Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	
	Filing Date	
	First Named Inventor	Robert Frederick Veasey
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	10-1188-US-CON4

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5626566	A	1997-05-06	Petersen et al.	
	2	6083197	A	2000-07-04	Umbaugh	
	3	6221046	B1	2001-04-24	Burroughs et al.	
	4	6899698	B2	2005-05-31	Sams	
	5	5688251	A	1997-11-18	Chanoch	
	6	5674204	A	1997-10-07	Chanoch	
	7	5304152	A	1994-04-19	Sams	
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U.S.PATENT APPLICATION PUBLICATIONS						Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	Robert Frederick Veasey
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	10-1188-US-CON4

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

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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	0937476	EP	A2	1999-08-25	Becton, Dickinson and Company		☐
	2	0937471	EP	A2	1999-08-25	Becton, Dickinson and Company		☐
	3	91/14467	WO	A1	1991-10-03	SAMS BERNARD		☐
	4	99/38554	WO	A1	1999-08-05	NOVO NORDISK AS		☐

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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]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	
	Filing Date	
	First Named Inventor	Robert Frederick Veasey
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	10-1188-US-CON4

	1		☐
If you wish to add additional non-patent literature document citation information please click the Add button Add			
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	
	Filing Date	
	First Named Inventor	Robert Frederick Veasey
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	10-1188-US-CON4

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

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

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No.: 10-1188-US-CON4)

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

FILED VIA EFS-WEB ON JUNE 4, 2013

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

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

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

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

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

Respectfully submitted,

McDONNELL BOEHNEN HULBERT & BERGHOFF LLP

Date: June 4, 2013

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

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	Pen-Type Injector
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Filer:	Thomas E. Wettermann
Attorney Docket Number:	10-1188-US-CON4

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	280	280
Utility Search Fee	1111	1	600	600
Utility Examination Fee	1311	1	720	720
Pages:				
Claims:				
Claims in Excess of 20	1202	36	80	2880
Miscellaneous-Filing:				
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	4480

Electronic Acknowledgement Receipt	
EFS ID:	15945172
Application Number:	13909681
International Application Number:	
Confirmation Number:	8309
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-CON4
Receipt Date:	04-JUN-2013
Filing Date:	
Time Stamp:	16:38:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$4480
RAM confirmation Number	3923
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_CON4_Utility_Transmittal_2013_06_04.pdf	276088 3e8653d3222d6147f389485d4c271bc54de862c0	no	2
Warnings:					
Information:					
2	Application Data Sheet	10_1188_US_CON4_ADS_2013_06_04.pdf	1504242 44cabd28dbb88c73b230d440164d8a6f2f4b0bf3	no	7
Warnings:					
Information:					
3		10_1188_US_CON4_Specification_2013_06_04.pdf	85841 fa486066f8421a7dba79a83acb1154786dcc2f2b	yes	15

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	11
Claims	12	14
Abstract	15	15

Warnings:					
Information:					
4	Drawings-only black and white line drawings	10_1188_US_CON4_Figures_2013_06_04.pdf	518548 76ed17b52ef22fbdc08076af060ed1a9043340f2	no	7
Warnings:					
Information:					
5	Preliminary Amendment	10_1188_US_CON4_Preliminary_Amendment_2013_06_04.pdf	104251 ace75dc1850856272d467e5d7bba4fe6eff41893	no	14
Warnings:					
Information:					
6	Oath or Declaration filed	10_1188_US_CON4_Declaration_2013_06_04.pdf	525668 6ec2d689376d92e6f6213aee0b5b219d5b6f7b1a	no	4
Warnings:					
Information:					

7	Transmittal Letter	10_1188_US_CON4_IDS_Transmittal_2013_06_04.pdf	80655 de5c28e47721e8305459107ebf4eda94e2f1a7f7	no	2
Warnings:					
Information:					
8	Information Disclosure Statement (IDS) Form (SB08)	10_1188_US_CON4_IDS_2013_06_04.pdf	612830 88d20c1077c15f5820e6977fbc9360b3b54b8f0e	no	5
Warnings:					
Information:					
9	Authorization for Extension of Time all replies	10_1188_US_CON4_General_Authorization_2013_06_04.pdf	81376 6cecf2438081ae759d05c50c44db8f57f49761d4	no	1
Warnings:					
Information:					
10	Fee Worksheet (SB06)	fee-info.pdf	36267 34540e7d56982c9aefe7af59e4140aee56714cf8	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	3825766		

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.

<u>New Applications Under 35 U.S.C. 111</u>
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.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
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.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
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/AIA/15 (03-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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UTILITY PATENT APPLICATION TRANSMITTAL

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

Attorney Docket No.	10-1188-US-CON4
First Named Inventor	Robert Frederick Veasey
Title	Pen-Type Injector
Express Mail Label No.	

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

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

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

ACCOMPANYING APPLICATION PAPERS

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

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

19. CORRESPONDENCE ADDRESS

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

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	

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

This collection of information is required by 37 CFR 1.53(b). 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 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, 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.

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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 disclosure of these records is required by the Freedom of Information Act.
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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.
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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.

PTO/AIA/14 (03-13)
Approved for use through 01/31/2014. 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-CON4
	Application Number	
Title of Invention	Pen-Type Injector	

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

Secrecy Order 37 CFR 5.2

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

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Robert	Frederick	Veasey	

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

City	Warwickshire	Country of Residence i	GB

Mailing Address of Inventor:

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

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Robert		Perkins	

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

City	Oxfordshire	Country of Residence i	GB

Mailing Address of Inventor:

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

Inventor 3 Remove

Legal Name

PTO/AIA/14 (03-13)
Approved for use through 01/31/2014. 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-CON4
	Application Number	
Title of Invention	Pen-Type Injector	

Prefix	Given Name	Middle Name	Family Name	Suffix
	David	Aubrey	Plumptre	

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

City	Worcestershire	Country of Residence i	GB

Mailing Address of Inventor:

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Address 2	Droitwich		
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Application Information:

Title of the Invention	Pen-Type Injector		
Attorney Docket Number	10-1188-US-CON4	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	7	**Suggested Figure for Publication (if any)**	

Publication Information:

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

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PTO/AIA/14 (03-13)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON4
	Application Number	
Title of Invention	Pen-Type Injector	

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

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

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

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	Application Number	
Title of Invention	Pen-Type Injector	

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

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

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Clear

◯ Assignee	◯ Legal Representative under 35 U.S.C. 117	◯ Joint Inventor
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON4
	Application Number	
Title of Invention	Pen-Type Injector	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON4
	Application Number	
Title of Invention	Pen-Type Injector	

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Signature	/Thomas E. Wettermann/			Date (YYYY-MM-DD)	2013-06-04
First Name	Thomas E.	Last Name	Wettermann	Registration Number	41523

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PEN-TYPE INJECTOR

CROSS REFERENCE TO RELATED APPLICATIONS

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

BACKGROUND

Improvements in and relating to a pen-type injector

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

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

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

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

OVERVIEW

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

According to a first aspect of the present invention, a pen-type injector comprises a housing;

a piston rod adapted to operate through the housing;

a dose dial sleeve located between the housing and the piston rod, the dose dial sleeve having a helical thread of first lead;

a drive sleeve located between the dose dial sleeve and the piston rod, the drive sleeve having a helical groove of second lead;

characterized in that the first lead of the helical thread and the second lead of the helical groove are the same.

Preferably, the piston rod has a first threaded portion at a first end and a second threaded portion at a second end;

an insert or radially inwardly extending flange is located in the housing and through which the first threaded portion of the piston rod may rotate;

the dose dial sleeve being rotatable with respect to the housing and the insert;

the drive sleeve being releasably connected to the dose dial sleeve and connected to the piston rod for rotation with respect thereto along the second threaded portion of the piston rod;

a button is located on the dose dial sleeve and rotatable with respect to the dose dial sleeve; and

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

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

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

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

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

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

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

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

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DETAILED DESCRIPTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CLAIMS

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;
characterized 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, characterized 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.

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.

