersen et al.	

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

U.S.PATENT APPLICATION PUBLICATIONS Remove

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	

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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	0937471	EP	A2	1999-08-25	Becton, Dickinson and Company		☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12944544
	Filing Date	2010-11-11
	First Named Inventor	Robert Frederick Veasey et al.
	Art Unit	3763
	Examiner Name	
	Attorney Docket Number	10-1188-US-CON1

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		☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12944544
	Filing Date	2010-11-11
	First Named Inventor	Robert Frederick Veasey et al.
	Art Unit	3763
	Examiner Name	
	Attorney Docket Number	10-1188-US-CON1

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)	2012-01-20
Name/Print	Thomas E. Wettermann	Registration Number	41,523

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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.

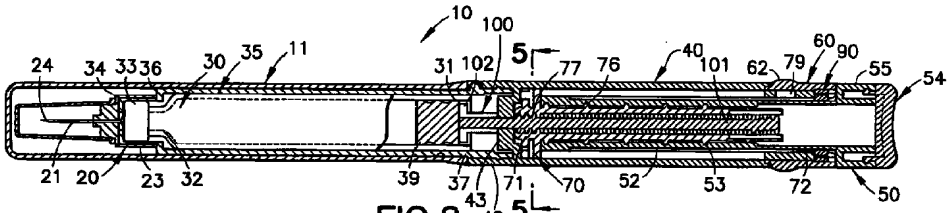

FIG.2

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.

