

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

First Named Inventor:	Robert Frederick Veasey	Nonprovisional Application Number (if known):	
Title of Invention:	IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR		

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

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.
2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.
3. The applicable box is checked below:

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

- i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.
---OR---
- (b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.
- ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, or the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

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

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

Signature /David M. Frischkorn/	Date May 17, 2016
Name (Print/Typed) David M. Frischkorn	Practitioner Registration Number 32,833

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

*Total of _____ forms are submitted.

Privacy Act Statement

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

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

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.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	10-1188-US-CON8
		Application Number	
Title of Invention	IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR		
<p>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.</p>			

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 <input type="radio"/> Non US Residency Active US Military Service					
City	Warwickshire	Country of Residence ⁱ		GB	
Mailing Address of Inventor:					
Address 1	35 Hitchman Road, Leamington Spa				
Address 2					
City	Warwickshire	State/Province			
Postal Code	CV31 3QH	Country ⁱ	GB		
Inventor	2				Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Robert		Perkins		
Residence Information (Select One) US Residency <input checked="" type="radio"/> Non US Residency Active US Military Service					
City	Warwickshire	Country of Residence ⁱ		GB	
Mailing Address of Inventor:					
Address 1	67 Erica Drive, Leamington Spa				
Address 2					
City	Warwickshire	State/Province			
Postal Code	CV31 2RW	Country ⁱ	GB		
Inventor	3				Remove
Legal Name					

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	10-1188-US-CON8
		Application Number	
Title of Invention	IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR		

Prefix	Given Name	Middle Name	Family Name	Suffix
	David	Aubrey	Plumptre	
Residence Information (Select One) US Residency <input checked="" type="radio"/> Non US Residency Active US Military Service				
City	Worcestershire	Country of Residence ⁱ	GB	

Mailing Address of Inventor:				
Address 1	36 Shire Way, Droitwich Spa			
Address 2				
City	Worcestershire	State/Province		
Postal Code	WR9 7RQ	Country ⁱ	GB	
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button. Add				

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).			
<input type="checkbox"/> An Address is being provided for the correspondence information of this application.			
Customer Number	98548		
Email Address	PSGDOCKET@MBHB.COM	Add Email	Remove Email

Application Information:

Title of the Invention	IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR		
Attorney Docket Number	10-1188-US-CON8	Small Entity Status Claimed	<input type="checkbox"/>
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	7	Suggested Figure for Publication (if any)	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country ⁱ

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON8
	Application Number	
Title of Invention	IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR	

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

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

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

Please Select One:	<input checked="" type="radio"/> Customer Number	<input type="radio"/> US Patent Practitioner	<input type="radio"/> Limited Recognition (37 CFR 11.9)
Customer Number	98548		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove		
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
	Continuation of	14946203	2015-11-19		
Prior Application Status	Patented		Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14946203	Continuation of	14635573	2015-03-02	9233211	2016-01-12
Prior Application Status	Patented		Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14635573	Continuation of	13919251	2013-06-17	9011391	2015-04-21
Prior Application Status	Patented		Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13919251	Division of	13040198	2011-03-03	8512297	2013-08-20

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	10-1188-US-CON8			
		Application Number				
Title of Invention	IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR					
Prior Application Status	Patented				Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)	
13040198	Continuation of	11483546	2006-07-11	7918833	2011-04-05	
Prior Application Status	Abandoned				Remove	
Application Number	Continuity Type		Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
11483546	Continuation of		10790225	2004-03-02		
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.						Add

Foreign Priority Information:

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

			Remove
Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ⁱ (if applicable)
0304822.0	GB	2003-03-03	
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			Add

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.

NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON8
	Application Number	
Title of Invention	IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is 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 State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON8
	Application Number	
Title of Invention	IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR	

Applicant Information:

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

Applicant	1	<input type="button" value="Remove"/>
<p>If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.</p>		
<input type="button" value="Clear"/>		
<input checked="" type="radio"/> Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.		Person who shows sufficient proprietary interest
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:		
<div style="border: 1px solid black; height: 20px; width: 100%;"></div>		
Name of the Deceased or Legally Incapacitated Inventor: <input type="text"/>		
If the Applicant is an Organization check here. <input checked="" type="checkbox"/>		
Organization Name	SANOFI-AVENTIS DEUTSCHLAND GMBH	
Mailing Address Information For Applicant:		
Address 1	Brüningstrasse 50, 65929	
Address 2		
City	Frankfurt am Main	State/Province
Country	DE	Postal Code
Phone Number		Fax Number
Email Address		
Additional Applicant Data may be generated within this form by selecting the Add button. <input type="button" value="Add"/>		

Assignee Information including Non-Applicant Assignee Information:

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON8
	Application Number	
Title of Invention	IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR	

Assignee	1
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Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here.

Prefix	Given Name	Middle Name	Family Name	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

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

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). However, if this Application Data Sheet is submitted with the **INITIAL** filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/David M. Frischkorn/		Date (YYYY-MM-DD)	2016-05-17	
First Name	David M.	Last Name	Frischkorn	Registration Number	32833

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

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON8
	Application Number	
Title of Invention	IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR	

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

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.

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

SPECIFICATION

TITLE

IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation of U.S. Patent Application No. U.S. 14/946,203, filed November 19, 2015, which is a continuation of U.S. Patent Application No. U.S. 14/635,573, filed March 2, 2015, now U.S. Patent No. 9,233,211, which is a continuation of U.S. Patent Application No. 13/919,251, filed June 17, 2013, now U.S. Patent No. 9,011,391, which is a divisional of U.S. Patent Application No. 13/040,198, filed March 3, 2011, now U.S. Patent No. 8,512,297, which is a continuation 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 of U.S. Patent Application No. 10/790,225, filed March 2, 2004, which claims priority to GB 0304822.0 filed March 3, 2003, the entire contents of which are incorporated herein by reference.

BACKGROUND

[0002] 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.

[0003] 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.

[0004] 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).

SUMMARY

[0005] It is an advantage of the present invention that an improved pen-type injector is provided.

[0006] According to a first aspect of the present invention, a pen-type injector comprises
a housing;
a piston rod adapted to operate through 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.

[0007] 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.

[0008] 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.

[0009] 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.

[0010] Preferably, the first thread of the piston rod is oppositely disposed to the second thread of the piston rod.

[0011] 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.

[0012] Preferably, the pen-type injector further includes clicker means disposed between the clutch means and spline means provided on the housing.

[0013] 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.

[0014] 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.

[0015] 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.

[0016] 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 FIGURES

[0017] The invention will now be described with reference to the accompanying drawings in which:

[0018] Figure 1 shows a sectional view of a pen-type injector in accordance with the present invention in a first, cartridge full, position;

[0019] Figure 2 shows a sectional view of the pen-type injector of Figure 1 in a second, maximum first dose dialed, position;

[0020] Figure 3 shows a sectional view of the pen-type injector of Figure 1 in a third, first maximum first dose dispensed, position;

[0021] Figure 4 shows a sectional view of the pen-type injector of Figure 1 in a fourth, final dose dialed, position;

[0022] Figure 5 shows a sectional view of the pen-type injector of Figure 1 in a fifth, final dose dispensed, position;

[0023] Figure 6 shows a cut-away view of a first detail of the pen-type injector of Figure 1;

[0024] Figure 7 shows a partially cut-away view of a second detail of the pen-type injector of Figure 1;

[0025] Figure 8 shows a partially cut-away view of a third detail of the pen-type injector of Figure 1;

[0026] Figure 9 shows the relative movement of parts of the pen-type injector shown in Figure 1 during dialing up of a dose;

[0027] Figure 10 shows the relative movement of parts of the pen-type injector shown in Figure 1 during dialing down of a dose;

[0028] Figure 11 shows the relative movement of parts of the pen-type injector shown in Figure 1 during dispensing of a dose;

[0029] Figure 12 shows a partially cut-away view of the pen-type injector of Figure 1 in the second, maximum first dose dialed, position;

[0030] Figure 13 shows a partially cut-away view of the pen-type injector of Figure 1 in the fourth, final dose dialed, position;

[0031] 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;

[0032] Figure 15 shows a cut-away view of a first part of a main housing of the pen-type injector of Figure 1; and

[0033] 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

[0034] 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.

[0035] 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.

[0036] 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.

[0037] 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 replaceable 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.

[0038] 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.

[0039] 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.

[0040] 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.

[0041] 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.

[0042] A first end of the first flange 32 is adapted to conform to a second side of the insert 16.

[0043] 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.

[0044] 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.

[0045] 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).

[0046] 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 (of Figure 7). Each saw tooth comprises a longitudinally directed surface and an inclined surface.

[0047] 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.

[0048] 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.

[0049] 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.

[0050] The clicker 50 and the clutch means 60 are normally engaged, that is as shown in Figure 7.

[0051] 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.

[0052] 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).

[0053] 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.

[0054] 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.

[0055] 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.

[0056] 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.

[0057] 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.

[0058] 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.

[0059] 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.

[0060] 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.

[0061] 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.

[0062] Should a user inadvertently dial beyond the desired dosage, the pen-type injector allows the dosage to be dialed down without dispense of medicinal product from the cartridge (Figure 10). The dose dial grip 76 is counter rotated. This causes the system to act in reverse. The flexible arm 52 now acts as a ratchet preventing the clicker from rotating. The torque transmitted through the clutch means 60 causes the saw teeth 56,66 to ride over one another to create the clicks corresponding to dialed dose reduction. Preferably the saw teeth 56,66 are so disposed that the circumferential extent of each saw tooth corresponds to a unit dose.

[0063] 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).

[0064] 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.

[0065] The longitudinal axial movement of the drive sleeve 30 causes the piston rod 20 to rotate through 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 drive mechanism for use in a drug delivery device comprising:
 - a housing comprising an inner surface;
 - a dose dial sleeve threadedly engaged with the inner surface of the housing through an outer thread having a first lead;
 - an insert that is rotationally and axially fixed relative to the housing;
 - a piston rod engaged with the insert, where the piston rod is threaded with a second lead and remains axially fixed relative to the housing during dose setting and moves axially relative to the insert during dose delivery;
 - a clutch operatively engaged with the dose dial sleeve to allow rotation of the dose dial sleeve during dose setting and dose delivery; and
 - a drive sleeve that extends about the piston rod and is operatively engaged with the clutch, where the clutch connects the drive sleeve and dose dial sleeve so they rotate together and disconnects the drive sleeve and dose dial sleeve so the dose dial sleeve can rotate relative to the drive sleeve,wherein the drive sleeve is configured to rotate relative to the piston rod and traverse axially towards the distal end during dose delivery.

2. The drive mechanism of claim 1 where the first lead and second lead are different.

3. The drive mechanism of claim 1 where the dose dial sleeve rotates and moves axially relative to the piston rod during dose setting and dose delivery.

4. The drive mechanism of claim 1 where the piston rod has a circular cross-section.

5. The drive mechanism of claim 1 where the clutch provides audible and tactile feedback indicative of unit doses of medicament.

6. The drive mechanism of claim 1 where the clutch provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament.

7. The drive mechanism of claim 6 where the clutch allows the dose cancelling without dispensing medicament.

8. The drive mechanism of claim 1 further comprising a T-shaped button having a skirt that extends distally from a head portion of the button and is seated in an annular recess of a dose dial grip on a proximal end of the dose dial sleeve.

9. The drive mechanism of claim 8 where the button further comprises a stem extending in an opening in the dose dial grip.

10. The drive mechanism of claim 8 where the button is rotatable relative to the dose dial sleeve.

11. The drive mechanism of claim 8 where axial movement of the button caused by distally applied pressure to the head initiates dose delivery by displacing the clutch axially with respect to the dose dial sleeve and drive sleeve.

12. The drive mechanism of claim 1 further comprising a clicker that provides audible clicks during dose setting, where each click is equal to a unit dose of medicament.

13. The drive mechanism of claim 1 where the dose dial sleeve rotates and moves axially during dose setting and dose delivery.

14. The drive mechanism of claim 1 further comprises a nut that tracks each set dose of medicament delivered.

15. The drive mechanism of claim 14 where the nut is threaded, axially slidable and rotationally fixed relative to the housing.

16. The drive mechanism of claim 14 where the nut moves axially in a proximal direction relative to the housing and drive sleeve for each dose set and delivered.

17. The drive mechanism of claim 14 where the drive sleeve further comprises a final dose stop.

18. The drive mechanism of claim 17 where the nut further comprises a corresponding final dose stop that engages the final dose stop on drive sleeve.

19. The drive mechanism of claim 18 where engagement of the final dose stop and the corresponding final dose stop prevent rotation of the dose dial sleeve during dose setting.