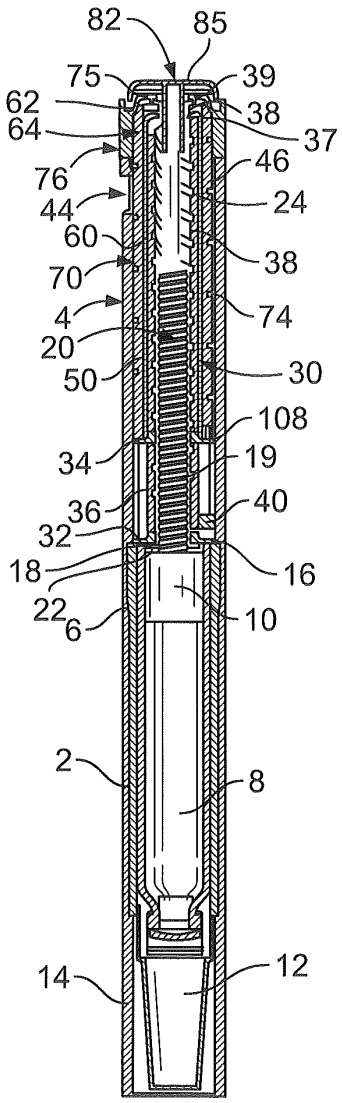
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FIG. 1

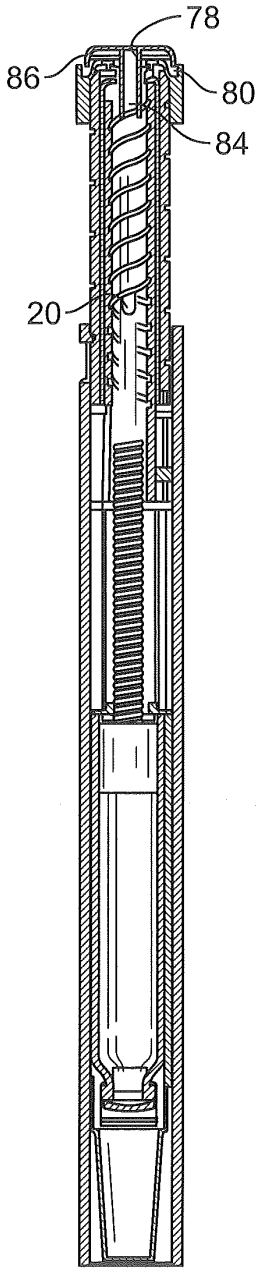
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FIG. 2