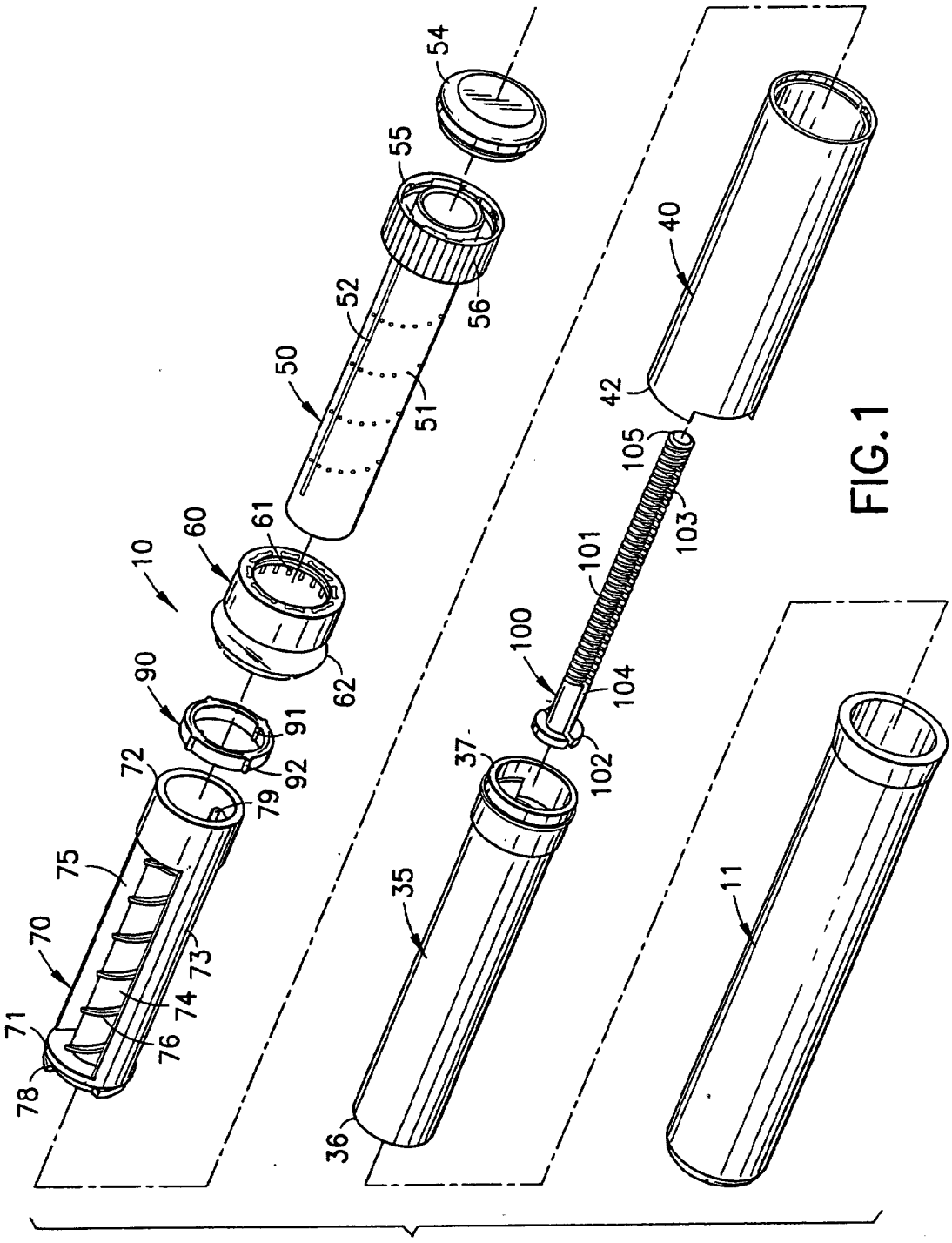

FIG.1

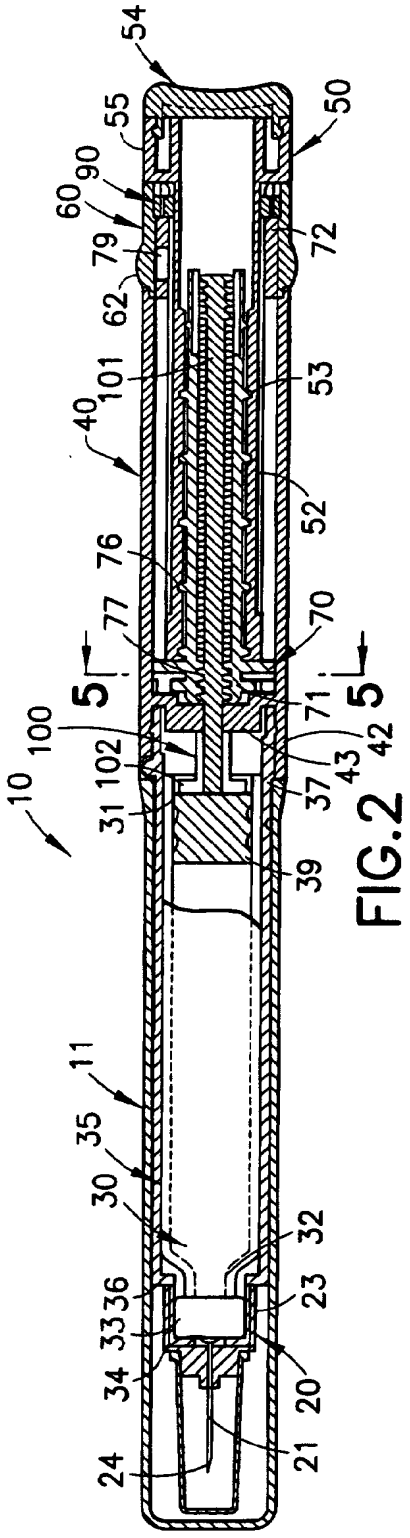

FIG.2

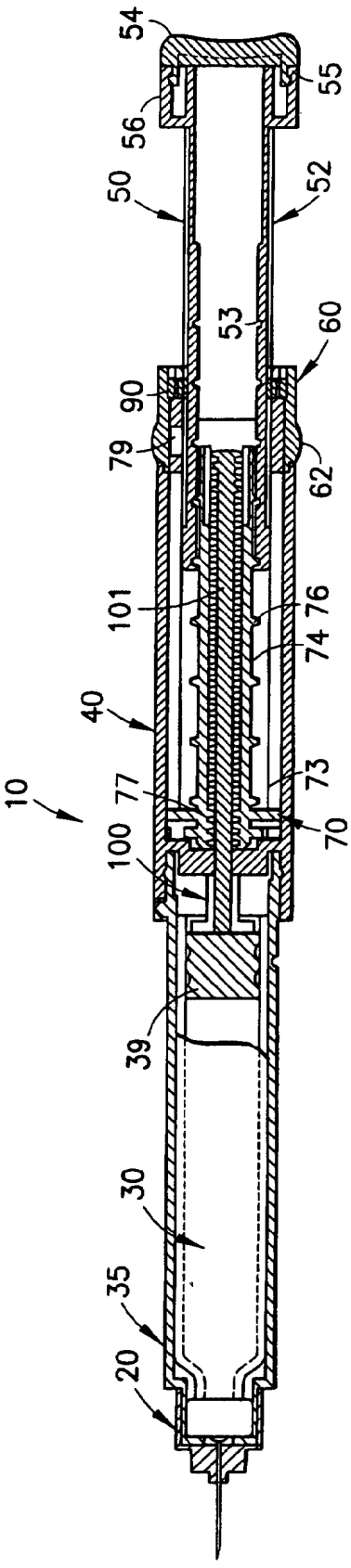

FIG.3

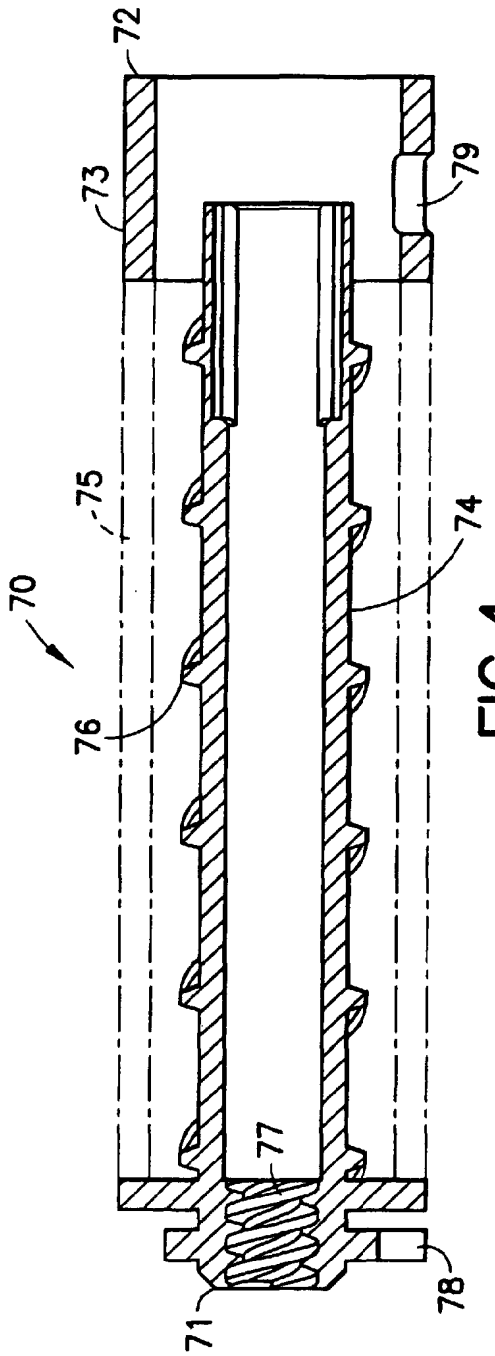

FIG.4

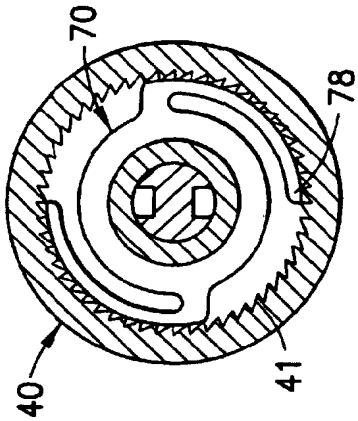

FIG.5

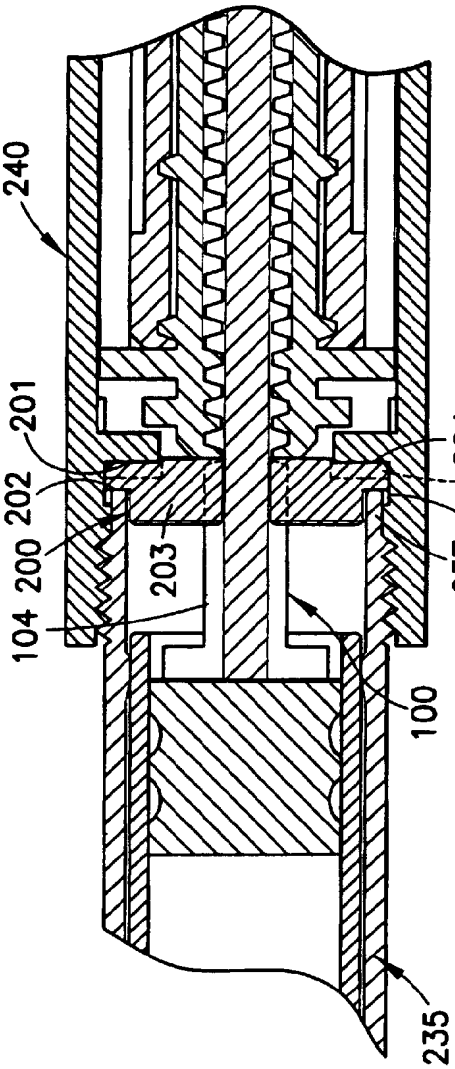

FIG.6

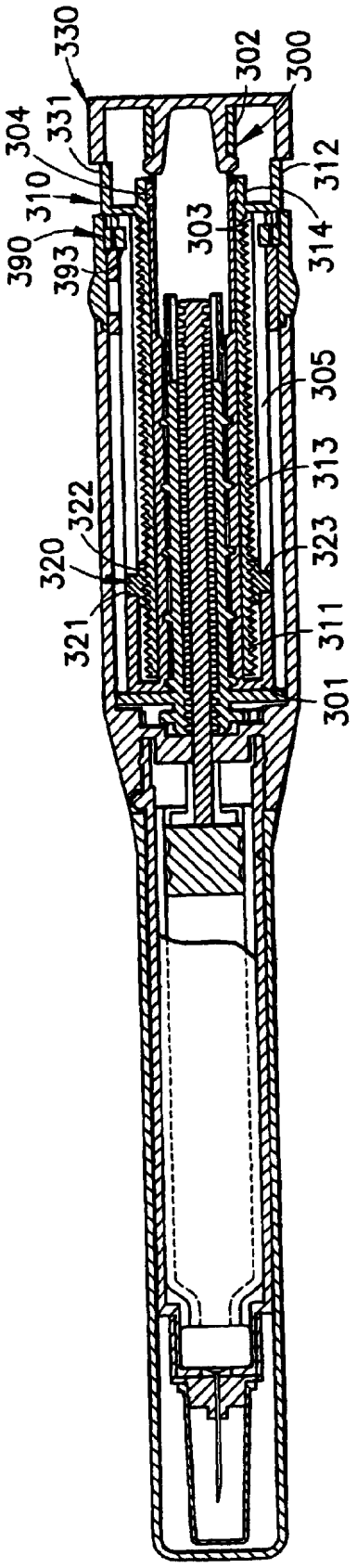

FIG.7

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON1)

In re Application of:	)	
	)	
Robert Frederick Veasey et al.	)	
	)	Examiner: Unassigned
Serial No.: 12/944,544	)	
	)	Group Art Unit: 3763
Filed: November 11, 2010	)	
	)	Confirmation No.: 5949
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: January 20, 2012

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

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312.913.0001

Electronic Acknowledgement Receipt

EFS ID:	11882006
Application Number:	12944544
International Application Number:	
Confirmation Number:	5949
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-CON1
Receipt Date:	20-JAN-2012
Filing Date:	11-NOV-2010
Time Stamp:	18:22:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

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_CON1_IDS_Transmittal_2012_01_20.pdf	140443 66afc602aa9da1fd2e3754a1a5931086196262e8	no	1

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	10_1188_US_CON1_IDS_2012_01_20.pdf	612300 f91cb6ff9dc77c74a36959af5821c81edc66c0bb	no	4
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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)

Application Number	12/944,544
Filing Date	November 11, 2010
First Named Inventor	Robert Frederick Veasey et al.
Art Unit	3763
Examiner Name	Unassigned
Total Number of Pages in This Submission	16
Attorney Docket Number	10-1188-US-CON1

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):
  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	January 20, 2012	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	January 20, 2012

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/944,544	11/11/2010	Robert Frederick Veasey	10-1188-US-CON1

CONFIRMATION NO. 5949

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

PUBLICATION NOTICE

OC00000053687151

Title: Pen-Type Injector

Publication No.US-2012-0089100-A1
Publication Date:04/12/2012

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.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12944544
Filing Date	2010-11-11
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	MENDEZ, MANUEL A
Attorney Docket Number	10-1188-US-CON1

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	5674204		1997-10-07	Chanoch	
	2	5688251		1997-11-18	Chanoch	
	3	6083197		2000-07-04	Umbaugh	
	4	6221046		2001-04-24	Burroughs, et al.	
	5	6899698		2005-05-31	Sams	

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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	20040059299		2004-03-25	Moller	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12944544
	Filing Date	2010-11-11
	First Named Inventor	Robert Frederick Veasey
	Art Unit	3763
	Examiner Name	MENDEZ, MANUEL A
	Attorney Docket Number	10-1188-US-CON1

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	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		1999-08-25	BECTON DICKINSON CO		☐
	2	91/14467	WO		1991-10-03	SAMS BERNARD		☐
	3	99/38554	WO		1999-08-05	NOVO NORDISK AS		☐

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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]
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Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12944544
	Filing Date	2010-11-11
	First Named Inventor	Robert Frederick Veasey
	Art Unit	3763
	Examiner Name	MENDEZ, MANUEL A
	Attorney Docket Number	10-1188-US-CON1

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)	2012-10-15
Name/Print	Thomas E. Wettermann	Registration Number	41523

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.**

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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.