20. A drug delivery device comprising;
a cartridge holder;
a cap; and
the drive mechanism of claim 1.

21. A drug delivery device comprising:
a housing comprising a dose dispensing end and a first thread;
a dose indicator comprising a second thread that engages with the first thread;
a driving member comprising a third thread;
a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator;
a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread;
a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing;
wherein:
the housing is disposed at an outermost position of the drug delivery device;
the dose indicator is disposed between the housing and the sleeve and is configured to (i) rotate and traverse axially away from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing;
the driving member is configured to rotate relative to the piston rod;

the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator; and

the piston rod and the driving member are configured to rotate relative to one another during dose dispensing;

and the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.

22. The drug delivery device of claim 21 where the piston rod has a circular cross-section.

23. The drug delivery device of claim 21 further comprising a clutch.

24. The drug delivery device of claim 24 where the clutch provides audible and tactile feedback indicative of unit doses of medicament.

25. The drug delivery device of claim 24 where the clutch provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament.

26. The drug delivery device of claim 24 where the clutch allows the dose cancelling without dispensing medicament.

27. The drug delivery device of claim 24 further comprising a button seated in an annular recess of a dose dial grip on a proximal end of the dose indicator, where the button is rotatable relative to the dose indicator.

28. The drug delivery device of claim 27 where axial movement of the button caused by distally applied pressure to the button initiates dose delivery by displacing the clutch axially with respect to the dose indicator and driving member.

29. The drug delivery device of claim 21 further comprising a clicker that provides audible clicks during dose setting, where each click is equal to a unit dose of medicament.

30. The drug delivery device of claim 21 further comprises a nut that tracks each set dose of medicament delivered.

ABSTRACT

The present invention relates to injectors, such as pen-type injectors, that provide for administration of medicinal products from a multidose-cartridge and permit a user to set the delivery dose. The injector may include a housing, a piston rod adapted to operate through the housing, a dose dial sleeve located between the housing and the piston rod, and a drive sleeve located between the dose dial sleeve and the piston rod. The dose dial sleeve may have a helical thread of first lead and the drive sleeve may have a helical groove of second lead. The first lead of the helical thread and the second lead of the helical groove may be the same.