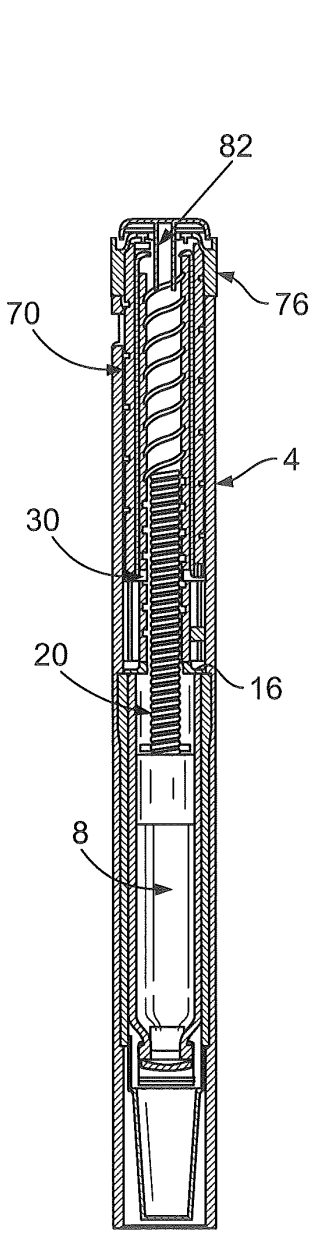

FIG. 3

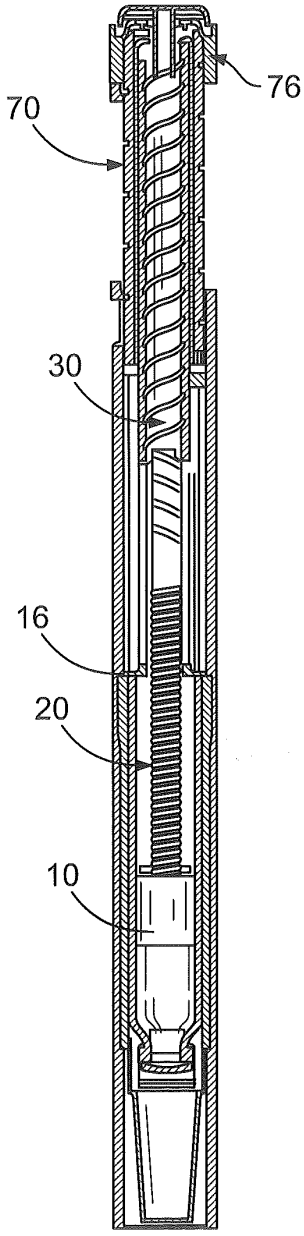

FIG. 4

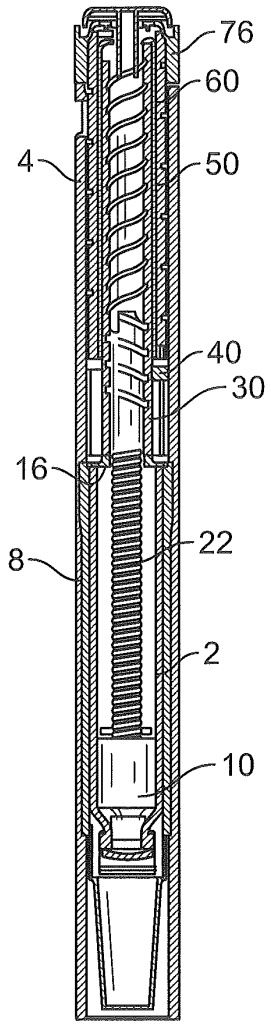

FIG. 5

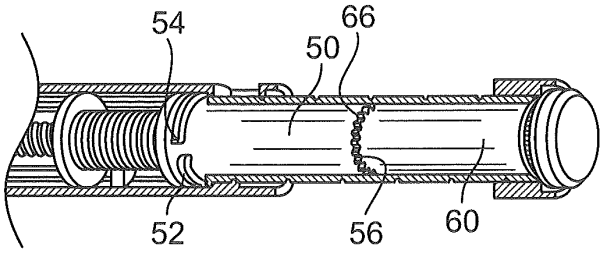

FIG. 6

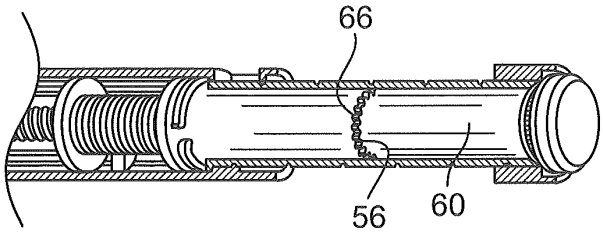

FIG. 7

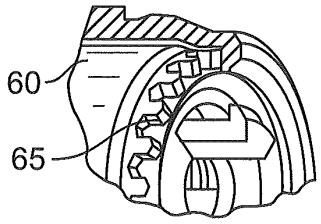

FIG. 8

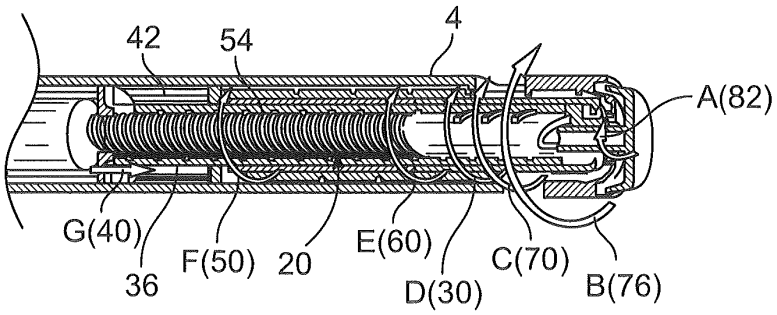

FIG. 9

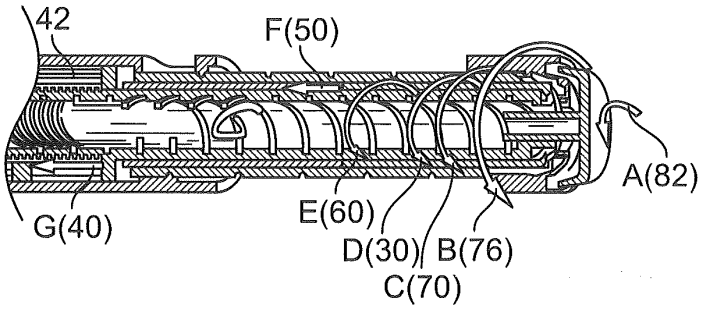

FIG. 10

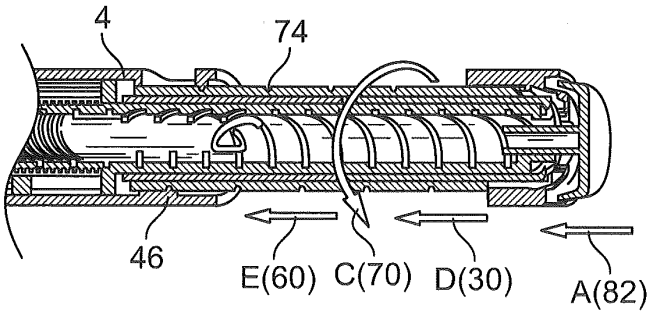

FIG. 11

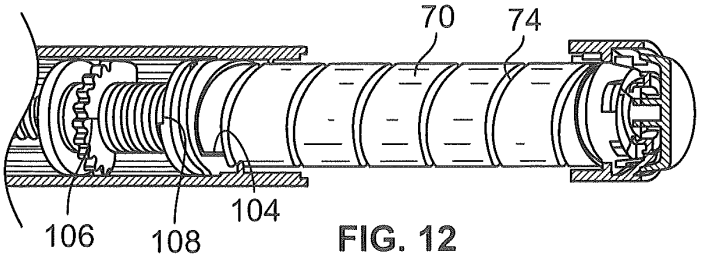

FIG. 12

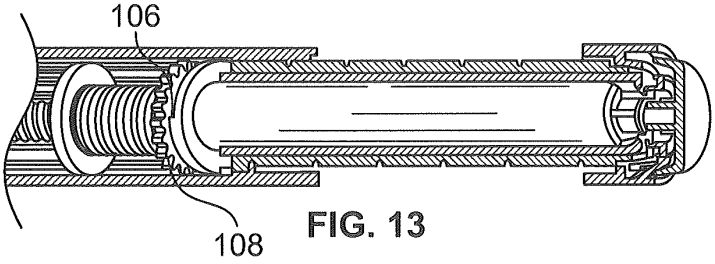

FIG. 13

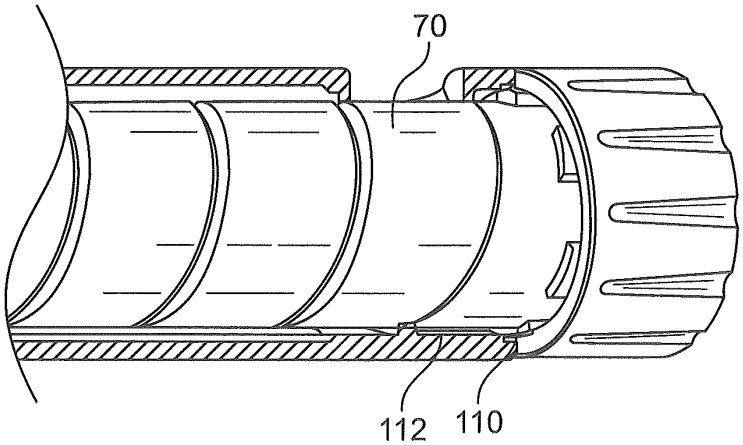

FIG. 14

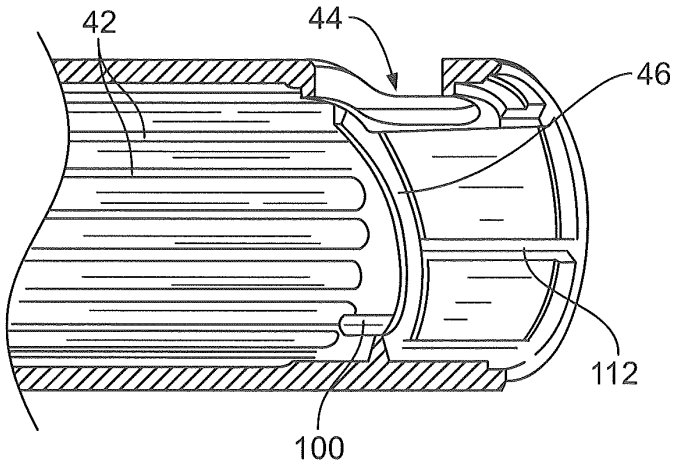

FIG. 15

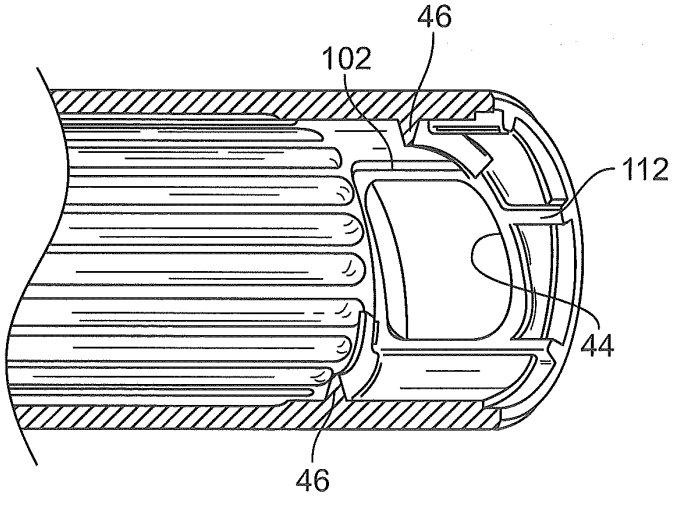

FIG. 16

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 10-1188-US-CON4)

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 claims begin on page 2.

Remarks begin of page 14.

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 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.

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17. (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.

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

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

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.

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 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, 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.

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

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.

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

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

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

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

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.

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

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 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 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.

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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.

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 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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57. (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;

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.

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58. (new) The pen type drug delivery device of claim 57, wherein said tubular barrel retainer is permanently coupled to said external housing.

59. (new) The pen type drug delivery device of claim 57, wherein said tubular barrel retainer is removably coupled to said external housing.

60. (new) The pen type drug delivery device of claim 57, wherein said pen type drug delivery device comprises a prefilled, variable dose pen type drug delivery device.

61. (new) The pen type drug delivery device of claim 57, wherein said outer surface of said dialing element further comprises dosage indicator markings.

62. (new) The pen type drug delivery device of claim 57, 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.

63. (new) The pen type drug delivery device of claim 57, wherein said driver comprises a cylindrical, tube-shaped body.

64. (new) The pen type drug delivery device of claim 57, wherein said clutch comprises a cylindrical clutch.

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65. (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.

66. (new) The clutch of claim 65, wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob.

67. (new) The clutch of claim 65, further comprising a plurality of axially extending teeth formed in an interior of a flange of said clutch.

68. (new) The clutch of claim 65, 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.

69. (new) The clutch of claim 66, 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.

70. (new) The clutch of claim 66, wherein said pen type drug delivery device further comprises

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

71. (new) The clutch of claim 70, 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.

Claims 1-14 are cancelled without prejudice or disclaimer, and new claims 15-71 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.

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: June 4, 2013

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

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

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

Attorney Docket Number	10-1188-US-CON4
First Named Inventor	Robert Frederick Veasey
COMPLETE IF KNOWN	
Application Number	
Filing Date	
Art Unit	
Examiner Name	

Pen-Type Injector

(Title of the Invention)

As a below named inventor, I hereby declare that:

This declaration is directed to:

☒ The attached application,

OR

☐ United States Application Number or PCT International application number _____

filed on _____.

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

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

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

Authorization To Permit Access To Application by Participating Office

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

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

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

PTO/AIA/08 (06-12)
Approved for use through 01/31/2014. 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:	20306	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* .