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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 inspections or an issued patent.

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Electronic Acknowledgement Receipt

EFS ID:	13981779
Application Number:	12944544
International Application Number:	
Confirmation Number:	5949
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-CON1
Receipt Date:	17-OCT-2012
Filing Date:	11-NOV-2010
Time Stamp:	15:58:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	10-1188-US-CON1_Supp_IDS.pdf	612524 692d1091dcd41ad53c6d960ca3ffb7535f1d5fc5	no	4

Warnings:	
Information:	

2	Foreign Reference	EP0937476A2.pdf	421015 5c34134e0b35c9dbf01af4bdba9f434730ee0851	no	9
Warnings:					
Information:					
3	Foreign Reference	WO9114467A1.pdf	1212033 19d72d3e0ac8f33d0bf23fa8aa6fb9b6eb7b0f21	no	27
Warnings:					
Information:					
4	Foreign Reference	WO9938554A1.pdf	1423176 b40583b8fc8e8ab064417db16a7f745a2e9f436f	no	30
Warnings:					
Information:					
			Total Files Size (in bytes):	3668748	

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

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 10-1188-US-CON1)

In the Application of:	)	
	)	
Robert Frederick Veasey et al.	)	Examiner: Manuel A. MENDEZ
	)	
Serial No. 12/944,544	)	Group Art Unit: 3763
	)	
Filed: November 11, 2010	)	Confirmation No.: 5949
	)	
For: Pen-Type Injector	)	Customer No.: 20306

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

SUPPLEMENTAL PRELIMINARY AMENDMENT

Dear Sir:

Applicant submits the following supplemental preliminary amendment, and respectfully requests that it be entered prior to examination of this application.

Amendments to the claims begin on page 2.

Remarks begin of page 4.

General Authorization: Applicant generally authorizes the Office to charge any underpayment or credit any overpayment to Deposit Account No. 13-2490, and to treat any communication that requires an extension of time as incorporating a request for such an extension.

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE, 32ND FLOOR
CHICAGO, IL 60606
(312)913-0001

AMENDMENTS TO THE CLAIMS

1-14. (Canceled)

15. (Previously presented) 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.

16. (Canceled)

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HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE, 32ND FLOOR
CHICAGO, IL 60606
(312)913-0001

17. (Currently amended) The housing part of claim 15, further comprising

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, wherein during a dose setting step, said dose knob is rotated and moves away from said proximal end of said main housing so that a dose of said medicament contained within said medicament filled reservoir can be selected.

18. (Canceled)

19. (Currently amended) The housing part of claim [[18]]17, wherein said dose knob is operatively configured to said tubular clutch so that, during said dose setting step, said tubular clutch, said dose dial sleeve, and said dose knob rotate out of said proximal end of said main housing.

20-75. (Canceled)

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CHICAGO, IL 60606
(312)913-0001

REMARKS

Prior to examination of this application on the merits, entry of the above amendments to the specification and claims are requested.

In this supplemental preliminary amendment, Applicant has (i) amended claim 17 to include the features of claim 18, (ii) amended claim 19 to make it dependent on claim 17 rather than claim 18, and (iii) canceled claims 16, 18, and 20-75. As a result, claims 15, 17, and 19 are pending.

Applicant reserves the right to pursue in a continuation application the subject matter of any of the claims without the present amendments, and any other subject matter disclosed by this application.

If there are any matters that may be resolved or clarified through a telephone interview, the Examiner is respectfully requested to contact Applicant's undersigned representative at (312) 913-0001.

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff LLP

Date: April 16, 2013

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

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE, 32ND FLOOR
CHICAGO, IL 60606
(312)913-0001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON1)

In re Application of:	)	
	)	
Robert Frederick Veasey et al.	)	
	)	Examiner: Manual A. Mendez
Serial No.: 12/944,544	)	
	)	Group Art Unit: 3763
Filed: November 11, 2010	)	
	)	Confirmation No.: 5949
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: April 16, 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 Acknowledgement Receipt

EFS ID:	15532169
Application Number:	12944544
International Application Number:	
Confirmation Number:	5949
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-CON1
Receipt Date:	16-APR-2013
Filing Date:	11-NOV-2010
Time Stamp:	18:57:52
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

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_CON1_Supplemental_Prelim_Amendment_Transmittal_2013_04_16.pdf	140245 801b8908a7f3462d61cc4ef1d7d4da94c30609b6	no	1

Warnings:	
Information:	

2	Preliminary Amendment	10_1188_US_CON1_Supplemental_Preliminary_Amendment_2013_04_16.pdf	88516 5a107c6cc20b843ae6ab67c7bba74137a784fe68	no	4
Warnings:					
Information:					
3	Authorization for Extension of Time all replies	10_1188_US_CON1_General_Authorization_2013_04_16.pdf	58792 cb1fd3b3a0cd03f35cea1b1d2d8587424eff5ae1	no	1
Warnings:					
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		Total Files Size (in bytes):	287553		

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PTO/SB/21 (07-09)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

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Total Number of Pages in This Submission	6

Application Number	12/944,544
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First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	Manual A. Mendez
Attorney Docket Number	10-1188-US-CON1

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- ☐ 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):
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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	April 16, 2013	Reg. No.	41,523

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Signature	/Thomas E. Wettermann/		
Typed or printed name	Thomas E. Wettermann	Date	April 16, 2013

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/944,544	Filing Date 11/11/2010	☐ 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)		
	04/16/2013	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	* 3	Minus	** 20	= 0	X $80 =	0
AMENDMENT	Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $420 =	0
AMENDMENT	☐ Application Size Fee (37 CFR 1.16(s))						
AMENDMENT	☐ 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 $ =	
AMENDMENT	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
AMENDMENT	☐ Application Size Fee (37 CFR 1.16(s))						
AMENDMENT	☐ 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
/VICTORIA BROWN/

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/944,544	11/11/2010	Robert Frederick Veasey	10-1188-US-CON1	5949

20306 7590 08/30/2013

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
08/30/2013	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. 12/944,544	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 *4/16/2013*.

☐ 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) *15,17 and 19* 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) *15, 17, and 19* 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 *11/11/2010* 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 *10/17/2012 and 1/20/2012*.

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

4) ☐ Other: _____.

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 15, 17, and 19 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.

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 6 of claim 15 appears to have no support in the specification.

The specification also fails to disclose the term “driver” referring to the "driver extending along a portion of the piston rod" disclosed in line 9 of claim 15. 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 15, 17, and 19 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 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 job", 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 15, 17, and 19 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 7,918,833. 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.

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. 12/944,544	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	12944544
Filing Date	2010-11-11
First Named Inventor	Robert Frederick Veasey et al.
Art Unit	3763
Examiner Name	
Attorney Docket Number	10-1188-US-CON1

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	5626566		1997-05-06	Petersen et al.	

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

U.S.PATENT APPLICATION PUBLICATIONS Remove

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	

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	0937471	EP	A2	1999-08-25	Becton, Dickinson and Company		☐

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

NON-PATENT LITERATURE DOCUMENTS Remove

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

Receipt date: 01/20/2012	Application Number	12944544 12944544 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2010-11-11
	First Named Inventor	Robert Frederick Veasey et al.
	Art Unit	3763
	Examiner Name	
	Attorney Docket Number	10-1188-US-CON1

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	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.

Receipt date: 01/20/2012	Application Number	12944544 12944544 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	2010-11-11
	First Named Inventor	Robert Frederick Veasey et al.
	Art Unit	3763
	Examiner Name	
	Attorney Docket Number	10-1188-US-CON1

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)	2012-01-20
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./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12944544
Filing Date	2010-11-11
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	MENDEZ, MANUEL A
Attorney Docket Number	10-1188-US-CON1

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	5674204		1997-10-07	Chanoch	
	2	5688251		1997-11-18	Chanoch	
	3	6083197		2000-07-04	Umbaugh	
	4	6221046		2001-04-24	Burroughs, et al.	
	5	6899698		2005-05-31	Sams	

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

U.S.PATENT APPLICATION PUBLICATIONS Remove

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	20040059299		2004-03-25	Moller	

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

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

Receipt date: 10/17/2012

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12944544 12944544 - GAU: 3763
Filing Date	2010-11-11
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	MENDEZ, MANUEL A
Attorney Docket Number	10-1188-US-CON1

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	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		1999-08-25	BECTON DICKINSON CO		☐
	2	91/14467	WO		1991-10-03	SAMS BERNARD		☐
	3	99/38554	WO		1999-08-05	NOVO NORDISK AS		☐

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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	08/25/2013

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Receipt date: 10/17/2012	Application Number	12944544 12944544 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	2010-11-11
	First Named Inventor	Robert Frederick Veasey
	Art Unit	3763
	Examiner Name	MENDEZ, MANUEL A
	Attorney Docket Number	10-1188-US-CON1

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Signature	/Thomas E. Wettermann/	Date (YYYY-MM-DD)	2012-10-15
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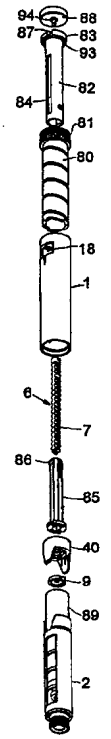
(54) Title: AN INJECTION SYRINGE

(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.