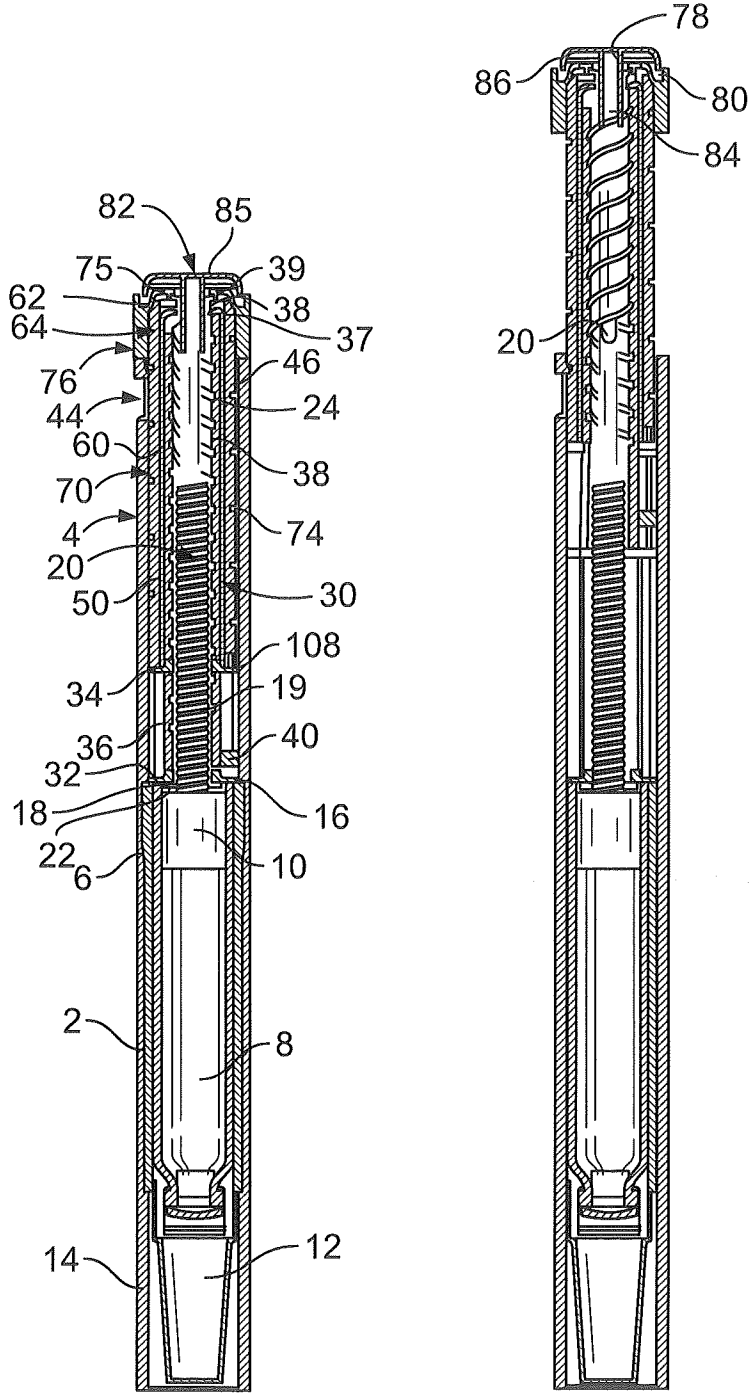


FIG. 1

FIG. 2

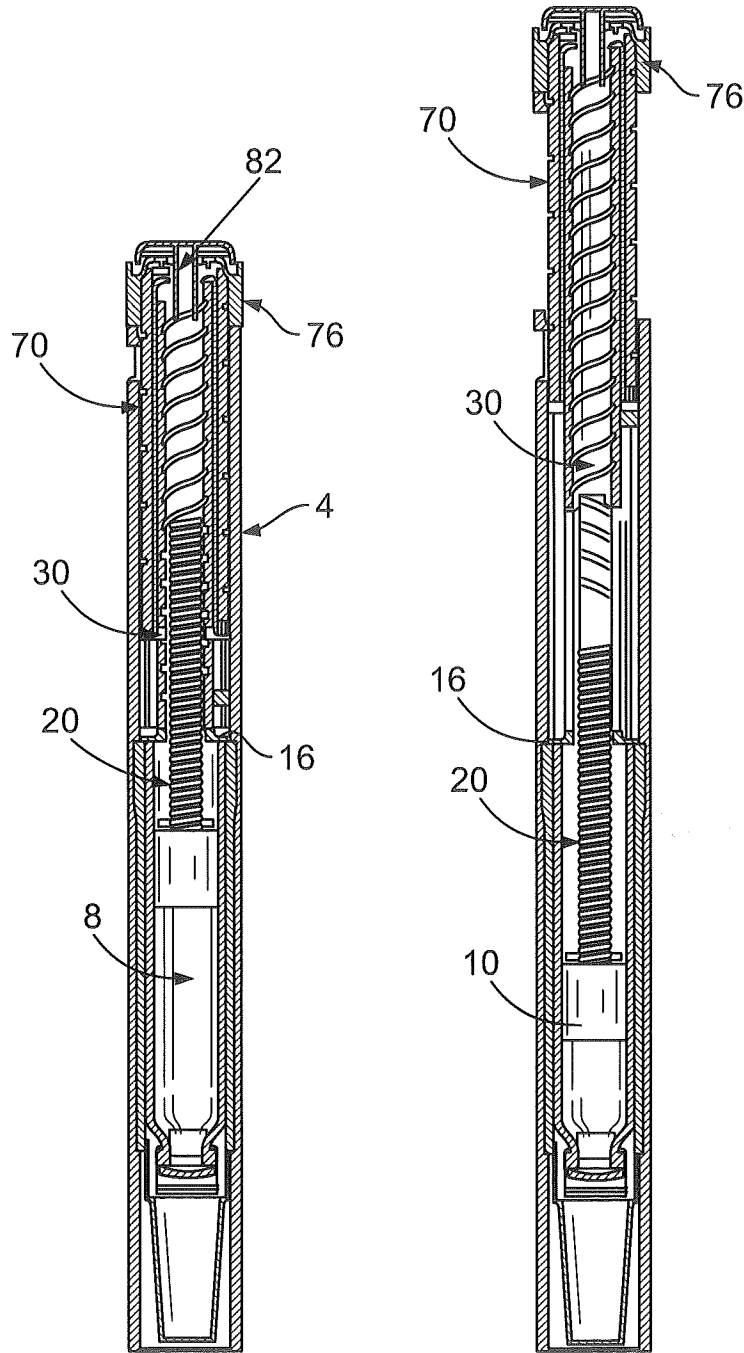


FIG. 3

FIG. 4

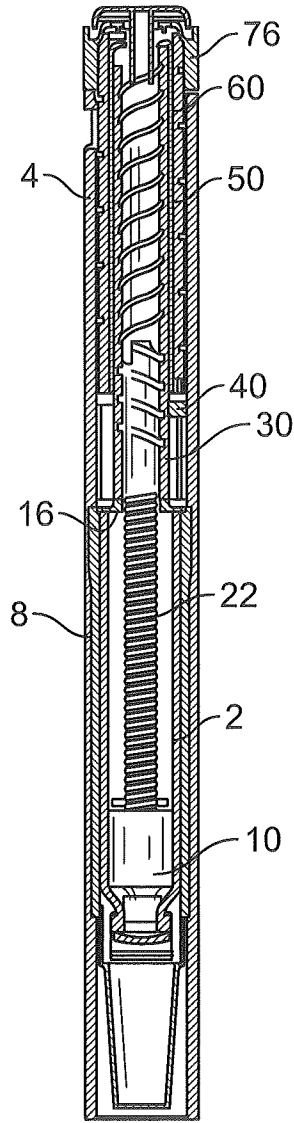


FIG. 5

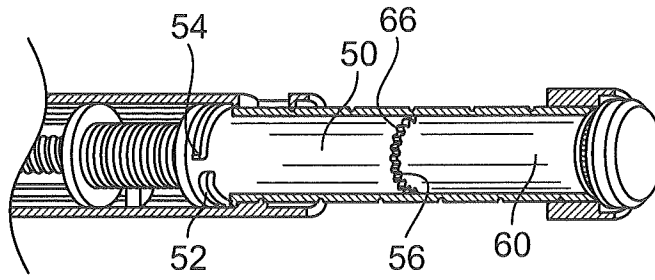


FIG. 6

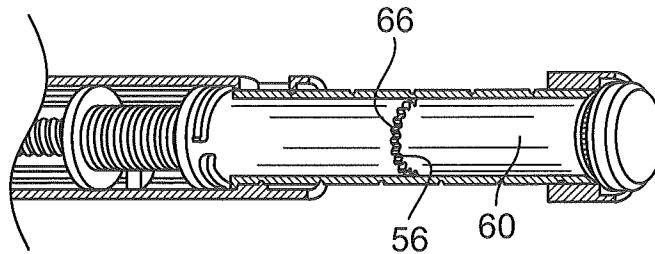


FIG. 7

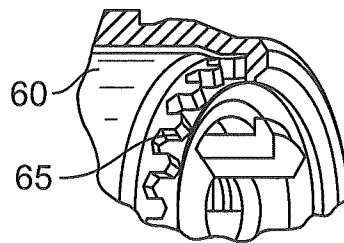


FIG. 8

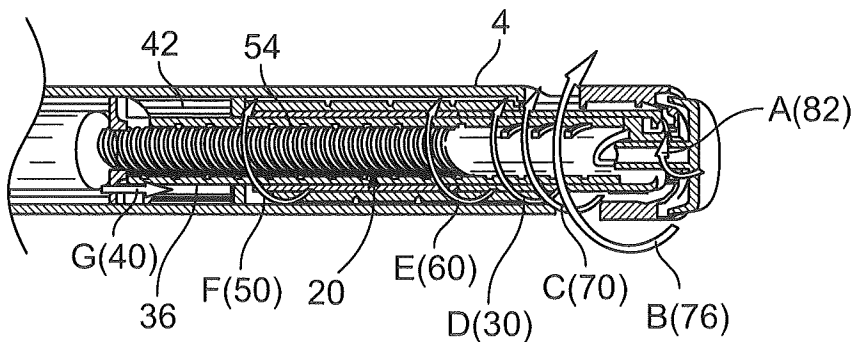


FIG. 9

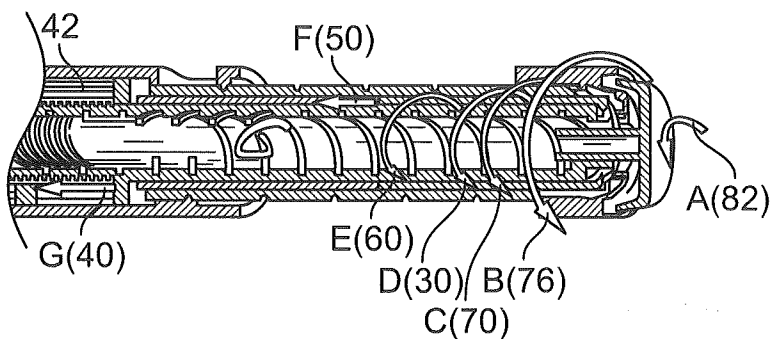


FIG. 10

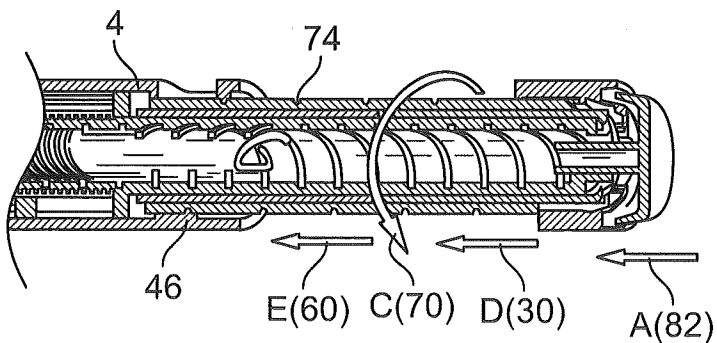


FIG. 11

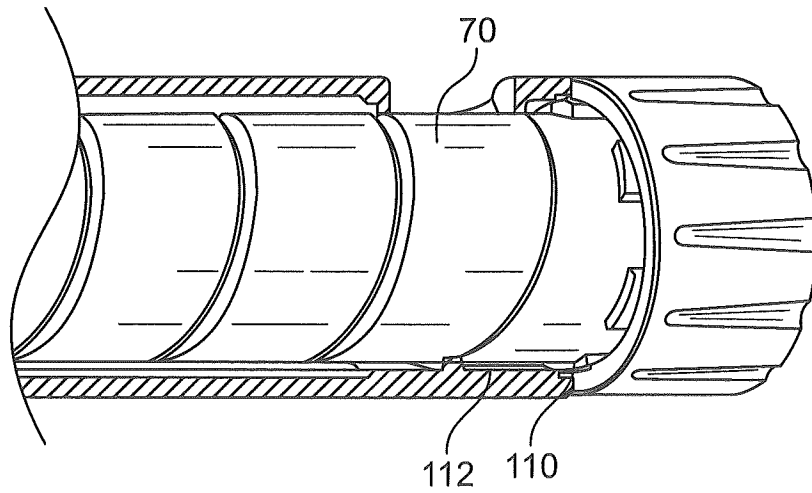
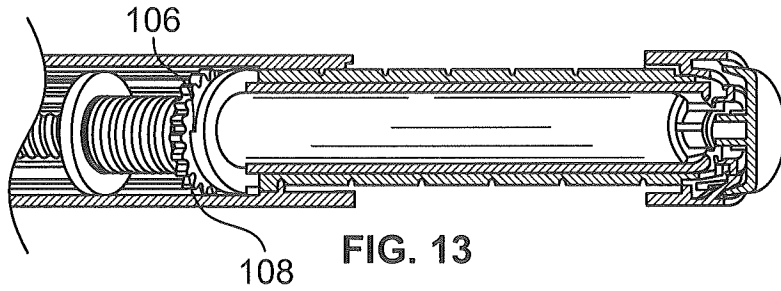
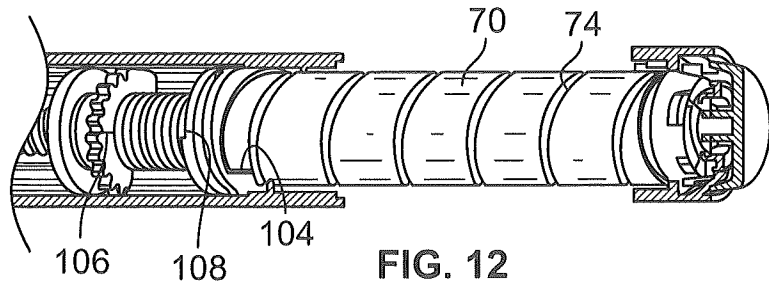


FIG. 14

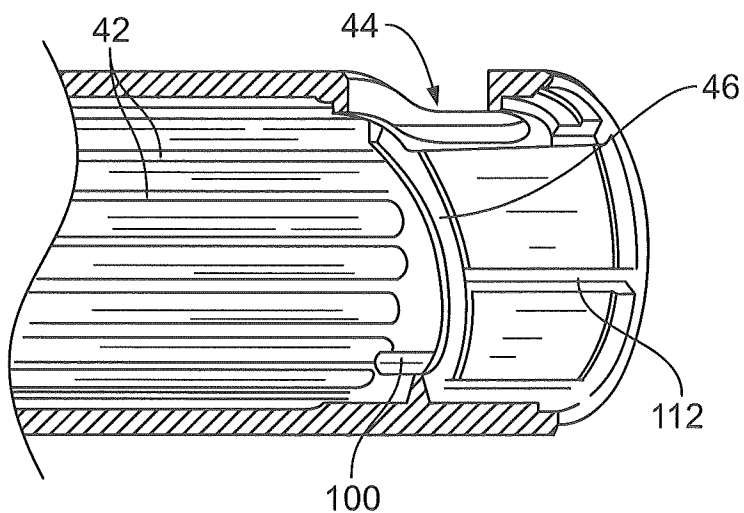


FIG. 15

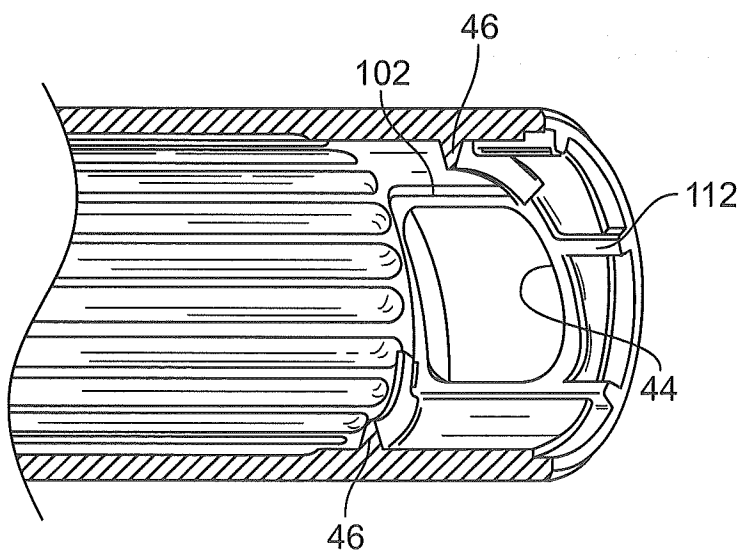
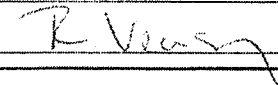


FIG. 16

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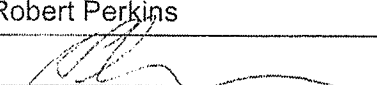
Title of Invention	PEN-TYPE INJECTOR
<p>As the below named inventor, I hereby declare that:</p> <p>This declaration is directed to: <input type="checkbox"/> The attached application, or <input checked="" type="checkbox"/> United States application or PCT international application number <u>13/919,251</u> filed on <u>June 17, 2013</u></p> <p>The above-identified application was made or authorized to be made by me.</p> <p>I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.</p> <p>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.</p> <p align="center">WARNING:</p> <p>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.</p>	
LEGAL NAME OF INVENTOR	
Inventor: <u>Robert Frederick Veasey</u>	Date (Optional): <u>6/3/13</u>
Signature: <u></u>	
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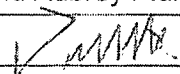
**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)**

Title of Invention	PEN-TYPE INJECTOR
<p>As the below named inventor, I hereby declare that:</p> <p>This declaration is directed to: <input type="checkbox"/> The attached application, or <input checked="" type="checkbox"/> United States application or PCT international application number <u>13/919,251</u> filed on <u>June 17, 2013</u></p> <p>The above-identified application was made or authorized to be made by me.</p> <p>I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.</p> <p>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.</p> <p align="center">WARNING:</p> <p>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.</p>	
LEGAL NAME OF INVENTOR	
Inventor: <u>Robert Perkins</u>	Date (Optional): <u>11 MAR 2015</u>
Signature: 	
<p>Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.</p>	

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute 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.

**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)**

Title of Invention	PEN-TYPE INJECTOR
<p>As the below named inventor, I hereby declare that:</p> <p>This declaration is directed to: <input type="checkbox"/> The attached application, or <input checked="" type="checkbox"/> United States application or PCT international application number <u>13/919,251</u> filed on <u>June 17, 2013</u></p> <p>The above-identified application was made or authorized to be made by me.</p> <p>I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.</p> <p>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.</p> <p align="center">WARNING:</p> <p>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.</p>	
LEGAL NAME OF INVENTOR	
Inventor: <u>David Aubrey Plumptre</u> Date (Optional): <u>6/3/13</u>	
Signature: 	
<p>Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.</p>	

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute 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.

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.

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:



Practitioners associated with Customer Number:

98548

OR

Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignments documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:



The address associated with Customer Number:

98548

OR


<input type="checkbox"/>	Firm or Individual Name		
<input type="checkbox"/>	Address		
<input type="checkbox"/>	City		
<input type="checkbox"/>	Country		
<input type="checkbox"/>	Telephone		Email

Assignee Name and Address: Sanofi-Aventis Deutschland GmbH
Brüningstrasse 50, D65929 Frankfurt am Main, Germany

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of the practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	September 24, 2012
Name	Dr. Michael Bankmann Dieter Breuer	Telephone	0049-69-305-5794
Title	Prokurist Authorized Signatory		

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. 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 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 10-1188-US-CON8)

Applicant: Robert Frederick Veasey, et al.
Appl. No.: TBD
Filed: May 17, 2016
Title: IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR
TC/A.U.: 3763
Confirmation No.: TBD
Examiner: TBD

INFORMATION DISCLOSURE STATEMENT LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 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 numbers to which the above-identified parent application claims priority to under 35 U.S.C. §120 are 14/946,203; 14/635,573; 13/919,251; 13/040,198; 11/483,546; and 10/790,225.

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.

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.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff LLP

Dated: May 17, 2016

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

McDonnell Boehnen
Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, IL 60606
Tel: 312-913-0001

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		
	Filing Date		2016-05-17
	First Named Inventor	Robert Frederick Veasey	
	Art Unit		
	Examiner Name		
	Attorney Docket Number		10-1188-US-CON8

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	4470317		1984-09-11	Sabloewski et al.	
	2	4498904		1985-02-12	Turner et al.	
	3	4568335		1986-02-04	Updike et al.	
	4	4585439		1986-04-29	Michel	
	5	4833379		1989-05-23	Kaibel et al.	
	6	4863072		1989-09-05	Perler	
	7	4865591		1989-09-12	Sams	
	8	4883472		1989-11-28	Michel	

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Examiner Name		
Attorney Docket Number	10-1188-US-CON8	

9	4919596		1990-04-24	Slate et al.
10	4936833		1990-06-26	Sams
11	4973318		1990-11-27	Holm et al.
12	4994033		1991-02-19	Shockey et al.
13	5112317		1992-05-12	Michel
14	5207752		1993-05-04	Sorenson et al.
15	5226895		1993-07-13	Harris
16	5246417		1993-09-21	Haak et al.
17	5257987		1993-11-02	Athayde et al.
18	5271527		1993-12-21	Haber et al.
19	5279585		1994-01-18	Balkwill

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20	5279586		1994-01-18	Balkwill
21	5281198		1994-01-25	Haber et al.
22	5304152		1994-04-19	Sams
23	5308340		1994-05-03	Harris
24	5314412		1994-05-24	Rex
25	5318540		1994-06-07	Athayde et al.
26	5320609		1994-06-14	Haber et al.
27	5328486		1994-07-12	Woodruff
28	5331954		1994-07-26	Rex et al.
29	5370629		1994-12-06	Michel et al.
30	5383865		1995-01-24	Michel

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31	5440976		1995-08-15	Giuliano et al.
32	5445606		1995-08-29	Haak et al.
33	5447150		1995-09-05	Bacon
34	5478316		1995-12-26	Bitdinger et al.
35	5480387		1996-01-02	Gabriel et al.
36	5492534		1996-02-20	Athayde et al.
37	5505704		1996-04-09	Pawelka et al.
38	5546932		1996-08-20	Galli
39	5549575		1996-08-27	Giambattista et al.
40	5584815		1996-12-17	Pawelka et al.
41	5591136		1997-01-07	Gabriel

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42	5599314		1997-02-04	Neill
43	5611783		1997-03-18	Mikkelsen
44	5626566		1997-05-06	Peterson et al.
45	5645052		1997-07-08	Kersey
46	5674204		1997-10-07	Chanoch
47	5681285		1997-10-28	Ford et al.
48	5688251		1997-11-18	Chanoch
49	5709662		1998-01-20	Olive et al.
50	5716990		1998-02-10	Bagshawe et al.