LEGAL NAME OF SOLE OR FIRST INVENTOR:

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

Robert Frederick Veasey

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

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

PTO/AIA/10 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Legal Name of Additional Joint Inventor, if any:

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

Robert Perkins

Inventor's Signature | Date (Optional): 24 APRIL 2013

Residence: City: Oxfordshire | State | Country: GB

Mailing Address: 6 Printers Court Abingdon

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

#RP 24-Apr-2013

Legal Name of Additional Joint Inventor, if any:

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

David Aubrey Plumptre

Inventor's Signature | Date (Optional)

Residence: City: Worcestershire | State | Country: GB

Mailing Address: 36 Shire Way Droitwich

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

Legal Name of Additional Joint Inventor, if any:

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

Inventor's Signature | Date (Optional)

Residence: City | State | Country

Mailing Address

City | State | Zip | Country

PTO/AIA/10 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

SUPPLEMENTAL SHEET FOR DECLARATION | **ADDITIONAL INVENTOR(S)**
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Robert Perkins

Inventor's Signature | Date (Optional)

Residence: City: Oxfordshire | State | Country: GB

Mailing Address: 6 Printers Court Abingdon

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

Legal Name of Additional Joint Inventor, if any:

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

David Aubrey Plumptre

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

Residence: City: Worcestershire | State | Country: GB

Mailing Address: 36 Shire Way Droitwich

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

Legal Name of Additional Joint Inventor, if any:

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

Inventor's Signature | Date (Optional)

Residence: City | State | Country

Mailing Address

City | State | Zip | Country

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No.: 10-1188-US-CON4)

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

FILED VIA EFS-WEB ON JUNE 4, 2013

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL LETTER

Mail Stop: AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Examiner,

In accordance with the duty of candor provisions set forth under 37 C.F.R. §1.56, submitted herewith on Form PTO/SB/08 is a listing of documents that Applicant wishes to make of record in the above-identified application.

In compliance with the provisions set forth under 37 C.F.R. §1.98(d), a copy of any reference that was previously submitted and/or provided by the Examiner in the parent application for the above-identified Continuation application are not being resubmitted herewith. For the Examiner's convenience, the parent application serial number to which the above-identified application claims priority to under 35 U.S.C. §120 is 12/944,544.

The submission of any document herewith is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 C.F.R. § 1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

In compliance with 37 C.F.R. §1.97(b), the listed documents are being submitted concurrently with the filing of the present application.

Applicant respectfully requests that the listed document(s) be considered by the Examiner and be made of record in the present application, and that a copy of Form PTO/SB/08 be returned in accordance with M.P.E.P. §609.

Although Applicant believes that no fee is required for this submission, the Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 13-2490.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff LLP

Dated: June 4, 2013

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

McDonnell Boehnen
Hulbert & Berghoff LLP
300 South Wacker Drive
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Document code: WFEE

United States Patent and Trademark Office
Sales Receipt for Accounting Date: 06/24/2013

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01 FC : 1202 80.00 DA

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 13/909,681

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	280
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	720
TOTAL CLAIMS (37 CFR 1.16(i))	57 minus 20 =	* 37			OR	x 80 =	2960
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*				x 420 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	4560

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	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/909,681	06/04/2013	3767	4560	10-1188-US-CON4	57	3

CONFIRMATION NO. 8309

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

FILING RECEIPT

OC000000062167919

Date Mailed: 07/01/2013

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

Inventor(s)

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

Applicant(s)

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

Assignment For Published Patent Application

DCA DESIGN INTERNATIONAL LTD, Warwick, UNITED KINGDOM

Power of Attorney: None

Domestic Priority data as claimed by applicant

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

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

Permission to Access - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

If Required, Foreign Filing License Granted: 06/21/2013

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/909,681**

Projected Publication Date: 10/10/2013

Non-Publication Request: No

Early Publication Request: No
Title

Pen-Type Injector

Preliminary Class

604

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

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 (1-866-999-4258).

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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	13909681
Filing Date	2013-06-04
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	
Attorney Docket Number	10-1188-US-CON4

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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13909681
	Filing Date	2013-06-04
	First Named Inventor	Robert Frederick Veasey
	Art Unit	3763
	Examiner Name	
	Attorney Docket Number	10-1188-US-CON4

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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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		☐

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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		☐

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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	13909681
	Filing Date	2013-06-04
	First Named Inventor	Robert Frederick Veasey
	Art Unit	3763
	Examiner Name	
	Attorney Docket Number	10-1188-US-CON4

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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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.

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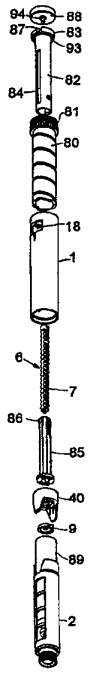
(57) Abstract