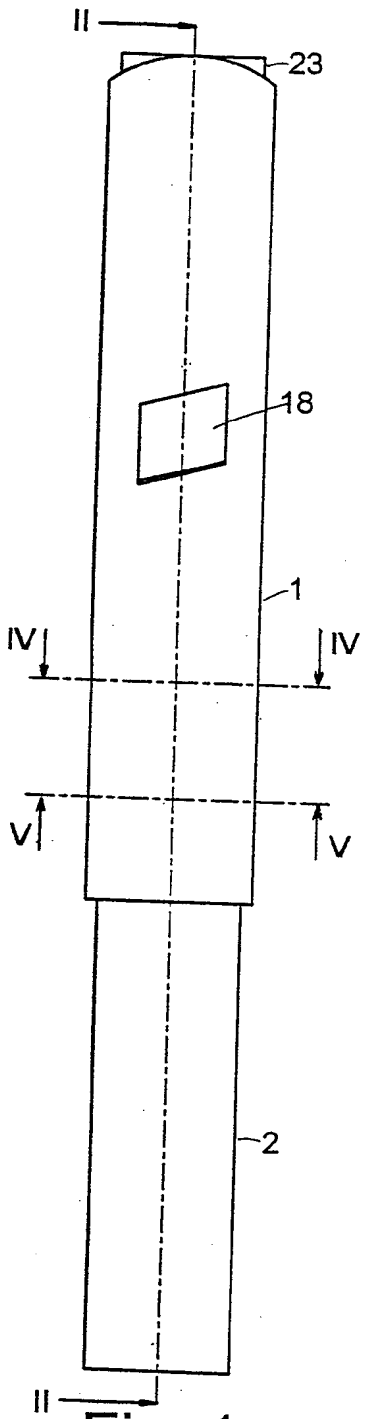

Fig. 1

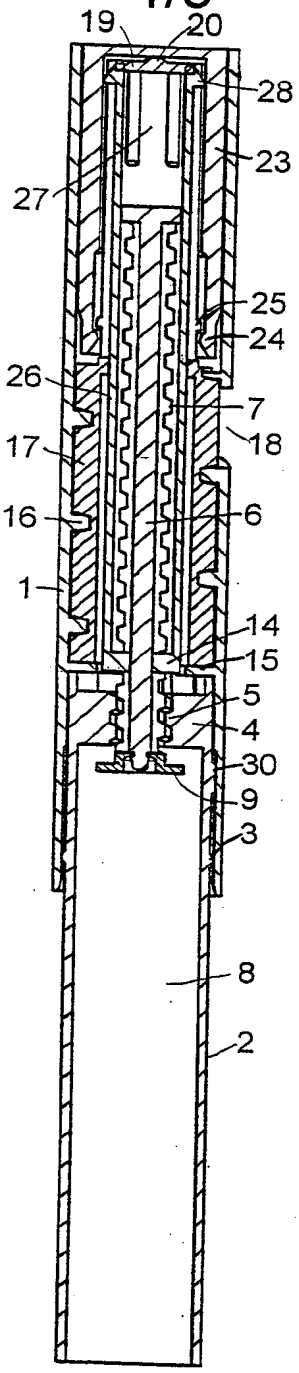

Fig.2

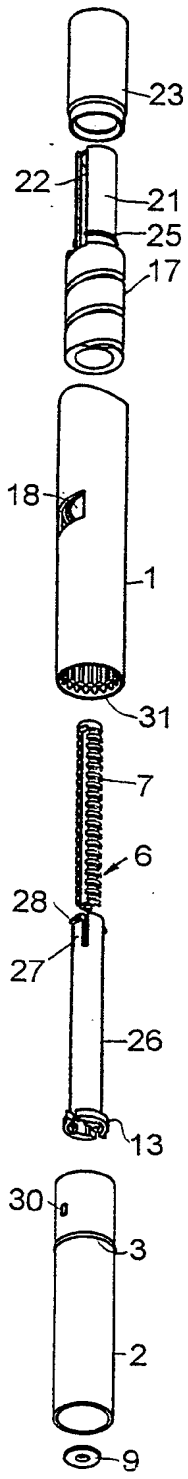

Fig.3

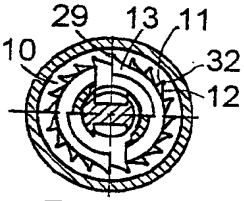

Fig.4

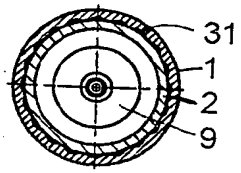

Fig. 5

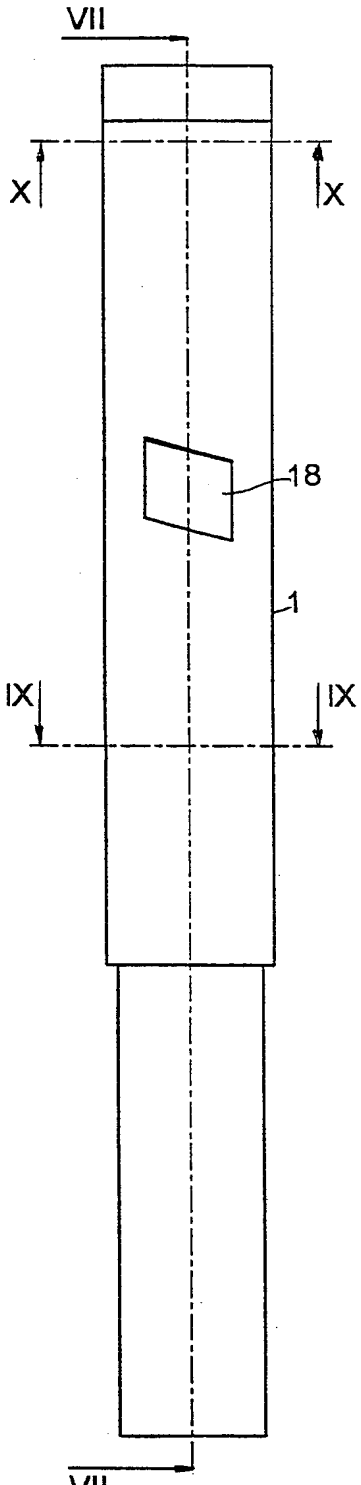

Fig. 6

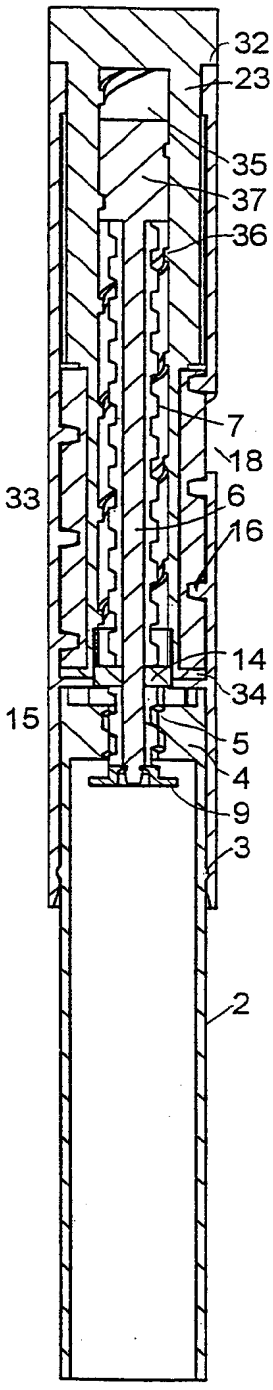

Fig. 7

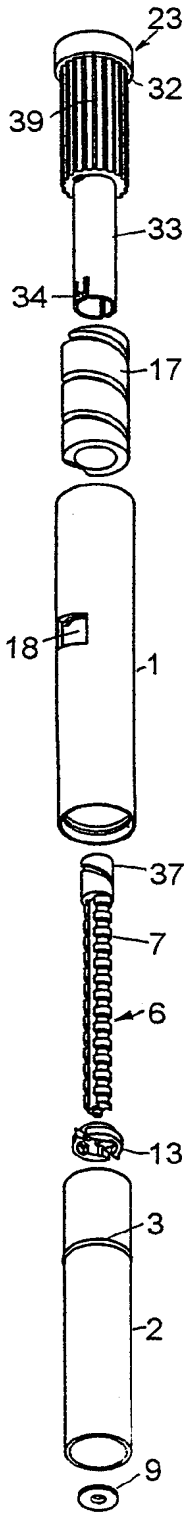

Fig.8

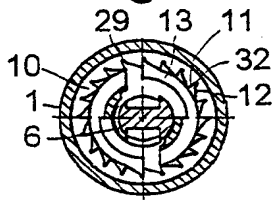

Fig. 9

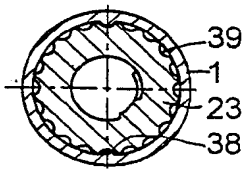

Fig.10

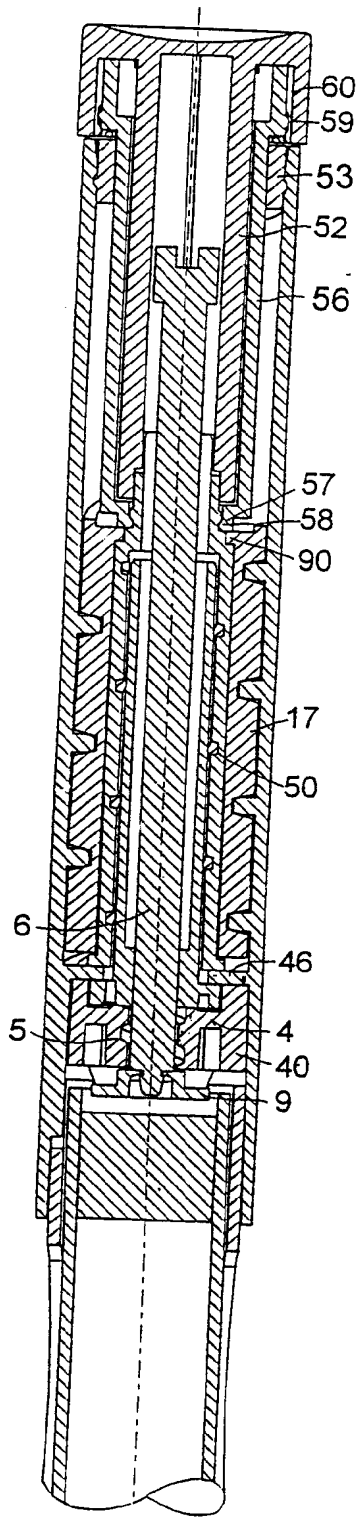

Fig. 11

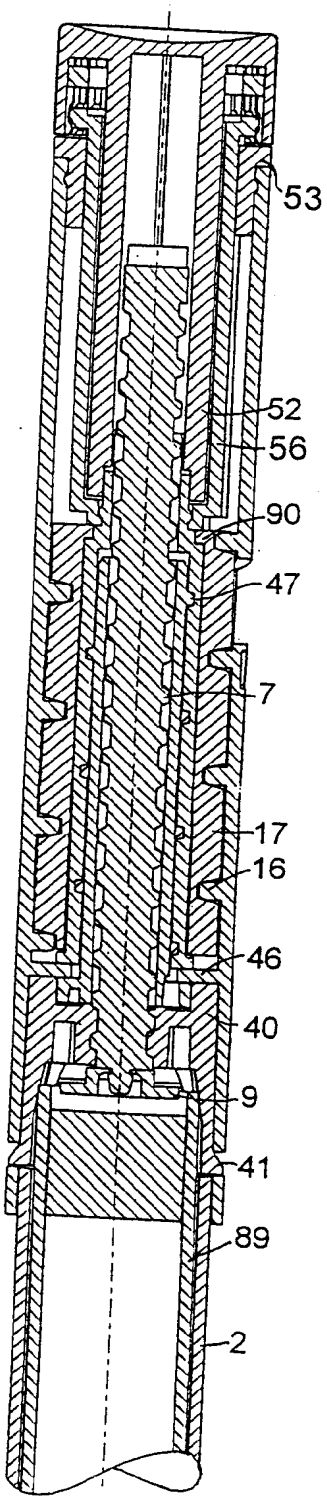

Fig. 12

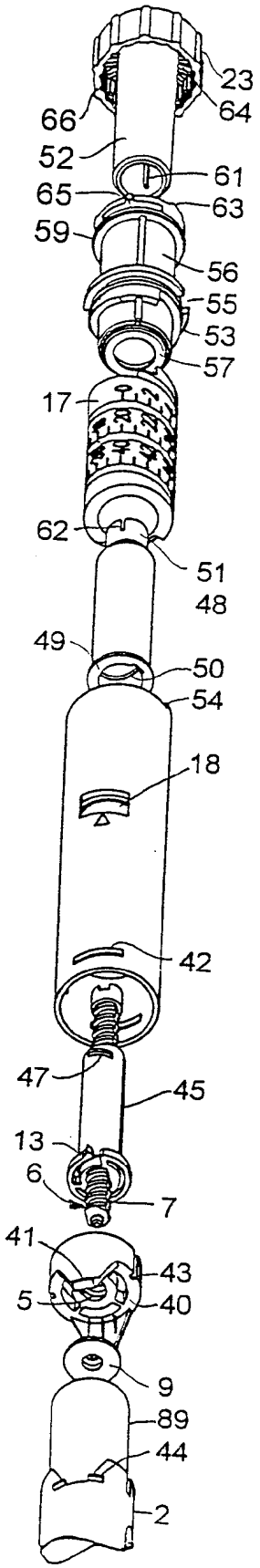

Fig. 13

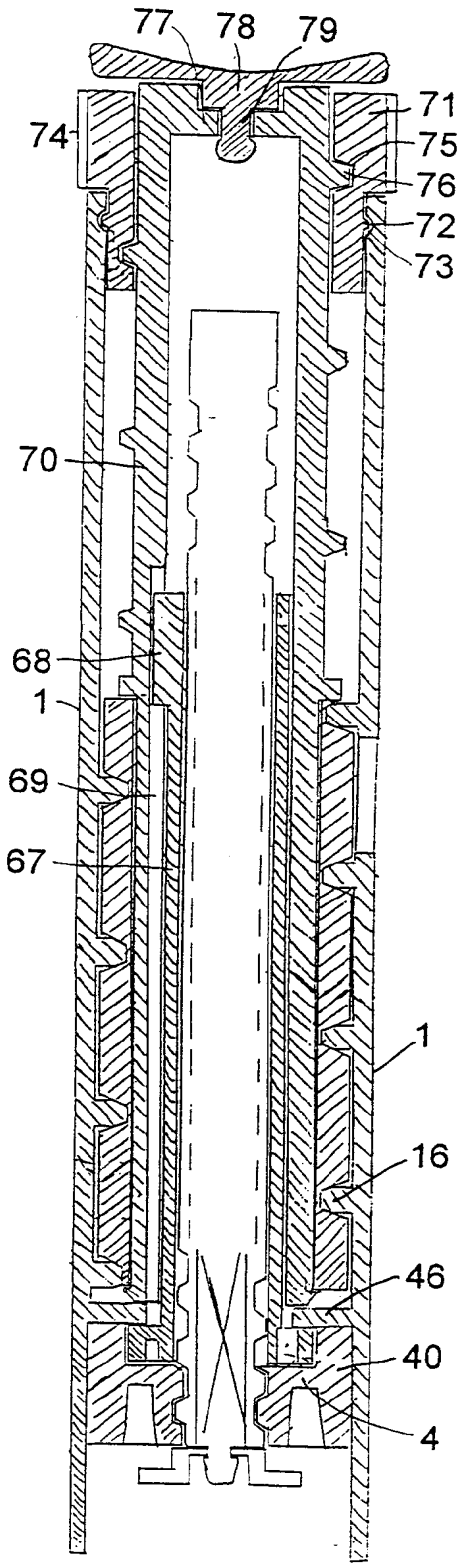

Fig. 14

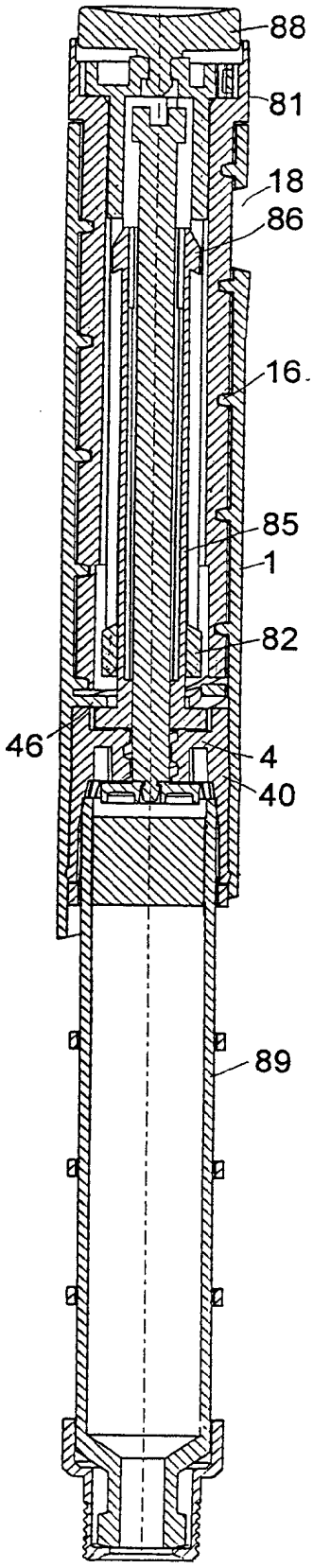

Fig. 15

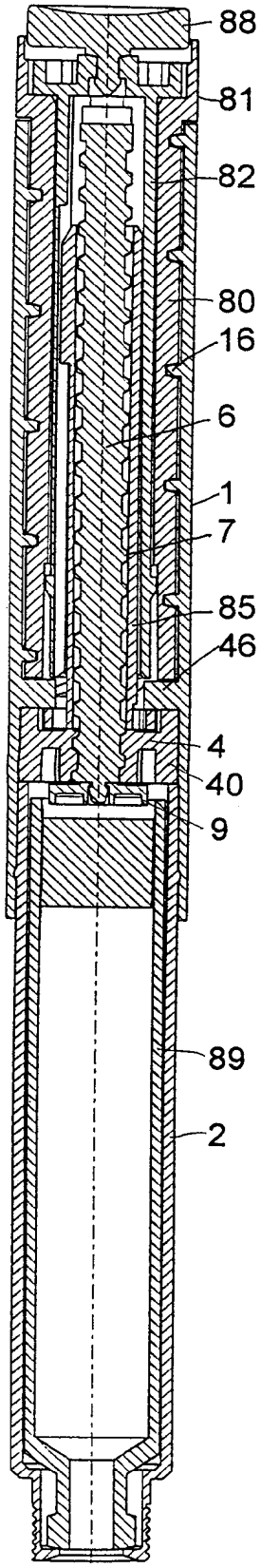

Fig.16

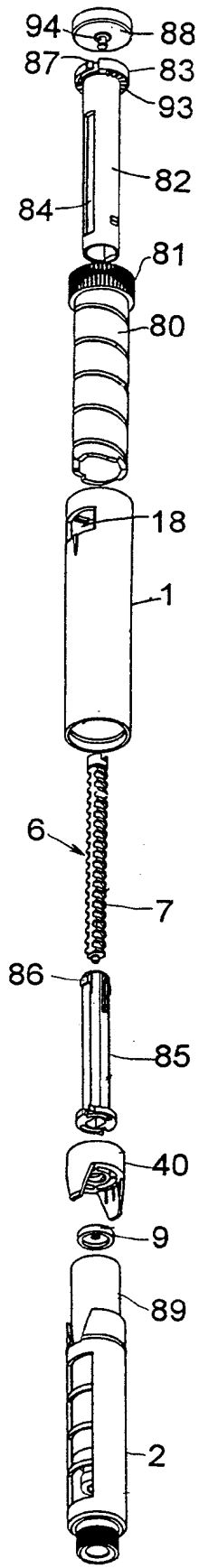

Fig. 17

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

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5674204 A	07/10/97	EP 0861101 A	02/09/98
		WO 9710865 A	27/03/97
WO 9307922 A1	29/04/93	AT 160946 T	15/12/97
		AU 662021 B	17/08/95
		AU 2795192 A	21/05/93
		CA 2119913 A	29/04/93
		DE 69223521 D,T	18/06/98
		EP 0608343 A,B	03/08/94
		SE 0608343 T3	
		ES 2112915 T	16/04/98
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		JP 7500039 T	05/01/95
		RU 2091087 C	27/09/97
		US 5626566 A	06/05/97
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		AT 74777 T	15/05/92
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		CS 8900905 A	16/12/92
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		RU 2053798 C	10/02/96
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		SK 278253 B	05/06/96
		US 4973318 A	27/11/90
		WO 8907463 A	24/08/89
		YU 31589 A	30/06/91

INTERNATIONAL SEARCH REPORT
Information on patent family members

01/06/99

International application No.
PCT/DK 99/00042

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0450905 A1	09/10/91	SE 0450905 T3	
		AT 129162 T	15/11/95
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		AU 7402691 A	10/10/91
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		ES 2079565 T	16/01/96
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		IE 69664 B	02/10/96
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		JP 4224764 A	14/08/92
		JP 6006159 B	26/01/94
		KR 9600846 B	13/01/96
		MX 173301 B	14/02/94
		NO 300306 B	12/05/97
		NZ 237622 A	25/02/94
		PT 97248 A,B	31/01/92
		RU 2033193 C	20/04/95
		US 5226896 A	13/07/93
		US 5295976 A	22/03/94

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON1)