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

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U.S.PATENT APPLICATION PUBLICATIONS

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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
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1	20020052578	2002-05-02	Moller
2	20020077852	2002-06-20	Ford et al.
3	20020120235	2002-08-29	Enggaard
4	20030039679	2003-02-27	Duirs
5	20030172924	2003-09-18	Staniforth et al.
6	20040059299	2004-03-25	Moller et al.
7	20040186431	2004-09-23	Graf et al.
8	20040210199	2004-10-21	Atterbury et al.
9	20040236282	2004-11-25	Braithwaite
10	20040249348	2004-12-09	Wimpenny et al.
11	20040260247	2004-12-23	Veasey et al.

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Art Unit		
Examiner Name		
Attorney Docket Number	10-1188-US-CON8	

12	20040267207	2004-12-30	Veasey et al.
13	20040267208	2004-12-30	Veasey et al.
14	20050004529	2005-01-06	Veasey et al.
15	20050019400	2005-01-27	Deveney et al.
16	20050033244	2005-02-10	Veasey et al.
17	20050055011	2005-03-10	Enggaard
18	20050113765	2005-05-26	Veasey et al.
19	20050205083	2005-09-22	Staniforth et al.
20	20050209570	2005-09-22	Moller
21	20050268915	2005-12-08	Wassenaar et al.

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FOREIGN PATENT DOCUMENTS

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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	3609555	DE		1987-09-24	Pomer		
	2	0673482	EP		1998-04-29	Sams		
	3	0937471	EP		1999-08-25	Becton, Dickinson & Co.		
	4	0937476	EP		1999-08-25	Becton, Dickinson & Co.		
	5	1294418	EP		2005-07-09	Moeller, Claus Schmidt		
	6	2583291	FR		1986-12-19	Hazon et al.		
	7	2767479	FR		1999-02-26	Frezza		
	8	05-337179	JP		1993-12-21	Balkwill		
	9	06-296691	JP		1994-10-25	Michel et al.		
	10	2111019	RU		1998-05-20	Khvorostov		

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11	1990/09202	WO		1990-08-23	Ejlersen		
12	1991/10460	WO		1991-07-25	Bonnichsen		
13	1991/14467	WO		1991-10-03	Bernard SAMS		
14	1996/26754	WO		1996-09-06	Sams		
15	1998/57688	WO		1998-12-23	Klitmose et al.		
16	1999/16487	WO		1999-04-08	Bitdinger et al.		
17	1999/38554	WO		1999-08-05	Steenfeldt-Jensen et al.		
18	2001/10484	WO		2000-07-31	Charles et al.		

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

NON-PATENT LITERATURE DOCUMENTS

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	J.S. Reissue Patent Application No. 10/442,855, "Injection Syringe", Filed May 21, 2003, including copies of as-filed specification, drawings, abstract, and claims, as well as the reissue declaration and a copy of list of documents found in image file wrapper in PAIR as of January 23, 2008	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number			
	Filing Date		2016-05-17	
	First Named Inventor	Robert Frederick Veasey		
	Art Unit			
	Examiner Name			
	Attorney Docket Number		10-1188-US-CON8	

2	U.S. Reissue Patent Application No. 10/960,900, "Injection Syringe", Filed October 7, 2004, including copies of as-filed specification, drawings, abstract, and claims, as well as the reissue declaration and a copy of list of documents found in image file wrapper in PAIR as of January 23, 2008.
3	U.S. Reissue Patent Application No. 11/121,331, "Injection Syringe", Filed May 3, 2005, including copies of as-filed specification, drawings, abstract, and claims, as well as the reissue declaration and a copy of list of documents found in image file wrapper in PAIR as of January 23, 2008.
4	U.S. Reissue Patent Application No. 11/640,610, "Injection Syringe", Filed December 18, 2006, including copies of as-filed specification, drawings, abstract, and claims, as well as the reissue declaration and a copy of list of documents found in image file wrapper in PAIR as of January 23, 2008.
5	First Office Action on merits mailed March 14, 2006 in U.S. Application No. 10/790,866 (11 pages).

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

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			
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	First Named Inventor	Robert Frederick Veasey		
	Art Unit			
	Examiner Name			
	Attorney Docket Number		10-1188-US-CON8	

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	/David M. Frischkorn/	Date (YYYY-MM-DD)	2016-05-17
Name/Print	David M. Frischkorn	Registration Number	32833

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 records.
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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		
	Filing Date		2016-05-17
	First Named Inventor	Robert Frederick Veasey	
	Art Unit		
	Examiner Name		
	Attorney Docket Number		10-1188-US-CON8

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	5743889		1998-04-28	Sams	
	2	5755692		1998-05-26	Manicom	
	3	5823998		1998-10-20	Yamagata	
	4	5843036		1998-12-01	Olive et al.	
	5	5882718		1999-03-16	Pommer et al.	
	6	5898028		1999-04-27	Jensen et al.	
	7	5921966		1999-07-13	Bendek et al.	
	8	5928201		1999-07-27	Poulsen et al.	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Application Number		
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First Named Inventor	Robert Frederick Veasey	
Art Unit		
Examiner Name		
Attorney Docket Number	10-1188-US-CON8	

9	5947934		1999-09-07	Hansen et al.
10	5951530		1999-09-14	Steengaard et al.
11	5954689		1999-09-21	Poulsen
12	5961496		1999-10-05	Nielsen et al.
13	5980491		1999-11-09	Hansen
14	5984900		1999-11-16	Mikkelson
15	6003736		1999-12-21	Ljunggren
16	6004297		1999-12-21	Steenfeldt-Jensen et al.
17	6010485		2000-01-04	Buch-Rasmussen et al.
18	6033376		2000-03-07	Rockley
19	6033377		2000-03-07	Rasmussen et al.

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Application Number		
Filing Date		2016-05-17
First Named Inventor	Robert Frederick Veasey	
Art Unit		
Examiner Name		
Attorney Docket Number	10-1188-US-CON8	

20	6074372		2000-06-13	Hansen
21	6083197		2000-07-04	Umbaugh
22	6110149		2000-08-29	Klitgaard et al.
23	6129080		2000-10-10	Pitcher et al.
24	6146361		2000-11-14	DiBiasi et al.
25	6193698		2001-02-27	Kirchhofer et al.
26	6221046		2001-04-24	Burroughs et al.
27	6221053		2001-04-24	Walters et al.
28	6231540		2001-05-15	Smedegaard
29	6235004		2001-05-22	Steenfeldt-Jensen et al.
30	6248090		2001-06-19	Jensen et al.

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Application Number		
Filing Date		2016-05-17
First Named Inventor	Robert Frederick Veasey	
Art Unit		
Examiner Name		
Attorney Docket Number		10-1188-US-CON8

31	6248095		2001-06-19	Giambattista et al.
32	6258062		2001-07-10	Thielen et al.
33	6269340		2001-07-31	Ford et al.
34	6277097		2001-08-21	Mikkelsen et al.
35	6277098		2001-08-21	Klitmose et al.
36	6281225		2001-08-28	Hearst et al.
37	6283941		2001-09-04	Schoenfeld et al.
38	6287283		2001-09-11	Ljunggreen et al.
39	6302869		2001-10-16	Klitgaard
40	6312413		2001-11-06	Jensen et al.
41	6340357		2002-01-22	Poulsen et al.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Filing Date		2016-05-17
First Named Inventor	Robert Frederick Veasey	
Art Unit		
Examiner Name		
Attorney Docket Number	10-1188-US-CON8	

42	6514230		2003-02-04	Munk et al.
43	6547763		2003-04-15	Steenfeldt-Jensen et al.
44	6547764		2003-04-15	Larsen et al.
45	6562011		2003-05-13	Buch-Rasmussen et al.
46	6569126		2003-05-27	Poulsen et al.
47	6582404		2003-06-24	Klitgaard et al.
48	6605067		2003-08-12	Larsen
49	6613019		2003-09-02	Munk
50	6663602		2003-12-16	Moller
51	6692472		2004-02-17	Hansen et al.
52	6716198		2004-04-06	Larsen

**INFORMATION DISCLOSURE
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Application Number		
Filing Date		2016-05-17
First Named Inventor	Robert Frederick Veasey	
Art Unit		
Examiner Name		
Attorney Docket Number	10-1188-US-CON8	

53	6726661		2004-04-27	Munk et al.
54	6770288		2004-08-03	Duirs
55	6796970		2004-09-28	Klitmose et al.
56	6893415		2005-05-17	Madsen et al.
57	6899698		2005-05-31	Sams
58	6899699		2005-05-31	Enggaard
59	6945961		2005-09-20	Miller et al.
60	7008399		2006-03-07	Larsen et al.
61	7090662		2006-08-15	Wimpenny et al.
62	7094221		2006-08-22	Veasey et al.
63	7104972		2006-09-12	Moller et al.

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

Application Number		
Filing Date		2016-05-17
First Named Inventor	Robert Frederick Veasey	
Art Unit		
Examiner Name		
Attorney Docket Number		10-1188-US-CON8

64	7133329		2006-11-07	Skyggebjerg et al.
65	7175055		2007-02-13	Hansen et al.
66	7241278		2007-07-10	Moller
67	7935088		2011-05-03	Veasey et al.
68	8512297		2013-08-20	Veasey et al.
69	2722931		1955-11-08	May
70	2717597		1955-09-13	Hein, Jr.

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

Add

U.S.PATENT APPLICATION PUBLICATIONS

Remove

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

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

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FOREIGN PATENT DOCUMENTS

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

Application Number		
Filing Date		2016-05-17
First Named Inventor	Robert Frederick Veasey	
Art Unit		
Examiner Name		
Attorney Docket Number		10-1188-US-CON8

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							

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

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1		

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

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		2016-05-17	
	First Named Inventor	Robert Frederick Veasey		
	Art Unit			
	Examiner Name			
	Attorney Docket Number		10-1188-US-CON8	

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	/David M. Frischkorn/	Date (YYYY-MM-DD)	2016-05-17
Name/Print	David M. Frischkorn	Registration Number	32833

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 records.
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.
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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.

Electronic Patent Application Fee Transmittal

Application Number:				
Filing Date:				
Title of Invention:	IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR			
First Named Inventor/Applicant Name:	Robert Frederick Veasey			
Filer:	David M. Frischkorn			
Attorney Docket Number:	10-1188-US-CON8			
Filed as Large Entity				
Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Utility application filing	1011	1	280	280
Utility Search Fee	1111	1	600	600
Utility Examination Fee	1311	1	720	720
Request for Prioritized Examination	1817	1	4000	4000
Pages:				
Claims:				
Claims in Excess of 20	1202	10	80	800
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Publ. Fee- Early, Voluntary, or Normal	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				6540

Electronic Acknowledgement Receipt

EFS ID:	25797754
Application Number:	15156616
International Application Number:	
Confirmation Number:	1083
Title of Invention:	IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Customer Number:	98548
Filer:	David M. Frischkorn
Filer Authorized By:	
Attorney Docket Number:	10-1188-US-CON8
Receipt Date:	17-MAY-2016
Filing Date:	
Time Stamp:	13:44:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$6540
RAM confirmation Number	11236
Deposit Account	132490
Authorized User	FRISCHKORN, DAVID M.

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 CFR 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	TrackOne Request	10-1188-US- CON8_TrackOne_Request.PDF	136695	no	2
			198b6cb5ef77dfe09f3fafb5d67e3d6bf7928f26		
Warnings:					
Information:					
2	Application Data Sheet	10-1188-US-CON8_ADS.PDF	1823837	no	9
			f78b0b85ddb7c2ee6ecc802457083c0026e94ba0		
Warnings:					
Information:					
3		10-1188-US-CON8_Spec.pdf	121862	yes	16
			fa4003916f82db8572e678badeeb13e49e52ad2b		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	10	
	Claims		11	15	
	Abstract		16	16	
Warnings:					
Information:					
4	Drawings-only black and white line drawings	10-1188-US-CON8_Drawings.PDF	558914	no	7
			7fd86377c4005bab6ebc6152f02ca4f97eb6c3d5		
Warnings:					
Information:					
5	Oath or Declaration filed	10-1188-US- CON8_Declarations.PDF	268101	no	3
			91e1f4327becf6332f1f993a7bae6e9e8bc0b0d7		
Warnings:					
Information:					
6	Power of Attorney	10-1188-US-CON8_POA.PDF	181881	no	1
			e66a06d15e3941882aaad0152ea902403b00257e		

Warnings:					
Information:					
7	Transmittal Letter	10-1188-US- CON8_IDS_Transmittal.pdf	91256 <small>ec7197613c4eac89b2f4d92e415696a21c720aab</small>	no	2
Warnings:					
Information:					
8	Information Disclosure Statement (IDS) Form (SB08)	10-1188-US-CON8_IDS_1.PDF	1009890 <small>95010830e446f5f1fb4ab9d3c9d4c777c294a9f0</small>	no	12
Warnings:					
Information:					
9	Information Disclosure Statement (IDS) Form (SB08)	10-1188-US-CON8_IDS_2.PDF	1008818 <small>d0f89b167d366cee46cdce4ae1412374e6a5f7e4</small>	no	10
Warnings:					
Information:					
10	Fee Worksheet (SB06)	fee-info.pdf	41968 <small>4e9b0c2fa8c2c59220438bd31d735fb8261c75c9</small>	no	2
Warnings:					
Information:					
Total Files Size (in bytes):				5243222	
<p>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.</p> <p><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.</p> <p><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.</p> <p><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.</p>					

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number
15/156,616

APPLICATION AS FILED - PART I

(Column 1) (Column 2)

FOR	NUMBER FILED	NUMBER EXTRA
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A
TOTAL CLAIMS (37 CFR 1.16(j))	30 minus 20 = *	10
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 = *	
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))		

SMALL ENTITY

RATE(\$)	FEE(\$)
N/A	
N/A	
N/A	
TOTAL	

OR OTHER THAN SMALL ENTITY

RATE(\$)	FEE(\$)
N/A	280
N/A	600
N/A	720
x 80 =	800
x 420 =	0.00
	0.00
	0.00
TOTAL	2400

* If the difference in column 1 is less than zero, enter "0" in column 2.