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



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An injection syringe

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

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

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

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

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

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

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

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

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

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

a housing

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

a piston rod drive comprising two elements

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

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

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

which syringe according to the invention is characterised in that

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CLAIMS

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

a housing

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

a piston rod drive comprising two elements

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

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

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

characterised in that

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

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

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

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

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

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

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

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

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

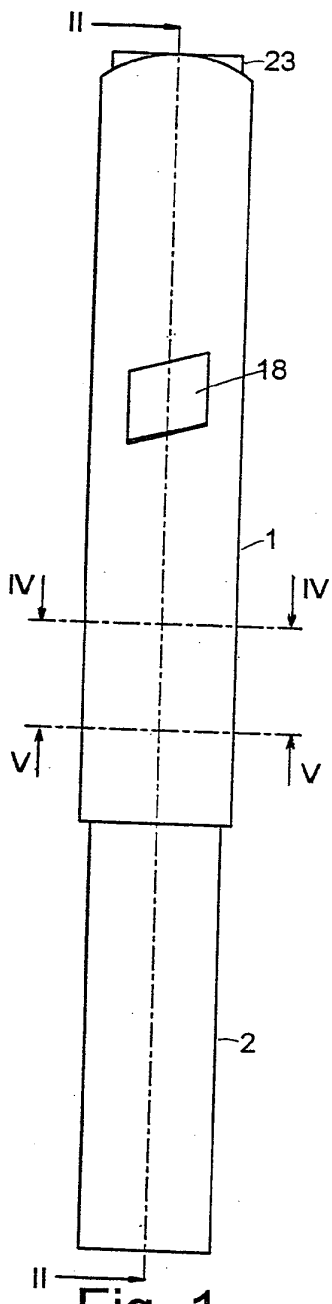

Fig. 1

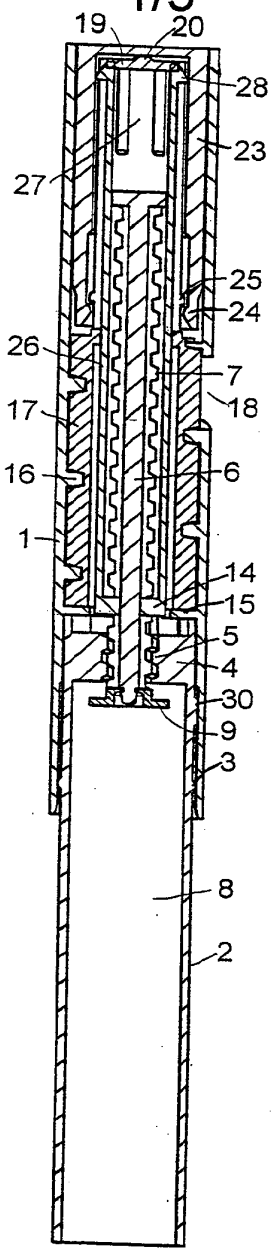

Fig.2

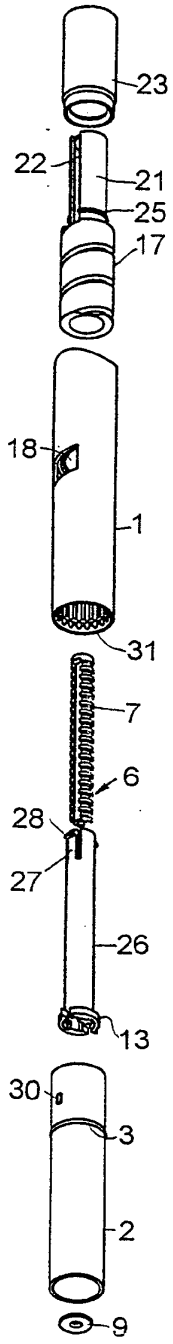

Fig.3

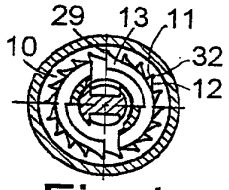

Fig.4

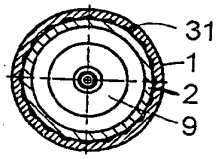

Fig. 5

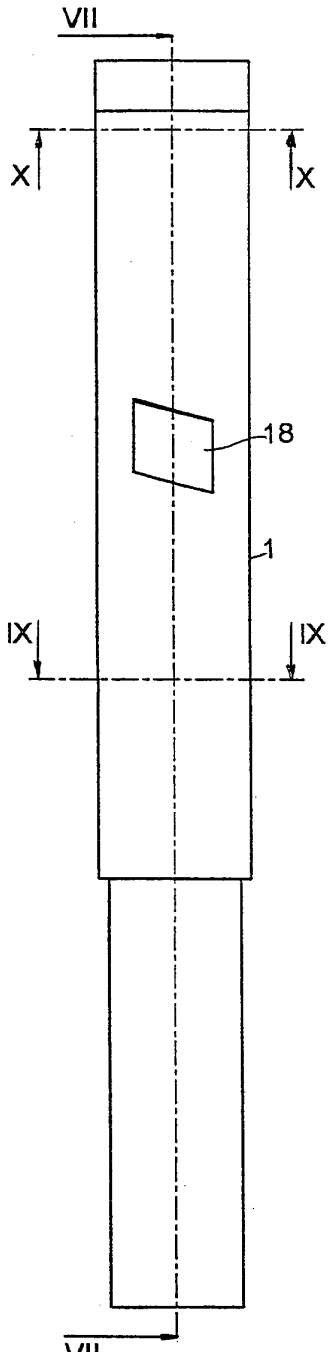

Fig. 6

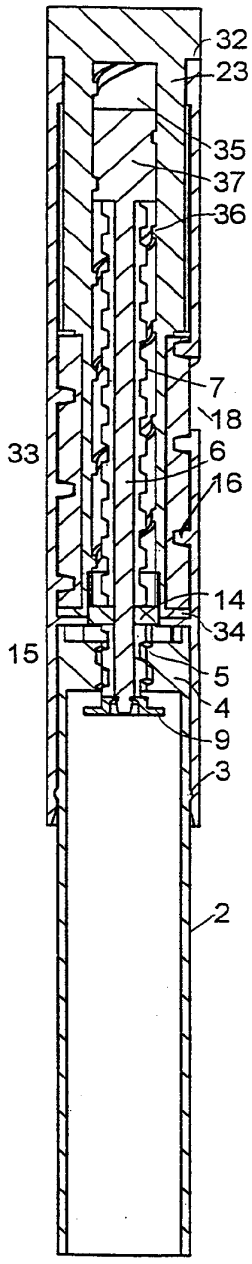

Fig. 7

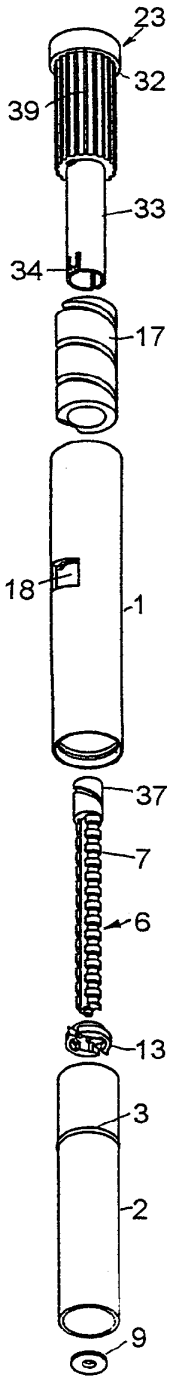

Fig.8

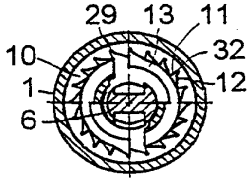

Fig. 9

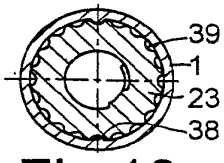

Fig.10

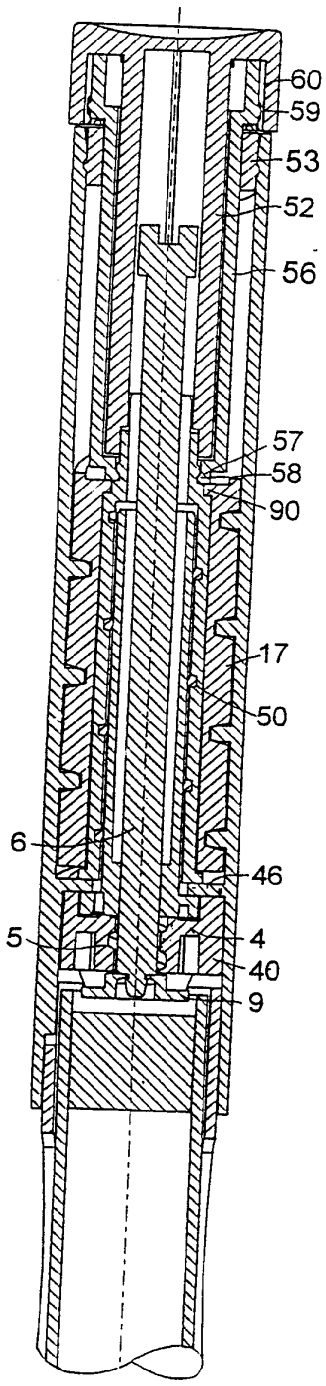

Fig. 11

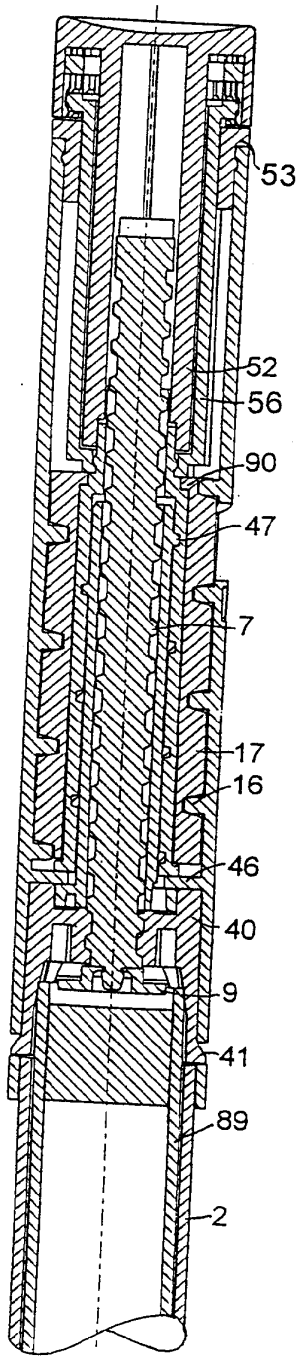

Fig. 12

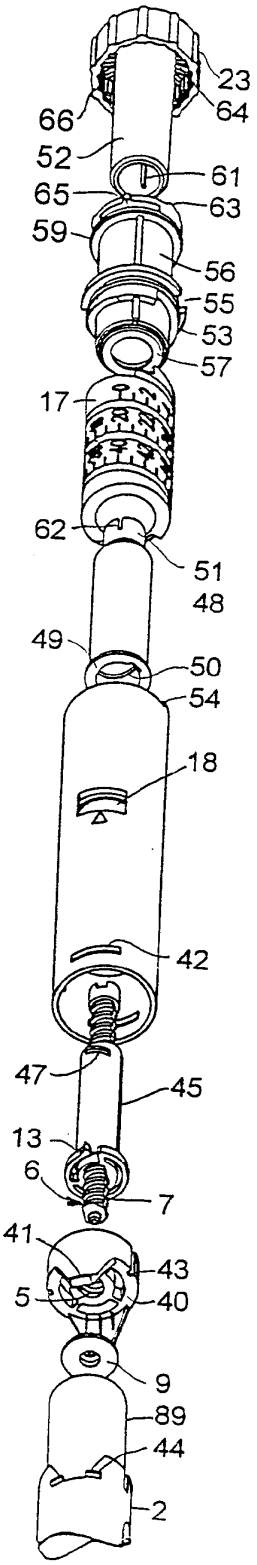

Fig. 13

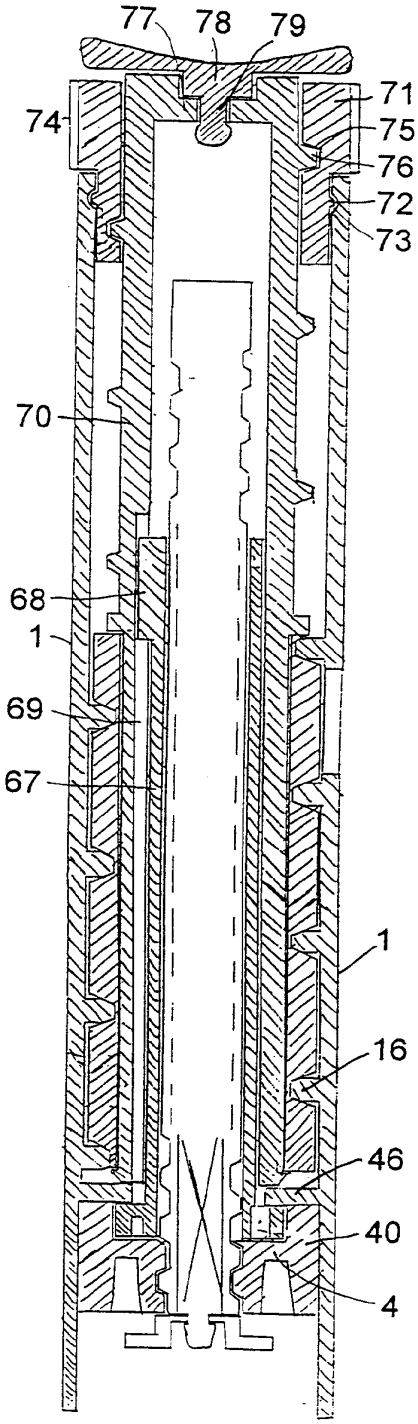

Fig. 14

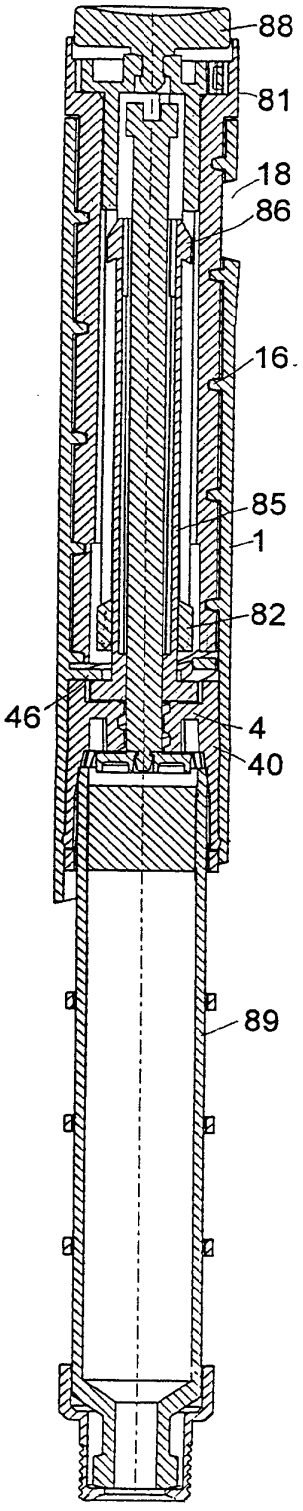

Fig. 15

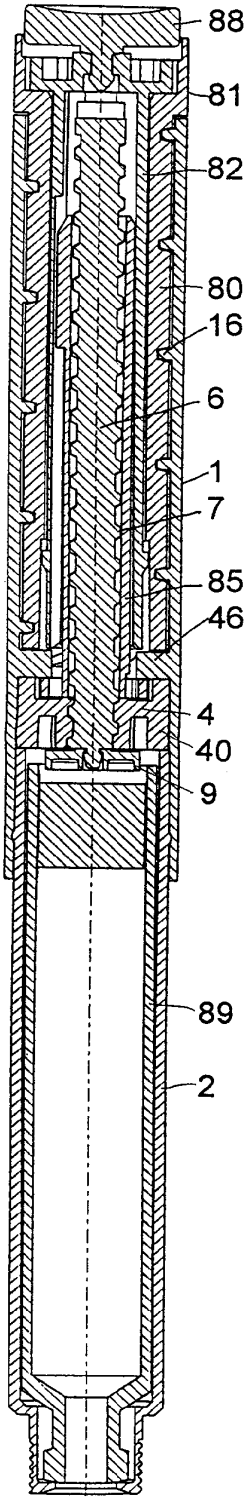

Fig.16

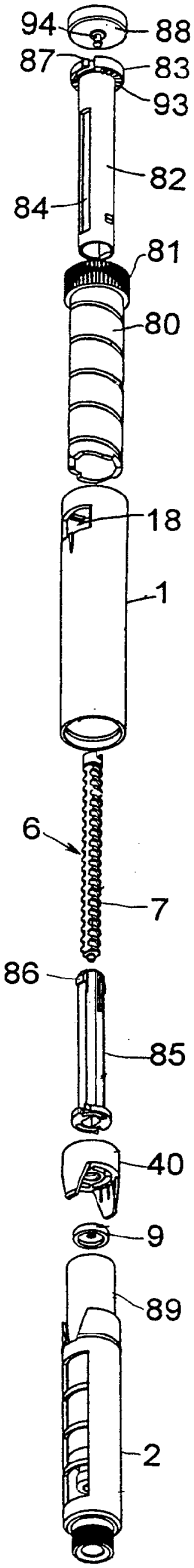

Fig. 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 99/00042

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 5/315, A61M 5/24
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