In re Application of:	)	
	)	
Robert Frederick Veasey et al.	)	
	)	Examiner: Mendez, Manuel A.
Serial No.: 12/944,544	)	
	)	Group Art Unit: 3763
Filed: November 11, 2010	)	
	)	Confirmation No.: 5949
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
Chicago, Illinois 60606
312.913.0001

Electronic Patent Application Fee Transmittal

Application Number:	12944544
Filing Date:	11-Nov-2010
Title of Invention:	Pen-Type Injector
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Filer:	Thomas E. Wettermann
Attorney Docket Number:	10-1188-US-CON1

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:	16731839
Application Number:	12944544
International Application Number:	
Confirmation Number:	5949
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-CON1
Receipt Date:	31-AUG-2013
Filing Date:	11-NOV-2010
Time Stamp:	16:18:52
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	8194
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_CON1_Supplemental_IDS_Transmittal_2013_08_30.pdf	140338 fd17d695bca5ba46b60e6b76f5df30186613eb8a	no	1
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	10_1188_US_CON1_Supplemental_IDS_2013_08_30.pdf	612508 202357856db73c94bec032d277f7539bb55f2b53	no	4
Warnings:					
Information:					
3	Foreign Reference	10_1188_US_CON1_Foreign_Ref_1.pdf	1419669 75943f9b2c2d6321d26b15381a71b41e81e4b022	no	30
Warnings:					
Information:					
4	Authorization for Extension of Time all replies	10_1188_US_CON1_General_Authorization_2013_08_30.pdf	58797 8c2a86a625c4c224563be074b5c3a55ca3e340b3	no	1
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30226 cafc80d9d8d128735e56ff4e623acb84e2b55241	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2261538		

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	12/944,544
Filing Date	November 11, 2010
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	Mendez, Manuel A.
Attorney Docket Number	10-1188-US-CON1

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ 2nd 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)
- ☐ 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):
  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

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	August 30, 2013

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No.: 10-1188-US-CON1)

In the Application of:	)	
	)	
Robert Frederick Veasey et al.	)	Examiner: Manuel A. Mendez
	)	
Serial No. 12/944,544	)	Group Art Unit: 3763
	)	
Filed: November 11, 2010	)	Confirmation No.: 5949
	)	
For: Pen-Type Injector	)	