APPLICATION AS AMENDED - PART II

(Column 1) (Column 2) (Column 3)

AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total (37 CFR 1.16(i))	*	Minus	**	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=
	Application Size Fee (37 CFR 1.16(s))				
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					

SMALL ENTITY

RATE(\$)	ADDITIONAL FEE(\$)
x =	
x =	
TOTAL ADD'L FEE	

OR OTHER THAN SMALL ENTITY

RATE(\$)	ADDITIONAL FEE(\$)
x =	
x =	
TOTAL ADD'L FEE	

(Column 1) (Column 2) (Column 3)

AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total (37 CFR 1.16(i))	*	Minus	**	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=
	Application Size Fee (37 CFR 1.16(s))				
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					

SMALL ENTITY

RATE(\$)	ADDITIONAL FEE(\$)
x =	
x =	
TOTAL ADD'L FEE	

OR OTHER THAN SMALL ENTITY

RATE(\$)	ADDITIONAL FEE(\$)
x =	
x =	
TOTAL ADD'L FEE	

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



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Alexandria, Virginia 22313-1450
www.uspto.gov

Table with 7 columns: APPLICATION NUMBER, FILING or 371(c) DATE, GRP ART UNIT, FIL FEE REC'D, ATTY DOCKET NO, TOT CLAIMS, IND CLAIMS. Row 1: 15/156,616, 05/17/2016, 3763, 2400, 10-1188-US-CON8, 30, 2

CONFIRMATION NO. 1083

FILING RECEIPT

98548
McDonnell Boehnen Hulbert & Berghoff LLP
Sanofi - Aventis
300 South Wacker Drive
Chicago, IL 60606



Date Mailed: 06/02/2016

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, Warwickshire, UNITED KINGDOM;
David Aubrey Plumptre, Worcestershire, UNITED KINGDOM;

Applicant(s)

SANOFI-AVENTIS DEUTSCHLAND GMBH, Frankfurt am Main, GERMANY;

Power of Attorney: The patent practitioners associated with Customer Number 98548

Domestic Priority data as claimed by applicant

This application is a CON of 14/946,203 11/19/2015
which is a CON of 14/635,573 03/02/2015 PAT 9233211
which is a CON of 13/919,251 06/17/2013 PAT 9011391
which is a DIV of 13/040,198 03/03/2011 PAT 8512297
which is a CON of 11/483,546 07/11/2006 PAT 7918833
which 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 Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 06/01/2016

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/156,616**

Projected Publication Date: 09/08/2016

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 37, Code of Federal Regulations, 5.11 & 5.15**

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

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

NOT GRANTED

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

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The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

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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
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www.uspto.gov

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
15/156,616 05/17/2016 Robert Frederick Veasey 10-1188-US-CON8 1083

98548 7590 06/23/2016
McDonnell Boehnen Hulbert & Berghoff LLP
Sanofi - Aventis
300 South Wacker Drive
Chicago, IL 60606

EXAMINER

Table with 2 columns: ART UNIT, PAPER NUMBER
3763

Table with 2 columns: MAIL DATE, DELIVERY MODE
06/23/2016 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.



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Commissioner for Patents
United States Patent and Trademark Office
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Alexandria, VA 22313-1450
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Doc Code: TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.:15/156,616
<p>1. THE REQUEST FILED <u>May 17, 2016</u> IS GRANTED.</p> <p>The above-identified application has met the requirements for prioritized examination</p> <p>A. <input checked="" type="checkbox"/> for an original nonprovisional application (Track I).</p> <p>B. <input type="checkbox"/> for an application undergoing continued examination (RCE).</p> <p>2. The above-identified application will undergo prioritized examination. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:</p> <p>A. filing a <u>petition for extension of time</u> to extend the time period for filing a reply;</p> <p>B. filing an <u>amendment to amend the application to contain more than four independent claims, more than thirty total claims</u>, or a multiple dependent claim;</p> <p>C. filing a <u>request for continued examination</u>;</p> <p>D. filing a notice of appeal;</p> <p>E. filing a request for suspension of action;</p> <p>F. mailing of a notice of allowance;</p> <p>G. mailing of a final Office action;</p> <p>H. completion of examination as defined in 37 CFR 41.102; or</p> <p>I. abandonment of the application.</p> <p>Telephone inquiries with regard to this decision should be directed to Vanitha Elgart at 571-272-7395.</p> <p>/Vanitha Elgart/ Vanitha Elgart [Signature]</p> <p>Petitions Examiner, Office of Petitions (Title)</p>	

U.S. Patent and Trademark Office
PTO-2298 (Rev. 02-2012)

Office of Petitions: Decision Count Sheet

Mailing Month

Application No.

15156616



For US serial numbers: enter number only, no slashes or commas. Ex: 10123456

For PCT: enter "51+single digit of year of filing+last 5 numbers", Ex. for PCT/US05/12345, enter 51512345

Deciding Official:

ELGART, VANITHA

Count (1) - Palm Credit

15/156,616

Decision: GRANT

FINANCE WORK NEEDED

Select Check Box for YES



Decision Type: 643 - Track One request



Notes:

Count (2)

Decision: n/a

FINANCE WORK NEEDED

Select Check Box for YES

Decision Type: NONE

Notes:

Count (3)

Decision: n/a

FINANCE WORK NEEDED

Select Check Box for YES

Decision Type: NONE

Notes:

Initials of Approving Official (if required)

If more than 3 decisions, attach 2nd count sheet & mark this box

Printed on:

Office of Petitions Internal Document - Ver. 5.0

Office of Petitions: Routing Sheet



Application No. 15/156,616

This application is being forwarded to your office for further processing. A decision has been rendered on a petition filed in this application, as indicated below. For details of this decision, please see the document PET.OP.DEC filed on the same date as this document.

GRANTED

DISMISSED

DENIED



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15/156,616 05/17/2016 Robert Frederick Veasey 10-1188-US-CON8 1083

98548 7590 08/10/2016
McDonnell Boehnen Hulbert & Berghoff LLP
Sanofi - Aventis
300 South Wacker Drive
Chicago, IL 60606

EXAMINER

MENDEZ, MANUEL A

ART UNIT PAPER NUMBER

3763

MAIL DATE DELIVERY MODE

08/10/2016

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. 15/156,616	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) 1-30 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) Claim(s) _____ is/are allowed.
- 7) Claim(s) 1-30 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 5/17/2016 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. 10/790225.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

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

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 3) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____. |
| 2) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date <u>5/17/2016, 5/17/2016, and 5/17/2016</u> . | 4) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Specification

The disclosure is objected to because of the following informalities:

In paragraph [0001], U.S. Patent Application No. 14/946,203 must be updated to disclose the respective U.S. Patent Number of the allowed application.

Appropriate correction is required.

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 conflicting claims 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); *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 nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) 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 www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 7,918,833. Although the claims at issue are not identical, they are not patentably distinct from each other because the cited patent discloses (1) a housing [see claim 1; line 2], (2) a dose dial sleeve [see

Art Unit: 3763

claim 1; line 4], (3) an insert [see claim 2; line 4], (4) a piston rod [see claim 1; line 3], (5) a clutch [see claim 2; line 15], (6) a drive sleeve [claim 1; line 7].

Allowable Subject Matter

In relation to prior art rejections, claims 1-30 are considered to be allowable over the prior art of record. As stated above, a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

The following is a statement of reasons for the indication of allowable subject matter:

In relation to claim 1, the prior art of record does not disclose or suggest, *inter alia*, a clutch operatively engaged with the dose dial sleeve to allow rotation of the dose dial sleeve during dose setting and dose delivery; and a drive sleeve that extends about the piston rod and is operatively engaged with the clutch, where the clutch connects the drive sleeve and dose dial sleeve so they rotate together and disconnects the drive sleeve and dose dial sleeve so the dose dial sleeve can rotate relative to the drive sleeve, wherein the drive sleeve is configured to rotate relative to the piston rod and traverse axially towards the distal end during dose delivery.

In relation to claim 21, the prior art of record does not disclose or suggest, *inter alia*, the functional language disclosing “wherein: the housing is disposed at an outermost position of the drug delivery device; the dose indicator is disposed between

Art Unit: 3763

the housing and the sleeve and is configured to (i) rotate and traverse axially away from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing; the driving member is configured to rotate relative to the piston rod; the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator; and the piston rod and the driving member are configured to rotate relative to one another during dose dispensing; and the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.”

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. Nathan R. Price can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

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. 15/156,616	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	CPC Classification	US Classification
*	A US-7,918,833 B2	04-2011	Veasey; Robert Frederick	A61M5/31546	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	CPC Classification
N					
O					
P					
Q					
R					
S					
T					

NON-PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	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.


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BIB DATA SHEET
CONFIRMATION NO. 1083

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO. 10-1188-US-CON8	
15/156,616	05/17/2016	604	3763		
APPLICANTS SANOFI-AVENTIS DEUTSCHLAND GMBH, Frankfurt am Main, GERMANY;					
INVENTORS Robert Frederick Veasey, Warwickshire, UNITED KINGDOM; Robert Perkins, Warwickshire, UNITED KINGDOM; David Aubrey Plumptre, Worcestershire, UNITED KINGDOM;					
** CONTINUING DATA ***** This application is a CON of 14/946,203 11/19/2015 PAT 9408979 which is a CON of 14/635,573 03/02/2015 PAT 9233211 which is a CON of 13/919,251 06/17/2013 PAT 9011391 which is a DIV of 13/040,198 03/03/2011 PAT 8512297 which is a CON of 11/483,546 07/11/2006 PAT 7918833 which is a CON of 10/790,225 03/02/2004 ABN					
** FOREIGN APPLICATIONS ***** UNITED KINGDOM 0304822.0 03/03/2003					
** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 06/01/2016					
Foreign Priority claimed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No 35 USC 119(a-d) conditions met <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Verified and /MANUEL A MENDEZ/ Acknowledged Examiner's Signature	<input type="checkbox"/> Met after Allowance Initials	STATE OR COUNTRY UNITED KINGDOM	SHEETS DRAWINGS 7	TOTAL CLAIMS 30	INDEPENDENT CLAIMS 2
ADDRESS McDonnell Boehnen Hulbert & Berghoff LLP Sanofi - Aventis 300 South Wacker Drive Chicago, IL 60606 UNITED STATES					
TITLE PEN-TYPE INJECTOR					
FILING FEE RECEIVED 2400	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:			<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit	

Doc code: IDS

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2016. OMB 0651-0031
 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	
	Filing Date	2016-05-17
	First Named Inventor	Robert Frederick Veasey
	Art Unit	
	Examiner Name	
	Attorney Docket Number	10-1188-US-CON8

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	4470317		1984-09-11	Sabloewski et al.	
	2	4498904		1985-02-12	Turner et al.	
	3	4568335		1986-02-04	Updike et al.	
	4	4585439		1986-04-29	Michel	
	5	4833379		1989-05-23	Kaibel et al.	
	6	4863072		1989-09-05	Perler	
	7	4865591		1989-09-12	Sams	
	8	4883472		1989-11-28	Michel	

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

Application Number		
Filing Date		2016-05-17
First Named Inventor	Robert Frederick Veasey	
Art Unit		
Examiner Name		
Attorney Docket Number	10-1188-US-CON8	

9	4919596		1990-04-24	Slate et al.
10	4936833		1990-06-26	Sams
11	4973318		1990-11-27	Holm et al.
12	4994033		1991-02-19	Shockey et al.
13	5112317		1992-05-12	Michel
14	5207752		1993-05-04	Sorenson et al.
15	5226895		1993-07-13	Harris
16	5246417		1993-09-21	Haak et al.
17	5257987		1993-11-02	Athayde et al.
18	5271527		1993-12-21	Haber et al.
19	5279585		1994-01-18	Balkwill