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

SE,DK,FI,NO classes as above

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

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

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

01/06/99

International application No.
PCT/DK 99/00042

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Form PCT/ISA/210 (patent family annex) (July 1992)

INTERNATIONAL SEARCH REPORT
Information on patent family members

01/06/99

International application No.
PCT/DK 99/00042

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON4)

In re Application of:	)	
	)	
Robert Frederick Veasey et al.	)	
	)	Examiner: Unassigned
Serial No.: 13/909,681	)	
	)	Group Art Unit: 3763
Filed: June 4, 2013	)	
	)	Confirmation No.: 8309
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

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300 S. Wacker Drive
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312.913.0001

Electronic Patent Application Fee Transmittal

Application Number:	13909681
Filing Date:	04-Jun-2013
Title of Invention:	Pen-Type Injector
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Filer:	Thomas E. Wettermann
Attorney Docket Number:	10-1188-US-CON4

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:	16732143
Application Number:	13909681
International Application Number:	
Confirmation Number:	8309
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-CON4
Receipt Date:	31-AUG-2013
Filing Date:	04-JUN-2013
Time Stamp:	16:26:46
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	8201
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_CON4_Supplemental_IDS_Transmittal_2013_08_30.pdf	140425 88ae810555e795f8555f9b4541f6bf2acc9f3cc2	no	1
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	10_1188_US_CON4_Supplemental_IDS_2013_08_30.pdf	612531 54942da553d920adb098e3887de399de05bea27c	no	4
Warnings:					
Information:					
3	Foreign Reference	10_1188_US_CON4_Foreign_Ref_1.pdf	1419670 beebeedde8ca4239e78e6b646afa6af3a54af238	no	30
Warnings:					
Information:					
4	Authorization for Extension of Time all replies	10_1188_US_CON4_General_Authorization_2013_08_30.pdf	59242 6cd306e9e79e5c192035b51c951a2d4143a3a8a7	no	1
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30236 fbcf82caafbeb5eb69db1ba9a675595f1345bd5f	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2262104		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

PTO/SB/21 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	

Application Number	13/909,681
Filing Date	June 4, 2013
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	
Attorney Docket Number	10-1188-US-CON4

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Supplemental Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ 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

This collection of information is required by 37 CFR 1.5. 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 2 hours 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.