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

RESPONSE TO THE OFFICE ACTION MAILED AUGUST 30, 2013

Dear Sir:

This paper is submitted in response to the Office Action mailed August 30, 2013. Please enter the following remarks and amendments into the record for this application.

Also enclosed is a Petition for Extension of Time under 37 C.F.R. § 1.136(a) (1 Month), along with requisite fees.

Amendments to the Claims are reflected in the listing of claims that begins on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.

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AMENDMENTS

IN THE CLAIMS

1-14. (canceled)

15. (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 dial grip~~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 drive~~r~~ sleeve extending along a portion of said piston rod, said drive~~r~~ sleeve comprising an internal threading near a distal portion of said drive~~r~~ 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 dial grip~~knob~~, said tubular clutch operatively coupled to said dose dial grip~~knob~~,

wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

16. (canceled)

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17. (currently amended) The housing part of claim 15, further comprising

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 at a proximal end and an outlet at a distal end,

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, wherein during a dose setting step, said dose dial grip~~knob~~ is rotated and moves away from said proximal end of said main housing so that a dose of ~~said~~ a medicament contained within said medicament filled reservoir can be selected.

18. (canceled)

19. (currently amended) The housing part of claim 17, wherein said dose dial grip~~knob~~ is operatively configured to said tubular clutch so that, during said dose setting step, said tubular clutch, said dose dial sleeve, and said dose dial grip~~knob rotate out of said proximal end of~~ rotate and move in a proximal direction in relation to said main housing.

20-75. (canceled)

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REMARKS

The Examiner has objected to claims 15, 17, and 19 under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as allegedly failing to comply with the written description requirement. Specifically, with respect to claims 15, 17, and 19, 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 30, 2013 Office Action, Page 2. 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. No new matter has been added.