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

Application Number		
Filing Date		2016-05-17
First Named Inventor	Robert Frederick Veasey	
Art Unit		
Examiner Name		
Attorney Docket Number	10-1188-US-CON8	

20	5279586		1994-01-18	Balkwill
21	5281198		1994-01-25	Haber et al.
22	5304152		1994-04-19	Sams
23	5308340		1994-05-03	Harris
24	5314412		1994-05-24	Rex
25	5318540		1994-06-07	Athayde et al.
26	5320609		1994-06-14	Haber et al.
27	5328486		1994-07-12	Woodruff
28	5331954		1994-07-26	Rex et al.
29	5370629		1994-12-06	Michel et al.
30	5383865		1995-01-24	Michel

**INFORMATION DISCLOSURE
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(Not for submission under 37 CFR 1.99)

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Art Unit		
Examiner Name		
Attorney Docket Number	10-1188-US-CON8	

31	5440976		1995-08-15	Giuliano et al.
32	5445606		1995-08-29	Haak et al.
33	5447150		1995-09-05	Bacon
34	5478316		1995-12-26	Bitdinger et al.
35	5480387		1996-01-02	Gabriel et al.
36	5492534		1996-02-20	Athayde et al.
37	5505704		1996-04-09	Pawelka et al.
38	5546932		1996-08-20	Galli
39	5549575		1996-08-27	Giambattista et al.
40	5584815		1996-12-17	Pawelka et al.
41	5591136		1997-01-07	Gabriel

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Application Number		
Filing Date		2016-05-17
First Named Inventor	Robert Frederick Veasey	
Art Unit		
Examiner Name		
Attorney Docket Number	10-1188-US-CON8	

42	5599314		1997-02-04	Neill
43	5611783		1997-03-18	Mikkelsen
44	5626566		1997-05-06	Peterson et al.
45	5645052		1997-07-08	Kersey
46	5674204		1997-10-07	Chanoch
47	5681285		1997-10-28	Ford et al.
48	5688251		1997-11-18	Chanoch
49	5709662		1998-01-20	Olive et al.
50	5716990		1998-02-10	Bagshawe et al.

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U.S.PATENT APPLICATION PUBLICATIONS

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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1	20020052578	2002-05-02	Moller
2	20020077852	2002-06-20	Ford et al.
3	20020120235	2002-08-29	Enggaard
4	20030039679	2003-02-27	Duirs
5	20030172924	2003-09-18	Staniforth et al.
6	20040059299	2004-03-25	Moller et al.
7	20040186431	2004-09-23	Graf et al.
8	20040210199	2004-10-21	Aitterbury et al.
9	20040236282	2004-11-25	Braithwaite
10	20040249348	2004-12-09	Wimpenny et al.
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12	20040267207	2004-12-30	Veasey et al.
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14	20050004529	2005-01-06	Veasey et al.
15	20050019400	2005-01-27	Deveney et al.
16	20050033244	2005-02-10	Veasey et al.
17	20050055011	2005-03-10	Enggaard
18	20050113765	2005-05-26	Veasey et al.
19	20050205083	2005-09-22	Staniforth et al.
20	20050209570	2005-09-22	Moller
21	20050268915	2005-12-08	Wassenaar et al.

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	1	3609555	DE		1987-09-24	Pomer		
	2	0673482	EP		1998-04-29	Sams		
	3	0937471	EP		1999-08-25	Becton, Dickinson & Co.		
	4	0937476	EP		1999-08-25	Becton, Dickinson & Co.		
	5	1294418	EP		2005-07-09	Moeller, Claus Schmidt		
	6	2583291	FR		1986-12-19	Hazon et al.		
	7	2767479	FR		1999-02-26	Frezza		
	8	05-337179	JP		1993-12-21	Balkwill		
	9	06-296691	JP		1994-10-25	Michel et al.		
	10	2111019	RU		1998-05-20	Khvorostov		

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11	1990/09202	WO		1990-08-23	Ejlersen		
12	1991/10460	WO		1991-07-25	Bonnichsen		
13	1991/14467	WO		1991-10-03	Bernard SAMS		
14	1996/26754	WO		1996-09-06	Sams		
15	1998/57688	WO		1998-12-23	Klitmose et al.		
16	1999/16487	WO		1999-04-08	Bitdinger et al.		
17	1999/38554	WO		1999-08-05	Steenfeldt-Jensen et al.		
18	2001/10484	WO		2000-07-31	Charles et al.		

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NON-PATENT LITERATURE DOCUMENTS

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	J.S. Reissue Patent Application No. 10/442,855, "Injection Syringe", Filed May 21, 2003, including copies of as-filed specification, drawings, abstract, and claims, as well as the reissue declaration and a copy of list of documents found in image file wrapper in PAIR as of January 23, 2008	

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2	J.S. Reissue Patent Application No. 10/960,900, "Injection Syringe", Filed October 7, 2004, including copies of as-filed specification, drawings, abstract, and claims, as well as the reissue declaration and a copy of list of documents found in image file wrapper in PAIR as of January 23, 2008.
3	J.S. Reissue Patent Application No. 11/121,331, "Injection Syringe", Filed May 3, 2005, including copies of as-filed specification, drawings, abstract, and claims, as well as the reissue declaration and a copy of list of documents found in image file wrapper in PAIR as of January 23, 2008.
4	J.S. Reissue Patent Application No. 11/640,610, "Injection Syringe", Filed December 18, 2006, including copies of as-filed specification, drawings, abstract, and claims, as well as the reissue declaration and a copy of list of documents found in image file wrapper in PAIR as of January 23, 2008.
5	First Office Action on merits mailed March 14, 2006 in U.S. Application No. 10/790,866 (11 pages).

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Examiner Signature	/MANUEL A MENDEZ/	Date Considered	08/07/2016
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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.

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Art Unit			
Examiner Name			
Attorney Docket Number		10-1188-US-CON8	

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	/David M. Frischkorn/	Date (YYYY-MM-DD)	2016-05-17
Name/Print	David M. Frischkorn	Registration Number	32833

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

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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.
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
(Case No. 10-1188-US-CON8)

Applicant: Robert Frederick Veasey, et al.
Appl. No.: TBD
Filed: May 17, 2016
Title: IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR
TC/A.U.: 3763
Confirmation No.: TBD
Examiner: TBD

INFORMATION DISCLOSURE STATEMENT LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 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 numbers to which the above-identified parent application claims priority to under 35 U.S.C. §120 are 14/946,203; 14/635,573; 13/919,251; 13/040,198; 11/483,546; and 10/790,225.

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.

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.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff LLP

Dated: May 17, 2016

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

McDonnell Boehnen
Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, IL 60606
Tel: 312-913-0001

/MANUEL A MENDEZ/

08/07/2016

Doc code: IDS

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

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	Filing Date		2016-05-17
	First Named Inventor	Robert Frederick Veasey	
	Art Unit		
	Examiner Name		
	Attorney Docket Number		10-1188-US-CON8

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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	5743889		1998-04-28	Sams	
	2	5755692		1998-05-26	Manicom	
	3	5823998		1998-10-20	Yamagata	
	4	5843036		1998-12-01	Olive et al.	
	5	5882718		1999-03-16	Pommer et al.	
	6	5898028		1999-04-27	Jensen et al.	
	7	5921966		1999-07-13	Bendek et al.	
	8	5928201		1999-07-27	Poulsen et al.	

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9	5947934		1999-09-07	Hansen et al.
10	5951530		1999-09-14	Steengaard et al.
11	5954689		1999-09-21	Poulsen
12	5961496		1999-10-05	Nielsen et al.
13	5980491		1999-11-09	Hansen
14	5984900		1999-11-16	Mikkelson
15	6003736		1999-12-21	Ljunggren
16	6004297		1999-12-21	Steenfeldt-Jensen et al.
17	6010485		2000-01-04	Buch-Rasmussen et al.
18	6033376		2000-03-07	Rockley
19	6033377		2000-03-07	Rasmussen et al.

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20	6074372		2000-06-13	Hansen
21	6083197		2000-07-04	Umbaugh
22	6110149		2000-08-29	Klitgaard et al.
23	6129080		2000-10-10	Pitcher et al.
24	6146361		2000-11-14	DiBiasi et al.
25	6193698		2001-02-27	Kirchhofer et al.
26	6221046		2001-04-24	Burroughs et al.
27	6221053		2001-04-24	Walters et al.
28	6231540		2001-05-15	Smedegaard
29	6235004		2001-05-22	Steenfeldt-Jensen et al.
30	6248090		2001-06-19	Jensen et al.

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31	6248095		2001-06-19	Giambattista et al.
32	6258062		2001-07-10	Thielen et al.
33	6269340		2001-07-31	Ford et al.
34	6277097		2001-08-21	Mikkelsen et al.
35	6277098		2001-08-21	Klitmose et al.
36	6281225		2001-08-28	Hearst et al.
37	6283941		2001-09-04	Schoenfeld et al.
38	6287283		2001-09-11	Ljunggreen et al.
39	6302869		2001-10-16	Klitgaard
40	6312413		2001-11-06	Jensen et al.
41	6340357		2002-01-22	Poulsen et al.

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42	6514230		2003-02-04	Munk et al.
43	6547763		2003-04-15	Steenfeldt-Jensen et al.
44	6547764		2003-04-15	Larsen et al.
45	6562011		2003-05-13	Buch-Rasmussen et al.
46	6569126		2003-05-27	Poulsen et al.
47	6582404		2003-06-24	Klitgaard et al.
48	6605067		2003-08-12	Larsen
49	6613019		2003-09-02	Munk
50	6663602		2003-12-16	Moller
51	6692472		2004-02-17	Hansen et al.
52	6716198		2004-04-06	Larsen

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53	6726661		2004-04-27	Munk et al.
54	6770288		2004-08-03	Duirs
55	6796970		2004-09-28	Klitmose et al.
56	6893415		2005-05-17	Madsen et al.
57	6899698		2005-05-31	Sams
58	6899699		2005-05-31	Enggaard
59	6945961		2005-09-20	Miller et al.
60	7008399		2006-03-07	Larsen et al.
61	7090662		2006-08-15	Wimpenny et al.
62	7094221		2006-08-22	Veasey et al.
63	7104972		2006-09-12	Moller et al.

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64	7133329		2006-11-07	Skyggebjerg et al.
65	7175055		2007-02-13	Hansen et al.
66	7241278		2007-07-10	Moller
67	7935088		2011-05-03	Veasey et al.
68	8512297		2013-08-20	Veasey et al.
69	2722931		1955-11-08	May
70	2717597		1955-09-13	Hein, Jr.

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Signature	/David M. Frischkorn/	Date (YYYY-MM-DD)	2016-05-17
Name/Print	David M. Frischkorn	Registration Number	32833

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:

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 10-1188-US-CON8)

Applicant: Robert Frederick Veasey, et al.

Appl. No.: 15/156,616

Filed: May 17, 2016

Title: PEN-TYPE INJECTOR

TC/A.U.: 3763

Confirmation No.: 1083

Examiner: MENDEZ, MANUEL A.

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

RESPONSE TO THE OFFICE ACTION MAILED AUGUST 10, 2016

Dear Examiner Mendez:

This paper is submitted in response to the Office Action mailed August 10, 2016. Please enter the following amendments and remarks into the record for this application.

The Commissioner is authorized to charge deposit account number 13-2490 for any fees due in connection with this patent application.

Amendments to the Specification begin on page 2 of this paper.

Listing of the Claims are begin on page 3 of this paper.

Remarks/Arguments begin on page 8 of this paper.

In the Specification

Please amend the specification as indicated below.

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation of U.S. Patent Application No. U.S. 14/946,203, filed November 19, 2015, now U.S. Patent No. 9,408,979, which is a continuation of U.S. Patent Application No. U.S. 14/635,573, filed March 2, 2015, now U.S. Patent No. 9,233,211, which is a continuation of U.S. Patent Application No. 13/919,251, filed June 17, 2013, now U.S. Patent No. 9,011,391, which is a divisional of U.S. Patent Application No. 13/040,198, filed March 3, 2011, now U.S. Patent No. 8,512,297, which is a continuation 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 of U.S. Patent Application No. 10/790,225, filed March 2, 2004, which claims priority to GB 0304822.0 filed March 3, 2003, the entire contents of which are incorporated herein by reference.