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/909,681	06/04/2013	Robert Frederick Veasey	10-1188-US-CON4

CONFIRMATION NO. 8309

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

PUBLICATION NOTICE

Title: Pen-Type Injector

Publication No.US-2013-0267906-A1
Publication Date:10/10/2013

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

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

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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.
13/909,681	06/04/2013	Robert Frederick Veasey	10-1188-US-CON4	8309

20306 7590 11/07/2014

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
11/07/2014	PAPER

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

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

Office Action Summary	Application No. 13/909,681	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* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

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

Status

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

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

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

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

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

Disposition of Claims*

5)☒ Claim(s) *15-71* 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) *15-71* 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 *6/04/2013* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☒ All b)☐ Some** c)☐ None of the:

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

2.☒ Certified copies of the priority documents have been received in Application No. 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)).

** 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/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *8/31/2013 and 6/04/2013*.

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

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

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 15-71 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 8,679,069.

US 8,679,069 B2

The invention claimed is:

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

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

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

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

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

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

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

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

Although the claims at issue are not identical, they are not patentably distinct from each other because the cited patent discloses a main housing, a dose dial sleeve, a piston rod, and a tubular clutch. The patent does not explicitly disclose the phrase “dose knob” or the term “driver”. However, the phrase “dose knob” is equivalent to the phrase “dose dial grip” disclosed in claim 1, line 10, which according to the claim is disposed near a proximal end of the dose dial sleeve. Similarly, the patent does not explicitly disclose the term "driver". However, the term "driver" is equivalent to the phrase "drive sleeve" disclosed in claim 1, line 15. According to the claim, the "drive sleeve" extends along a portion a portion of the piston rod and comprises of internal threading adapted to engage an external thread of the piston rod.

Based on the observations above, for an artisan skilled in the art, the modification of the terminology of the claims in question would have been considered obvious because, according to the facts provided above, the description of the structural elements is similar in both instances.

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

Notice of References Cited	Application/Control No. 13/909,681	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-8,679,069	03-2014	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	
	V	
	W	
	X	

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	
	Filing Date	
	First Named Inventor	Robert Frederick Veasey
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	10-1188-US-CON4

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5626566	A	1997-05-06	Petersen et al.	
	2	6083197	A	2000-07-04	Umbaugh	
	3	6221046	B1	2001-04-24	Burroughs et al.	
	4	6899698	B2	2005-05-31	Sams	
	5	5688251	A	1997-11-18	Chanoch	
	6	5674204	A	1997-10-07	Chanoch	
	7	5304152	A	1994-04-19	Sams	
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Receipt date: 06/04/2013	Application Number	13909681 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	
(Not for submission under 37 CFR 1.99)	First Named Inventor	Robert Frederick Veasey
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	10-1188-US-CON4

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

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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	0937476	EP	A2	1999-08-25	Becton, Dickinson and Company		☐
	2	0937471	EP	A2	1999-08-25	Becton, Dickinson and Company		☐
	3	91/14467	WO	A1	1991-10-03	SAMS BERNARD		☐
	4	99/38554	WO	A1	1999-08-05	NOVO NORDISK AS		☐

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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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Receipt date: 06/04/2013	Application Number	13909681 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	
	First Named Inventor	Robert Frederick Veasey
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	10-1188-US-CON4

	1		☐

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EXAMINER SIGNATURE

Examiner Signature	/Manuel Mendez/	Date Considered	11/06/2014

*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: 06/04/2013	Application Number	13909681 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	
	First Named Inventor	Robert Frederick Veasey
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	10-1188-US-CON4

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Thomas E. Wettermann/	Date (YYYY-MM-DD)	2013-06-04
Name/Print	Thomas E. Wettermann	Registration Number	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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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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

Application Number	13909681
Filing Date	2013-06-04
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	
Attorney Docket Number	10-1188-US-CON4

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Receipt date: 08/31/2013	Application Number	13909681 13909681 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2013-06-04
	First Named Inventor	Robert Frederick Veasey
(Not for submission under 37 CFR 1.99)	Art Unit	3763
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Examiner Signature	/Manuel Mendez/	Date Considered	11/06/2014

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Receipt date: 08/31/2013	Application Number	13909681 13909681 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2013-06-04
	First Named Inventor	Robert Frederick Veasey
(Not for submission under 37 CFR 1.99)	Art Unit	3763
	Examiner Name	
	Attorney Docket Number	10-1188-US-CON4

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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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

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Total Number of Pages in This Submission	

Application Number	13/909,681
Filing Date	June 4, 2013
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	Mendez, Manuel A.
Attorney Docket Number	10-1188-US-CON4

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)
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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	February 9, 2015	Reg. No.	41,523

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Typed or printed name	Thomas E. Wettermann	Date	February 9, 2015

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No.: 10-1188-US-CON4)

In the Application of:	)	
	)	
Robert Frederick Veasey	)	Examiner: Mendez, Manuel A.
	)	
Serial No. 13/909,681	)	Group Art Unit: 3763
	)	
Filed: June 4, 2013	)	Confirmation No.: 8309
	)	
For: Pen-Type Injector	)	

Mail Stop Amendment
Commissioner for Patents
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Alexandria, Virginia 22313-1450

AMENDMENT AND RESPONSE TO OFFICE ACTION

Dear Sir:

In response to the Office Action mailed November 7, 2014, please consider the following remarks.

No fees are believed to be due at this time. However, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment to Deposit Account No. 13-2490.

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

Remarks/Arguments begin on page 14 of this paper.

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IN THE CLAIMS:

1-14. (cancelled)

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

17. (previously presented) The housing part of claim 15, wherein said main

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housing comprises a window through which at least a portion of an outer surface of said dose dial sleeve may be viewable.

18. (previously presented) The housing part of claim 17, 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.

19. (previously presented) The housing part of claim 15, wherein said driver comprises a cylindrical shape.

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

21. (previously presented) 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.

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

23. (previously presented) The housing part of claim 15, further comprising a container housing operatively coupled to said main housing, said container

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

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

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

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

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

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

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

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

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

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

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

39. (previously presented) The housing part of claim 15,

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

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

40. (previously presented) 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. (previously presented) 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. (previously presented) 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. (previously presented) The housing part of claim 41, wherein said helical rib comprises a single start helical rib.

44. (previously presented) 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. (previously presented) 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

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inner surface of said main housing and thereby prevents rotation of said dose dial sleeve.

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

47. (previously presented) 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. (previously presented) 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. (previously presented) 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 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.

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

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

52. (previously presented) 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.

53. (previously presented) 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. (previously presented) 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. (previously presented) 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.

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56. (previously presented) 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.

57. (previously presented) 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;

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

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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.

58. (previously presented) The pen type drug delivery device of claim 57, wherein said tubular barrel retainer is permanently coupled to said external housing.

59. (previously presented) The pen type drug delivery device of claim 57, wherein said tubular barrel retainer is removably coupled to said external housing.

60. (previously presented) The pen type drug delivery device of claim 57, wherein said pen type drug delivery device comprises a prefilled, variable dose pen type drug delivery device.

61. (previously presented) The pen type drug delivery device of claim 57, wherein said outer surface of said dialing element further comprises dosage indicator markings.

62. (previously presented) The pen type drug delivery device of claim 57, 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.

63. (previously presented) The pen type drug delivery device of claim 57,

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wherein said driver comprises a cylindrical, tube-shaped body.

64. (previously presented) The pen type drug delivery device of claim 57, wherein said clutch comprises a cylindrical clutch.

65. (previously presented) 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.

66. (previously presented) The clutch of claim 65, wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob.

67. (previously presented) The clutch of claim 65, further comprising a plurality of axially extending teeth formed in an interior of a flange of said clutch.

68. (previously presented) The clutch of claim 65, 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.

69. (previously presented) The clutch of claim 66, wherein when said dose

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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.

70. (previously presented) The clutch of claim 66, 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.

71. (previously presented) The clutch of claim 70, wherein said cartridge comprises a multidose cartridge.