In addition, the Examiner states that the specification as filed fails to disclose the term "driver." August 30, 2013 Office Action, Page 2. Applicants replaced the 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. No new matter has been added.

Applicants have also replaced the term "container housing" in claim 17 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. A similar claim clarification was made in Applicants' corresponding application S/N: 13/909,649, herein entirely incorporated by reference.

Applicants have replaced the term "plunger" in with the term "cartridge piston" in claim 17. 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 Again, a similar claim clarification was made in Applicants' corresponding application S/N: 13/909,649, herein entirely incorporated by reference.

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In addition, claims 15, 17 and 19 stand rejected on the ground of nonstatutory double patenting over claims of 1-14 of US Patent No. 7,918,833. 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 30, 2013 Office Action, Page 5. It is Applicants' present position 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 claim 15 and therefore traverses these rejections.

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.

As just one example, Applicants' presently pending independent claim 15 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 dial grip;

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- the tubular clutch located adjacent a distal end of the dose dial grip, the tubular clutch operatively coupled to the dose dial grip; and
- a dose dial sleeve that extends circumferentially around at least a portion of the tubular clutch.

As such, pending claim 15 is neither anticipated nor rendered obvious by any of the claim of the 7,918,833 Patent and that this double patenting rejection should be withdrawn.

With respect to the prior art rejections, the Examiner has rejected all pending claims 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. In particular, the present invention relates to such injectors where a user may set the dose. Applicants' Specification, Page 1 Lines 14-17.

With respect to the present rejections in view of Walters 471, Applicants initially note that this reference 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 "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 amended claim 1 slightly as follows: "dose dial sleeve . . . comprising a helical groove configured to engage a threading provided by said main housing, <u>said helical groove provided along an outer surface of said dose dial sleeve</u>." Support for this limitation may be found throughout Applicants' specification as filed, including Page 8, Lines23-25.

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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 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." 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 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 15, 17 and 19, 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.

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Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff LLP

Date: December 27, 2013

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

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PTO/AIA/22 (03-13)
Approved for use through 7/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): 10-1188-US-CON1`

Application Number: 12/944,544

Filed: November 11, 2010

For: Pen-Type Injector

Art Unit: 3763

Examiner: Mendez, Manuel A.

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	Micro Entity Fee	
☑ One month (37 CFR 1.17(a)(1))	$200	$100	$50	$ 200.00
☐ Two months (37 CFR 1.17(a)(2))	$600	$300	$150	$
☐ Three months (37 CFR 1.17(a)(3))	$1,400	$700	$350	$
☐ Four months (37 CFR 1.17(a)(4))	$2,200	$1,100	$550	$
☐ Five months (37 CFR 1.17(a)(5))	$3,000	$1,500	$750	$

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☑ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 13-2490.

☑ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 41,523.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Thomas E. Wettermann/
Signature

December 27, 2013
Date

Thomas E. Wettermann
Typed or printed name

41,523
Telephone Number

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

☑ * Total of 1 forms are submitted.

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:

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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.
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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON1)

In re Application of:	)	
	)	
Robert Frederick Veasey et al.	)	
	)	Examiner: Mendez, Manuel A.
Serial No.: 12/944,544	)	
	)	Group Art Unit: 3763
Filed: November 11, 2010	)	
	)	Confirmation No.: 5949
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: December 27, 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:	12944544
Filing Date:	11-Nov-2010
Title of Invention:	Pen-Type Injector
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Filer:	Thomas E. Wettermann
Attorney Docket Number:	10-1188-US-CON1

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:				
Extension - 1 month with $0 paid	1251	1	200	200

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**200**

Electronic Acknowledgement Receipt

EFS ID:	17766072
Application Number:	12944544
International Application Number:	
Confirmation Number:	5949
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-CON1
Receipt Date:	27-DEC-2013
Filing Date:	11-NOV-2010
Time Stamp:	12:57:16
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$200
RAM confirmation Number	7047
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_CON1_OA_Transmittal_2013_12_27.pdf	140268 bb2e3fec12b13e4e055c625a5dbeadfe7a054832	no	1
Warnings:					
Information:					
2	Amendment Copy Claims/Response to Suggested Claims	10_1188_US_CON1_OA_Response_2013_12_27.pdf	134417 246bcb5fe6b5c7a7de28f77a1fde2d02985797c6	no	8
Warnings:					
Information:					
3	Extension of Time	10_1188_US_CON1_1Mo_Ext_Time_2013_12_27.pdf	163423 9637fb3aeb9bd119c7ec31e802a03dc1b0e4479e	no	2
Warnings:					
Information:					
4	Authorization for Extension of Time all replies	10_1188_US_CON1_General_Authorization_2013_12_27.pdf	58794 3bd109e7b06c23e6db88f646b29526b960e8095f	no	1
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30121 bc58aac0c384b9cd51fc54aea265b49f49be011b	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	527023		

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.

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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.

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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	12/944,544
Filing Date	November 11, 2010
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	Mendez, Manuel A.
Attorney Docket Number	10-1188-US-CON1

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):
  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	December 27, 2013	Reg. No.	41,523

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Signature	/Thomas E. Wettermann/		
Typed or printed name	Thomas E. Wettermann	Date	December 27, 2013

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/944,544	Filing Date 11/11/2010	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) 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

AMENDMENT **12/27/2013**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 3	Minus	** 20	= 0	X $80 =	0
Independent (37 CFR 1.16(h))	* 1	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

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
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
/DEBRA SAVOY/

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NOTICE OF ALLOWANCE AND FEE(S) DUE

20306 7590 01/16/2014

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: 01/16/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/944,544	11/11/2010	Robert Frederick Veasey	10-1188-US-CON1	5949

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	$960	$0	$0	$960	04/16/2014

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 01/16/2014
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.
12/944,544	11/11/2010	Robert Frederick Veasey	10-1188-US-CON1	5949

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	$960	$0	$0	$960	04/16/2014

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 credits 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 forms 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: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

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.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/944,544	11/11/2010	Robert Frederick Veasey	10-1188-US-CON1	5949

20306 7590 01/16/2014

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: 01/16/2014

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 272 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 272 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.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B 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.

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.

Notice of Allowability	Application No. 12/944,544	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 12/27/2013*.
   ☐ 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 *15, 17, and 19*. 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. *10/790,225* .
   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 MENDEZ/
Primary Examiner, Art Unit 3763

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 12/27/2013. The examiner concurs with the arguments presented on pages 1-7 of the Remarks, and therefore, claims 15, 17, and 19 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 MENDEZ/

Primary Examiner, Art Unit 3763

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	12944544
Filing Date	2010-11-11
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	Mendez, Manuel A.
Attorney Docket Number	10-1188-US-CON1

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	

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

Receipt date: 08/31/2013	Application Number	12944544	12944544 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2010-11-11	
	First Named Inventor	Robert Frederick Veasey	
	Art Unit	3763	
	Examiner Name	Mendez, Manuel A.	
	Attorney Docket Number	10-1188-US-CON1	

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
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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	01/09/2014

*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	12944544 12944544 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2010-11-11
	First Named Inventor	Robert Frederick Veasey
	Art Unit	3763
	Examiner Name	Mendez, Manuel A.
	Attorney Docket Number	10-1188-US-CON1

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.**

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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.

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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).

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.

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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.

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 01/16/2014
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)
January 28, 2014	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/944,544	11/11/2010	Robert Frederick Veasey	10-1188-US-CON1	5949

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	$960	$0	$0	$960	04/16/2014

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: DCA Design International, LTD.
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Warwick, UNITED KINGDOM

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 credits 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 forms 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: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Thomas E. Wettermann/ Date January 28, 2014
Typed or printed name Thomas E. Wettermann Registration No. 41,523

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON1)

In re Application of:	)	
	)	
Robert Frederick Veasey et al.	)	
	)	Group Art Unit: 3763
Serial No.: 12-944,544	)	
	)	Examiner: Mendez, Manuel A.
Filed: November 11, 2010	)	
	)	Confirmation No.: 5949
For: Pen-Type Injector	)	

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 January 16, 2014, 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: January 28, 2014 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-CON1)

In re Application of:	)	
	)	
Robert Frederick Veasey et al.	)	
	)	Examiner: Mendez, Manuel A.
Serial No.: 12-944,544	)	
	)	Group Art Unit: 3763
Filed: November 11, 2010	)	
	)	Confirmation No.: 5949
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: January 28, 2014

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:	12944544
Filing Date:	11-Nov-2010
Title of Invention:	PEN-TYPE INJECTOR
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Filer:	Thomas E. Wettermann
Attorney Docket Number:	10-1188-US-CON1

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	960	960
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**960**