In the Claims

1. (previously presented) A drive mechanism for use in a drug delivery device comprising:
 - a housing comprising an inner surface;
 - a dose dial sleeve threadedly engaged with the inner surface of the housing through an outer thread having a first lead;
 - an insert that is rotationally and axially fixed relative to the housing;
 - a piston rod engaged with the insert, where the piston rod is threaded with a second lead and remains axially fixed relative to the housing during dose setting and moves axially relative to the insert during dose delivery;
 - a clutch operatively engaged with the dose dial sleeve to allow rotation of the dose dial sleeve during dose setting and dose delivery; and
 - a drive sleeve that extends about the piston rod and is operatively engaged with the clutch, where the clutch connects the drive sleeve and dose dial sleeve so they rotate together and disconnects the drive sleeve and dose dial sleeve so the dose dial sleeve can rotate relative to the drive sleeve,wherein the drive sleeve is configured to rotate relative to the piston rod and traverse axially towards the distal end during dose delivery.
2. (previously presented) The drive mechanism of claim 1 where the first lead and second lead are different.
3. (previously presented) The drive mechanism of claim 1 where the dose dial sleeve rotates and moves axially relative to the piston rod during dose setting and dose delivery.
4. (previously presented) The drive mechanism of claim 1 where the piston rod has a circular cross-section.

5. (previously presented) The drive mechanism of claim 1 where the clutch provides audible and tactile feedback indicative of unit doses of medicament.

6. (previously presented) The drive mechanism of claim 1 where the clutch provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament.

7. (previously presented) The drive mechanism of claim 6 where the clutch allows the dose cancelling without dispensing medicament.

8. (previously presented) The drive mechanism of claim 1 further comprising a T-shaped button having a skirt that extends distally from a head portion of the button and is seated in an annular recess of a dose dial grip on a proximal end of the dose dial sleeve.

9. (previously presented) The drive mechanism of claim 8 where the button further comprises a stem extending in an opening in the dose dial grip.

10. (previously presented) The drive mechanism of claim 8 where the button is rotatable relative to the dose dial sleeve.

11. (previously presented) The drive mechanism of claim 8 where axial movement of the button caused by distally applied pressure to the head initiates dose delivery by displacing the clutch axially with respect to the dose dial sleeve and drive sleeve.

12. (previously presented) The drive mechanism of claim 1 further comprising a clicker that provides audible clicks during dose setting, where each click is equal to a unit dose of medicament

13. (previously presented) The drive mechanism of claim 1 where the dose dial sleeve rotates and moves axially during dose setting and dose delivery

14. (previously presented) The drive mechanism of claim 1 further comprises a nut that tracks each set dose of medicament delivered.

15. (previously presented) The drive mechanism of claim 14 where the nut is threaded, axially slidable and rotationally fixed relative to the housing.

16. (previously presented) The drive mechanism of claim 14 where the nut moves axially in a proximal direction relative to the housing and drive sleeve for each dose set and delivered.

17. (previously presented) The drive mechanism of claim 14 where the drive sleeve further comprises a final dose stop.

18. (previously presented) The drive mechanism of claim 17 where the nut further comprises a corresponding final dose stop that engages the final dose stop on drive sleeve.

19. (previously presented) The drive mechanism of claim 18 where engagement of the final dose stop and the corresponding final dose stop prevent rotation of the dose dial sleeve during dose setting.

20. (previously presented) A drug delivery device comprising;
a cartridge holder;
a cap; and
the drive mechanism of claim 1.

21. (previously presented) A drug delivery device comprising:
a housing comprising a dose dispensing end and a first thread;
a dose indicator comprising a second thread that engages with the first thread;
a driving member comprising a third thread;

a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator;

a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread;

a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing;

wherein:

the housing is disposed at an outermost position of the drug delivery device;

the dose indicator is disposed between the housing and the sleeve and is configured to (i) rotate and traverse axially away from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing;

the driving member is configured to rotate relative to the piston rod;

the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator; and

the piston rod and the driving member are configured to rotate relative to one another during dose dispensing;

and the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.

22. (previously presented) The drug delivery device of claim 21 where the piston rod has a circular cross-section.

23. (previously presented) The drug delivery device of claim 21 further comprising a clutch.

24. (previously presented) The drug delivery device of claim 24 where the clutch provides audible and tactile feedback indicative of unit doses of medicament.

25. (previously presented) The drug delivery device of claim 24 where the clutch provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament.

26. (previously presented) The drug delivery device of claim 24 where the clutch allows the dose cancelling without dispensing medicament.

27. (previously presented) The drug delivery device of claim 24 further comprising a button seated in an annular recess of a dose dial grip on a proximal end of the dose indicator, where the button is rotatable relative to the dose indicator.

28. (previously presented) The drug delivery device of claim 27 where axial movement movement of the button caused by distally applied pressure to the button initiates dose dose delivery by displacing the clutch axially with respect to the dose indicator and driving member.

29. (previously presented) The drug delivery device of claim 21 further comprising a clicker that provides audible clicks during dose setting, where each click is equal to a unit dose of medicament

30. (previously presented) The drug delivery device of claim 21 further comprises a nut that tracks each set dose of medicament delivered.

REMARKS

Claims 1-30 are currently pending in the application. Applicant appreciates the Examiner's indication that all pending claims are allowable. The specification is now amended to indicate that USSN 14/946,203 is now issued as U.S. Pat. No. 9,408,979 update. No new matter is added.

Claims 1-30 are rejected on the ground of non-statutory obviousness-type double patenting over claims 1-14 of U.S. Pat. No. 7,918,833. Applicant encloses herewith a Terminal Disclaimers that overcomes this rejection. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

In view of the remarks above, the present application is now in condition for allowance and Applicant requests an early indication of same. If there are any matters that may be resolved or clarified through a telephone interview, the Examiner is respectfully requested to contact Applicants' undersigned representative at (312) 913-2143.

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff LLP

Date: September 1, 2016

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

Electronic Acknowledgement Receipt

EFS ID:	26809627
Application Number:	15156616
International Application Number:	
Confirmation Number:	1083
Title of Invention:	PEN-TYPE INJECTOR
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Customer Number:	98548
Filer:	David M. Frischkorn
Filer Authorized By:	
Attorney Docket Number:	10-1188-US-CON8
Receipt Date:	01-SEP-2016
Filing Date:	17-MAY-2016
Time Stamp:	13:30:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10-1188-US-CON8_Response.pdf	165672 4cc72b7ce9a382bccd0ef8c0354cefd9bf63fa86	yes	8

Multipart Description/PDF files in .zip description			
	Document Description	Start	End
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Specification	2	2
	Claims	3	7
	Applicant Arguments/Remarks Made in an Amendment	8	8

Warnings:

Information:

Total Files Size (in bytes):	165672
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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Electronic Petition Request	TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT
Application Number	15156616
Filing Date	17-May-2016
First Named Inventor	Robert Veasey
Attorney Docket Number	10-1188-US-CON8
Title of Invention	PEN-TYPE INJECTOR

- Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action
- This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
SANOFI-AVENTIS DEUTSCHLAND GMBH	100%

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

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as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:

- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicant claims the following fee status:

- Small Entity
- Micro Entity
- Regular Undiscounted

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

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

- An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

Registration Number 32833
- A sole inventor
- A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application
- A joint inventor; all of whom are signing this request

Signature	/David M. Frischkorn/
Name	David M. Frischkorn

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	15156616			
Filing Date:	17-May-2016			
Title of Invention:	PEN-TYPE INJECTOR			
First Named Inventor/Applicant Name:	Robert Frederick Veasey			
Filer:	David M. Frischkorn			
Attorney Docket Number:	10-1188-US-CON8			
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Statutory or Terminal Disclaimer	1814	1	160	160
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				160

Doc Code: DISQ.E.FILE

Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 15156616

Filing Date: 17-May-2016

Applicant/Patent under Reexamination: Veasey et al.

Electronic Terminal Disclaimer filed on September 1, 2016

APPROVED

This patent is subject to a terminal disclaimer

DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt

EFS ID:	26809790
Application Number:	15156616
International Application Number:	
Confirmation Number:	1083
Title of Invention:	PEN-TYPE INJECTOR
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Customer Number:	98548
Filer:	David M. Frischkorn
Filer Authorized By:	
Attorney Docket Number:	10-1188-US-CON8
Receipt Date:	01-SEP-2016
Filing Date:	17-MAY-2016
Time Stamp:	13:31:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$160
RAM confirmation Number	13193
Deposit Account	132490
Authorized User	FRISCHKORN, DAVID M.

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 CFR 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 CFR 1.17 (Patent application and reexamination processing fees)

0125

Mylan Exhibit - 1009

Mylan v. Sanofi

Charge any Additional Fees required under 37 CFR 1.19 (Document supply fees)
 Charge any Additional Fees required under 37 CFR 1.20 (Post Issuance fees)
 Charge any Additional Fees required under 37 CFR 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	Electronic Terminal Disclaimer-Filed	eTerminal-Disclaimer.pdf	33407 a1c42ec8835ee2cb7fca7cac7f159c3fa08ca53d	no	2

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30231 1deea5c9bd3565b6676c0bbf03062b07df7239eb	no	2
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Warnings:

Information:

Total Files Size (in bytes):			63638		
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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/156,616	Filing Date 05/17/2016	<input type="checkbox"/> To be Mailed
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ENTITY: LARGE SMALL MICRO

APPLICATION AS FILED – PART I

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	
<input type="checkbox"/> 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 \$ =	
<input type="checkbox"/> 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).			
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

	(Column 1)	(Column 2)	(Column 3)	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT	09/01/2016	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR			
	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0	X \$80 = 0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X \$420 = 0
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))					
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

	(Column 1)	(Column 2)	(Column 3)	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR			
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))					
<input type="checkbox"/> 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
/FLORENCE PATTERSON/

This collection of information is required by 37 CFR 1.16. 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, 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
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Address: COMMISSIONER FOR PATENTS
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www.uspto.gov

Table with 4 columns: APPLICATION NUMBER (15/156,616), FILING OR 371(C) DATE (05/17/2016), FIRST NAMED APPLICANT (Robert Frederick Veasey), ATTY. DOCKET NO./TITLE (10-1188-US-CON8)

CONFIRMATION NO. 1083

PUBLICATION NOTICE



98548
McDonnell Boehnen Hulbert & Berghoff LLP
Sanofi - Aventis
300 South Wacker Drive
Chicago, IL 60606

Title: PEN-TYPE INJECTOR

Publication No. US-2016-0256633-A1
Publication Date: 09/08/2016

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



NOTICE OF ALLOWANCE AND FEE(S) DUE

98548 7590 09/21/2016
McDonnell Boehnen Hulbert & Berghoff LLP
Sanofi - Aventis
300 South Wacker Drive
Chicago, IL 60606

EXAMINER

MENDEZ, MANUEL A

ART UNIT PAPER NUMBER

3763

DATE MAILED: 09/21/2016

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.

15/156,616 05/17/2016 Robert Frederick Veasey 10-1188-US-CON8 1083

TITLE OF INVENTION: PEN-TYPE INJECTOR

Table with 7 columns: 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 12/21/2016

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)

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.

98548 7590 09/21/2016
McDonnell Boehnen Hulbert & Berghoff LLP
Sanofi - Aventis
300 South Wacker Drive
Chicago, IL 60606

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.
15/156,616	05/17/2016	Robert Frederick Veasey	10-1188-US-CON8	1083

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	12/21/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
MENDEZ, MANUEL A	3763	604-209000

<p>1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).</p> <p><input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</p> <p><input type="checkbox"/> "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.</p>	<p>2. For printing on the patent front page, list</p> <p>(1) The names of up to 3 registered patent attorneys or agents OR, alternatively, _____ 1</p> <p>(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. _____ 2</p> <p>_____ 3</p>
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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

<p>4a. The following fee(s) are submitted:</p> <p><input type="checkbox"/> Issue Fee</p> <p><input type="checkbox"/> Publication Fee (No small entity discount permitted)</p> <p><input type="checkbox"/> Advance Order - # of Copies _____</p>	<p>4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)</p> <p><input type="checkbox"/> A check is enclosed.</p> <p><input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.</p> <p><input type="checkbox"/> 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).</p>
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5. **Change in Entity Status** (from status indicated above)

Applicant certifying micro entity status. See 37 CFR 1.29

Applicant asserting small entity status. See 37 CFR 1.27

Applicant changing to regular undiscounted fee status.

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.

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.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____



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

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
15/156,616 05/17/2016 Robert Frederick Veasey 10-1188-US-CON8 1083

98548 7590 09/21/2016
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300 South Wacker Drive
Chicago, IL 60606

EXAMINER

MELENDEZ, MANUEL A

ART UNIT PAPER NUMBER

3763

DATE MAILED: 09/21/2016

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.

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. 15/156,616	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 the terminal disclaimer filed on 9/01/2016.
 A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. The allowed claim(s) is/are 1-30. 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. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 2. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 7. <input type="checkbox"/> Other _____. |
| 4. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ . | |

/MANUEL MENDEZ/
Primary Examiner, Art Unit 3763

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In claim 24, line 1, the number "24" has been deleted and replaced with the number - - 23 - -.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The examiner of record acknowledges receipt of the terminal disclaimer filed on 09/01/2016. The terminal disclaimer was approved by the office on 09/01/2016. In relation to the patentability of claim 1-30, the examiner makes reference to the Allowable Subject Matter section of the non-final office action mailed on 8/10/2016. Accordingly, claims 1-30 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.