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REMARKS

In the Office Action mailed November 7, 2014, claims 15-71 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-3 of U.S. Pat. No. 8,679,069. The Examiner submits that the claims are not patentably distinct "because the cited patent discloses a main housing, a dose dial sleeve, a piston rod, and a tubular clutch." Applicants respectfully disagree. Although both the cited patent and present application disclose a housing, a dose dial sleeve, a piston rod, and a tubular clutch, Applicants submit that the claims are patentably distinct.

Regarding claims 15-56, at least dependent claims 16-56 include features that are patentably distinct from claims 1-3 of the cited patent, such as, for example, a window through which at least a portion of an outer surface of the dose dial may be viewable (claim 17), a clicker providing audible or tactile feedback to a user (claim 28), and an insert secured against longitudinal motion (claim 53). Thus, for at least these reasons, the rejection is improper and should be withdrawn.

As to claims 57-64, these claims are directed to a pen type drug delivery device, which is not claimed in the cited patent. Further, claims 65-71 are directed to a clutch for use with a pen type drug delivery device, which is also not claimed in the cited patent. Thus, for these additional reasons, the rejection is improper and should be withdrawn.

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Conclusion

In view of the foregoing, Applicants respectfully request that all of the rejections of the claims be withdrawn and that a Notice of Allowance be given. If there are any matters that may be resolved or clarified through a telephone interview, the Examiner is respectfully requested to contact Applicants' undersigned representative at (312) 913-0001.

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff LLP

Date: February 9, 2014

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

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON4)

In re Application of:	)	
	)	
Robert Frederick Veasey	)	
	)	Examiner: Mendez, Manuel A.
Serial No.: 13/909,681	)	
	)	Group Art Unit: 3763
Filed: June 4, 2013	)	
	)	Confirmation No.: 8309
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: February 9, 2015

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

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Chicago, Illinois 60606
312.913.0001

Electronic Acknowledgement Receipt

EFS ID:	21436828
Application Number:	13909681
International Application Number:	
Confirmation Number:	8309
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-CON4
Receipt Date:	09-FEB-2015
Filing Date:	04-JUN-2013
Time Stamp:	13:33:00
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_CON4_OA_Transmittal_2015_02_09.pdf	158652 5dd68e801a07925522b14ab33abd3dde5564 0b33	no	1
Warnings:					
Information:					

2	Applicant Arguments/Remarks Made in an Amendment	10_1188_US_CON4_OA_Response_2015_02_09.pdf	113747 ffd2497877ff9e1e8e4b233890ff5facc5ec87dc	no	15
Warnings:					
Information:					
3	Authorization for Extension of Time all replies	10_1188_US_CON4_General_Authorization_2015_02_09.pdf	59594 0420f6a0af79d455da0edb4b4321c1ef3662eab5	no	1
Warnings:					
Information:					
		Total Files Size (in bytes):	331993		

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 (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 13/909,681	Filing Date 06/04/2013	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

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

APPLICATION AS AMENDED – PART II

AMENDMENT	02/09/2015	(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))	* 57	Minus	** 57	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

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
/DAWN BREWER/

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
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NOTICE OF ALLOWANCE AND FEE(S) DUE

20306 7590 02/19/2015

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: 02/19/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/909,681	06/04/2013	Robert Frederick Veasey	10-1188-US-CON4	8309

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	05/19/2015

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 02/19/2015
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32ND FLOOR
CHICAGO, IL 60606

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/909,681	06/04/2013	Robert Frederick Veasey	10-1188-US-CON4	8309

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	05/19/2015

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. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/909,681	06/04/2013	Robert Frederick Veasey	10-1188-US-CON4	8309

20306 7590 02/19/2015

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: 02/19/2015

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

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.

PTOL-85 (Rev. 02/11)

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. 13/909,681	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 *response filed on 2/9/2015*.
   ☐ 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 *15-71*. 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 _____
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 2/9/2015. In relation to the pending double patenting rejection, the arguments presented on pages 14 and 15 of the Remarks are found to be persuasive. Therefore, claims 15-71 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

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 02/19/2015
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)
February 23, 2015	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/909,681	06/04/2013	Robert Frederick Veasey	10-1188-US-CON4	8309

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	05/19/2015

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 Hulbert
2 & Berghoff LLP
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Sanofi-Aventis Deutschland GmbH

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Frankfurt am Main, Germany

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The director is hereby authorized to charge the required fee(s), any deficiency, or 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 February 23, 2015
Typed or printed name Thomas E. Wettermann Registration No. 41,523

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON4)

In re Application of:	)	
	)	
Robert Frederick Veasey	)	
	)	Group Art Unit: 3763
Serial No.: 13/909,681	)	
	)	Examiner: Mendez, Manuel A.
Filed: June 4, 2013	)	
	)	Confirmation No.: 8309
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

Dear Commissioner:

Responsive to the Notice of Allowance mailed February 19, 2015 Applicant express appreciation for the allowance of the present application. The Applicant notes 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. Applicant understands that the Examiner has thoroughly examined the claims and prior art of record and has concluded that the art of record, whether considered alone or in combination, fails to disclose or suggest the entirety of each combination of steps and/or structure recited by each of the allowed claims, that the Examiner has found each claim as a whole to patentably distinguish over the art of record, and that patentability of the claims does not necessarily rest on only any aspect that the Examiner listed in the statement of reasons for allowance.

Applicant takes no position regarding the Reasons for Allowance presented by the Examiner other than the positions Applicant may have previously taken during prosecution.

Therefore, the Examiner's Reasons for Allowance should not be attributed to Applicant as a sole indication of the basis for Applicant's belief that the claims are patentable. Furthermore, Applicant respectfully asserts that there may also be additional reasons for patentability of the claimed subject matter not explicitly stated in this record and Applicant does not waive its rights to such arguments by not further addressing such reasons herein.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff LLP

Date: February 23, 2015 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

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 10-1188-US-CON4)

In re Application of:	)	
	)	
Robert Frederick Veasey	)	
	)	Examiner: Mendez, Manuel A.
Serial No.: 13/909,681	)	
	)	Group Art Unit: 3763
Filed: June 4, 2013	)	
	)	Confirmation No.: 8309
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: February 23, 2015

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:	13909681
Filing Date:	04-Jun-2013
Title of Invention:	Pen-Type Injector
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Filer:	Thomas E. Wettermann
Attorney Docket Number:	10-1188-US-CON4

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

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

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

Electronic Acknowledgement Receipt	
EFS ID:	21565950
Application Number:	13909681
International Application Number:	
Confirmation Number:	8309
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-CON4
Receipt Date:	23-FEB-2015
Filing Date:	04-JUN-2013
Time Stamp:	11:51:39
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	9403
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_CON4_Issue_Fee_Transmittal_2015_02_23.pdf	158742 122746f3785cb67e267b26b6995770ca78a21cd0	no	1
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	10_1188_US_CON4_Issue_Fee_2015_02_23.pdf	89503 9f710e28906e4221ba2c51aa94e699cd64e09d25	no	1
Warnings:					
Information:					
3	Miscellaneous Incoming Letter	10_1188_US_CON4_Comments_Statement_Reasons_allowance_2015_02_23.pdf	59376 b20452e818fd7e96bb8160417823926850dade07	no	2
Warnings:					
Information:					
4	Authorization for Extension of Time all replies	10_1188_US_CON4_General_Authorization_2015_02_23.pdf	59596 d6b5b48a125275c1340793200b50fc5a3363b70d	no	1
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30584 6135a0ad5c188f9dc8e3b43d391b89cd1088a6b8	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	397801		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

PTO/SB/21 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	

Application Number	13/909,681
Filing Date	June 4, 2013
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	Mendez, Manuel A.
Attorney Docket Number	10-1188-US-CON4

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 Transmittal, 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	February 23, 2015	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	February 23, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/909,681	03/31/2015	8992486	10-1188-US-CON4	8309

20306 7590 03/11/2015

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 95 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

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

AO 120 (Rev. 08/10)

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

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court FOR THE DISTRICT OF DELAWARE on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT FOR THE DISTRICT OF DELAWARE
PLAINTIFF SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS DEUTSCHLAND GMBH, and SANOFI WINTHROP INDUSTRIE		DEFENDANT 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
1		
2		
3		
4		
5		

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

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

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

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