Electronic Acknowledgement Receipt

EFS ID:	18044834
Application Number:	12944544
International Application Number:	
Confirmation Number:	5949
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-CON1
Receipt Date:	28-JAN-2014
Filing Date:	11-NOV-2010
Time Stamp:	13:44:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$960
RAM confirmation Number	14808
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_CON1_Issue_Fee_Transmittal_2014_01_28.pdf	140472 26d82cd0ae02afba740ac188e9cb6fbfb045da16	no	1
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	10_1188_US_CON1_Issue_Fee_2014_01_28.pdf	1597082 cd42a74b53e10ff44435d5fe98b487ca6756f8c3	no	1
Warnings:					
Information:					
3	Miscellaneous Incoming Letter	10_1188_US_CON1_Comments_Statement_Reasons_Allowance_2014_01_28.pdf	53018 751d5464a7ff12e3beb636f654a477c9d6e15fac	no	2
Warnings:					
Information:					
4	Authorization for Extension of Time all replies	10_1188_US_CON1_General_Authorization_2014_01_28.pdf	59372 674bac7ebc40f0cb12d7501bfa2669a572410813	no	1
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30277 5808a8302fab3f513f59cad1286f0e59800dde1a	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1880221		

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)

Application Number	10-1188-US-CON1
Filing Date	November 11, 2010
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	Mendez, Manuel A.
Attorney Docket Number	10-1188-US-CON1

Total Number of Pages in This Submission

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	January 28, 2014	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	January 28, 2014

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.
12/944,544	03/25/2014	8679069	10-1188-US-CON1	5949

20306 7590 03/05/2014

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 406 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;

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(10-1188-US-CON1)

Applicant:	Robert Frederick Veasey, *et al.*
Patent No.:	8,679,069
Issued:	March 25, 2014
Title:	PEN-TYPE INJECTOR
Art Unit:	3763
Confirmation No.:	5949
Examiner:	MENDEZ, MANUEL A.

ATTN: Certificate of Corrections Branch
Commissioner for Patents
P.O. Box 1450
Alexandria Virginia 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION

Sir:

The patentee hereby requests issuance of a certificate of correction pursuant to 35 U.S.C §3.81 and 37 C.F.R. § 1.323 for the above patent. The certificate is needed to correct an error on the cover page of the patent in the name of the assignee. The patent incorrectly states **DCA DESIGN INTERNATIONAL LTD.** as the assignee. The correct assignee, however, is **SANOFI-AVENTIS DEUTSCHLAND GMBH.** The Assignment from DCA Design International Ltd. To Sanofi-Aventis Deutschland GmbH was recorded pursuant to 37 C.F.R. § 3.11 before issuance of the '069 patent and can be found at Reel/Frame 026978 / 0938. The error is due to a mistake of the Applicant, and correctable under 37 C.F.R. § 1.323 and 35 U.S.C. §3.81.

McDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 South Wacker Drive
Chicago, IL 60606
Telephone: 312-913-0001
Facsimile: 312-913-0002

A PTO/SB/44 form for the certificate of correction is attached. All fees associated with this submission have been paid through the electronic filing process. However, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment to Deposit Account No. 13-2490.

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) 913-2143.

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff LLP

Date: April 18, 2014

By: /David M. Frischkorn/
David M. Frischkorn
Reg. No. 32,833

McDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 South Wacker Drive
Chicago, IL 60606
Telephone: 312-913-0001
Facsimile: 312-913-0002

PTO/SB/44 (09-07)
Approved for use through 08/31/2013. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 8,679,069

APPLICATION NO.: 12/944,544

ISSUE DATE : March 25, 2014

INVENTOR(S) : Robert Frederick Veasey, et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page, item 73, Assignee:

delete "DCA DESIGN INTERNATIONAL LTD."

replace with -- SANOFI-AVENTIS DEUTSCHLAND GMBH --

MAILING ADDRESS OF SENDER (Please do not use customer number below):

McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, IL 60606

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.

Electronic Patent Application Fee Transmittal

Application Number:	12944544
Filing Date:	11-Nov-2010
Title of Invention:	PEN-TYPE INJECTOR
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Filer:	David M. Frischkorn
Attorney Docket Number:	10-1188-US-CON1

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:				
Certificate of Correction	1811	1	100	100
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**100**

Electronic Acknowledgement Receipt

EFS ID:	18801952
Application Number:	12944544
International Application Number:	
Confirmation Number:	5949
Title of Invention:	PEN-TYPE INJECTOR
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Customer Number:	20306
Filer:	David M. Frischkorn
Filer Authorized By:	
Attorney Docket Number:	10-1188-US-CON1
Receipt Date:	18-APR-2014
Filing Date:	11-NOV-2010
Time Stamp:	13:19:46
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$100
RAM confirmation Number	10216
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 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Certificate of Correction	10-1188-US-CON1_Request.pdf	118004 f4b0bd25b7706b0fe3ae33b04afc91565858fb3d	no	2
Warnings:					
Information:					
2	Request for Certificate of Correction	10-1188-US-CON1_Cert_of_Corr.pdf	164506 9f2022df128b210d705f6e850e2146ea8e1e1a5b	no	2
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	29730 214ec0f87fba0a653a9a89ef1908dc386f1dde53	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	312240		

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.

Document code: WFEE

United States Patent and Trademark Office
Sales Receipt for Accounting Date: 06/25/2014

CKHLOK SALE #00000011 Mailroom Dt: 04/18/2014 12944544

01	FC : 1811	100.00	DA
02	FC : 1830	140.00	DA

Document code: WFEE

United States Patent and Trademark Office
Sales Receipt for Accounting Date: 06/25/2014

CKHLOK ADJ #00000012 Mailroom Dt: 04/18/2014
Seq No: 10216 Sales Acctg Dt: 04/18/2014 132490 12944544
01 FC : 1811 100.00 CR

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

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

In re Patent No. 8,679,069 :
Issue Date: March 25, 2014 :
Application No. 12/944,544 : ON PETITION
Filed: November 11, 2010 :
Attorney Docket No.: 10-1188-US-CON1 :

This is a decision in response to the communication filed April 18, 2014, which is being treated as a request under 37 CFR 3.81(b)[1] to correct the name of the assignee on the front page of the above-identified patent by way of a Certificate of Correction.

The request is **GRANTED**.

The present communication requests that a certificate of correction be issued to reflect the correct assignee on the front page of the Letters Patent. It is noted that an incorrect assignee's name was included on the Fee(s) Transmittal form PTOL-85(b).

37 CFR 3.81(b), effective June 25, 2004, reads:

> *After payment of the issue fee:* Any request for issuance of an application in the name of the assignee submitted after the date of payment of the issue fee, and any request for a patent to be corrected to state the name of the assignee, must state that the assignment was submitted for recordation as set forth in § 3.11 before issuance of the patent, and must include a request for a certificate of correction under § 1.323 of this chapter (accompanied by the fee set forth in § 1.20(a) and the processing fee set forth in § 1.17(i) of this chapter.

A review of the details of the assignment recorded on September 28, 2011 confirms that SANOFI-AVENTIS DEUTSCHLAND GMBH is the assignee of record. Further, a request for a certificate of

[1] *See* MPEP 1309, subsection II; and Official Gazette of June 22, 2004.

correction under § 1.323 and the fee required by § 1.20(a) has been provided. The $140 processing fee set forth in § 1.17(i) will be charged to counsel's deposit account as authorized.

In view of the above, the request is found to comply with the provisions of 37 CFR 3.81(b).

The Certificates of Correction Branch will be notified of this decision granting the petition under 37 CFR 3.81(b) and directing issuance of the requested Certificate of Correction.

Telephone inquiries concerning this decision may be directed to the undersigned at (571) 272-3204. Inquiries regarding the issuance of a certificate of correction should be directed to the Certificates of Correction Branch at (703) 756-1814.

/SDB/

Sherry D. Brinkley
Paralegal Specialist
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.	: 8,679,069 B2
APPLICATION NO.	: 12/944544
DATED	: March 25, 2014
INVENTOR(S)	: Robert Frederick Veasey et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page, item 73, Assignee:

delete "DCA DESIGN INTERNATIONAL LTD."

replace with -- SANOFI-AVENTIS DEUTSCHLAND GMBH --

Signed and Sealed this
Twenty-second Day of July, 2014

Michelle K. Lee

Michelle K. Lee
Deputy Director of the United States Patent and Trademark Office

AO 120 (Rev. 08/10)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

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
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	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

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
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT
see attached Order

CLERK	(BY) DEPUTY CLERK	DATE
John A. Cerino	N. Schmyer	5/11/15

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**

AO 120 (Rev. 08/10)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

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
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
3			
4			
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
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT
See attached Order

CLERK	(BY) DEPUTY CLERK	DATE
John A. Cerino	N. Schmyer	5/11/2015

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**

AO 120 (Rev. 08/10)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

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
		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:

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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Copy 2---Upon filing document adding patent(s), mail this copy to Director Copy 4---Case file copy

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