Art Unit: 3763


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nathan R. Price can be reached on 571-270-5421. 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

Index of Claims 	Application/Control No. 15156616	Applicant(s)/Patent Under Reexamination VEASEY ET AL.
	Examiner MANUEL MENDEZ	Art Unit 3763

✓	Rejected
=	Allowed

-	Cancelled
÷	Restricted

N	Non-Elected
I	Interference

A	Appeal
O	Objected

Claims renumbered in the same order as presented by applicant
 CPA
 T.D.
 R.1.47

CLAIM		DATE							
Final	Original	09/12/2016							
	1	=							
	2	=							
	3	=							
	4	=							
	5	=							
	6	=							
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	29	=							
	30	=							

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL (Submitted Only via EFS-Web)

Application Number	15156616	Filing Date	2016-05-17	Docket Number (if applicable)	10-1188-US-CON8	Art Unit	3763
First Named Inventor	Robert Frederick Veasey			Examiner Name	MENDEZ, MANUEL A.		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application. Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, to any international application that does not comply with the requirements of 35 U.S.C. 371, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV.

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

Other _____

Enclosed

Amendment/Reply

Information Disclosure Statement (IDS)

Affidavit(s)/ Declaration(s)

Other Certification and Request for Prioritized Examination Under 37 CFR 1.102(e)

MISCELLANEOUS

Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 132490

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

<input checked="" type="checkbox"/> Patent Practitioner Signature
<input type="checkbox"/> Applicant Signature

Signature of Registered U.S. Patent Practitioner			
Signature	David M. Frischkorn/	Date (YYYY-MM-DD)	2016-10-14
Name	David M. Frischkorn	Registration Number	32833

This collection of information is required by 37 CFR 1.114. 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.

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

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 records.
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
(Case No. 10-1188-US-CON8)

Applicant: Robert Frederick Veasey, et al.

Appl. No.: 15/156,616

Filed: May 17, 2016

Title: PEN-TYPE INJECTOR

TC/A.U.: 3763

Confirmation No.: 1083

Examiner: MENDEZ, MANUEL A.

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

AMENDMENT AFTER ALLOWANCE UNDER C.F.R. §1.312

Sir:

In response to the Notice of Allowance mailed September 21, 2016, please enter the following amendments and consider the accompanying remarks.

All fees associated with this response have been paid during the electronic filing process.

However, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment to Deposit Account No. 13-2490.

In the Claims

1. (currently amended) A drive mechanism for use in a drug delivery device comprising:
 - a housing comprising an inner surface;
 - a dose dial sleeve threadedly engaged with the inner surface of the housing through an outer thread having a first lead;
 - an insert that is rotationally and axially fixed relative to the housing;
 - a piston rod engaged with the insert, where the piston rod is threaded with a second lead and remains axially fixed relative to the housing during dose setting and moves axially relative to the insert during dose delivery;
 - a clutch operatively engaged with the dose dial sleeve to allow rotation of the dose dial sleeve during dose setting and dose delivery; and
 - a drive sleeve that extends about the piston rod and is operatively engaged with the clutch, where the clutch connects the drive sleeve and dose dial sleeve so they rotate together and disconnects the drive sleeve and dose dial sleeve so the dose dial sleeve can rotate relative to the drive sleeve,

wherein during dose delivery the drive sleeve and the piston rod are configured to rotate relative to one another and the drive sleeve is configured to traverse axially towards the distal end

~~wherein the drive sleeve is configured to rotate relative to the piston rod and traverse axially towards the distal end during dose delivery.~~
2. (previously presented) The drive mechanism of claim 1 where the first lead and second lead are different.
3. (previously presented) The drive mechanism of claim 1 where the dose dial sleeve rotates and moves axially relative to the piston rod during dose setting and dose delivery.
4. (previously presented) The drive mechanism of claim 1 where the piston rod has a circular cross-section.

5. (previously presented) The drive mechanism of claim 1 where the clutch provides audible and tactile feedback indicative of unit doses of medicament.

6. (previously presented) The drive mechanism of claim 1 where the clutch provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament.

7. (previously presented) The drive mechanism of claim 6 where the clutch allows the dose cancelling without dispensing medicament.

8. (previously presented) The drive mechanism of claim 1 further comprising a T-shaped button having a skirt that extends distally from a head portion of the button and is seated in an annular recess of a dose dial grip on a proximal end of the dose dial sleeve.

9. (previously presented) The drive mechanism of claim 8 where the button further comprises a stem extending in an opening in the dose dial grip.

10. (previously presented) The drive mechanism of claim 8 where the button is rotatable relative to the dose dial sleeve.

11. (previously presented) The drive mechanism of claim 8 where axial movement of the button caused by distally applied pressure to the head initiates dose delivery by displacing the clutch axially with respect to the dose dial sleeve and drive sleeve.

12. (previously presented) The drive mechanism of claim 1 further comprising a clicker that provides audible clicks during dose setting, where each click is equal to a unit dose of medicament

13. (previously presented) The drive mechanism of claim 1 where the dose dial sleeve rotates and moves axially during dose setting and dose delivery

14. (previously presented) The drive mechanism of claim 1 further comprises a nut that tracks each set dose of medicament delivered.

15. (previously presented) The drive mechanism of claim 14 where the nut is threaded, axially slidable and rotationally fixed relative to the housing.

16. (previously presented) The drive mechanism of claim 14 where the nut moves axially in a proximal direction relative to the housing and drive sleeve for each dose set and delivered.

17. (previously presented) The drive mechanism of claim 14 where the drive sleeve further comprises a final dose stop.

18. (previously presented) The drive mechanism of claim 17 where the nut further comprises a corresponding final dose stop that engages the final dose stop on drive sleeve.

19. (previously presented) The drive mechanism of claim 18 where engagement of the final dose stop and the corresponding final dose stop prevent rotation of the dose dial sleeve during dose setting.

20. (previously presented) A drug delivery device comprising;
a cartridge holder;
a cap; and
the drive mechanism of claim 1.

21. (previously presented) A drug delivery device comprising:
a housing comprising a dose dispensing end and a first thread;
a dose indicator comprising a second thread that engages with the first thread;
a driving member comprising a third thread;

a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator;

a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread;

a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing;

wherein:

the housing is disposed at an outermost position of the drug delivery device;

the dose indicator is disposed between the housing and the sleeve and is configured to (i) rotate and traverse axially away from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing;

the driving member is configured to rotate relative to the piston rod;

the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator; and

the piston rod and the driving member are configured to rotate relative to one another during dose dispensing;

and the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.

22. (previously presented) The drug delivery device of claim 21 where the piston rod has a circular cross-section.

23. (previously presented) The drug delivery device of claim 21 further comprising a clutch.

24. (previously presented) The drug delivery device of claim 23 where the clutch provides audible and tactile feedback indicative of unit doses of medicament.

25. (previously presented) The drug delivery device of claim 24 where the clutch provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament.

26. (previously presented) The drug delivery device of claim 24 where the clutch allows the dose cancelling without dispensing medicament.

27. (previously presented) The drug delivery device of claim 24 further comprising a button seated in an annular recess of a dose dial grip on a proximal end of the dose indicator, where the button is rotatable relative to the dose indicator.

28. (previously presented) The drug delivery device of claim 27 where axial movement of the button caused by distally applied pressure to the button initiates dose delivery by displacing the clutch axially with respect to the dose indicator and driving member.

29. (previously presented) The drug delivery device of claim 21 further comprising a clicker that provides audible clicks during dose setting, where each click is equal to a unit dose of medicament

30. (previously presented) The drug delivery device of claim 21 further comprises a nut that tracks each set dose of medicament delivered.

REMARKS

On September 21, 2016, a Notice of Allowance was mailed indicating the claims of the present application were allowed. Applicant thanks the Examiner for allowing the claims.

Applicant respectfully submits the following Request for Continued Examination and further amends claim 1. No new matter is added by this amendment. Applicant therefore submits that the present application is in condition for issuance.

If there are any matters that may be resolved or clarified through a telephone interview, the Examiner is respectfully requested to contact Applicants' undersigned representative at (312) 913-2143.

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff LLP

Date: October 14, 2016

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	15156616
	Filing Date	2016-05-17
	First Named Inventor	Robert Frederick Veasey
	Art Unit	3763
	Examiner Name	MENDEZ, MANUEL A.
	Attorney Docket Number	10-1188-US-CON8

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	0533575		1895-02-05	Wilkens	
	2	2717597		1955-09-13	Hein, Jr.	
	3	2722931		1955-11-08	May	
	4	3815785		1974-06-11	Gilmont	
	5	4592745		1986-06-03	Rex, et al.	
	6	4863072		1989-09-05	Perler	
	7	5030209		1991-07-09	Wanderer, et al.	
	8	5328486		1994-07-12	Woodruff	

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

Application Number	15156616
Filing Date	2016-05-17
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	MENDEZ, MANUEL A.
Attorney Docket Number	10-1188-US-CON8

9	5547131	1996-08-20	Brace
10	5582598	1996-12-10	Chanoch
11	5728075	1998-03-17	Levander
12	5957896	1999-09-28	Bendek, et al.
13	5961495	1999-10-05	Walters, et al.
14	6001089	1999-12-14	Burroughs, et al.
15	6059755	2000-05-09	Michel
16	6277099	2001-08-21	Stowe, et al.
17	6277101	2001-08-21	Kirchhofer, et al.
18	6383167	2002-05-07	Kirchhofer, et al.
19	6936032	2005-08-30	Bush, Jr., et al.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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First Named Inventor	Robert Frederick Veasey
Art Unit	3763
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Attorney Docket Number	10-1188-US-CON8

20	7195616	2007-03-27	Diller, et al.
21	7361161	2008-04-22	Bainton
22	7771400	2010-08-10	Nielsen
23	7905867	2011-03-15	Veasey, et al.
24	7918833	2011-04-05	Veasey, et al.
25	8021345	2011-09-20	Veasey, et al.
26	8512297	2013-08-20	Veasey, et al.
27	8608709	2013-12-17	Moller, et al.
28	8679069	2014-03-25	Veasey, et al.
29	9233211	2016-01-12	Veasey, et al.

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

Application Number	15156616
Filing Date	2016-05-17
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	MENDEZ, MANUEL A.
Attorney Docket Number	10-1188-US-CON8

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	20010034507		2001-10-25	Kirchhofer, et al.	
	2	20020165499		2002-11-07	Slate, et al.	
	3	20030050609		2003-03-13	Sams	
	4	20070123829		2007-05-31	Atterbury, et al.	
	5	20090275916		2009-11-05	Harms, et al.	
	6	20100042054		2010-02-18	Elahi, et al.	
	7	20120053528		2012-03-01	Bollenbach, et al.	

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

FOREIGN PATENT DOCUMENTS

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	0937477	EP	A2	1999-08-25	BECTON DICKINSON CO		

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

Application Number	15156616
Filing Date	2016-05-17
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	MENDEZ, MANUEL A.
Attorney Docket Number	10-1188-US-CON8

2	1855743	EP	B1	2008-12-17	NOVO NORDISK AS
3	96/25965	WO	A1	1996-08-29	SMITH MARK TIMOTHY
4	01/010484	WO	A1	2001-02-15	BECTON DICKINSON CO
5	02/053214	WO	A1	2002-07-11	NOVO NORDISK AS
6	02/092153	WO	A2	2002-11-21	LILLY CO ELI
7	03/080160	WO	A1	2003-10-02	LILLY CO ELI
8	2011/051366	WO	A2	2011-05-05	SANOFI AVENTIS DEUTSCHLAND

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NON-PATENT LITERATURE DOCUMENTS

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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	15156616
	Filing Date	2016-05-17
	First Named Inventor	Robert Frederick Veasey
	Art Unit	3763
	Examiner Name	MENDEZ, MANUEL A.
	Attorney Docket Number	10-1188-US-CON8

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	15156616
	Filing Date	2016-05-17
	First Named Inventor	Robert Frederick Veasey
	Art Unit	3763
	Examiner Name	MENDEZ, MANUEL A.
	Attorney Docket Number	10-1188-US-CON8

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	/David M. Frischkorn/	Date (YYYY-MM-DD)	2016-10-14
Name/Print	David M. Frischkorn	Registration Number	32833

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 records.
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.

Electronic Patent Application Fee Transmittal

Application Number:	15156616			
Filing Date:	17-May-2016			
Title of Invention:	PEN-TYPE INJECTOR			
First Named Inventor/Applicant Name:	Robert Frederick Veasey			
Filer:	David M. Frischkorn			
Attorney Docket Number:	10-1188-US-CON8			
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
REQUEST FOR PRIORITIZED EXAMINATION	1817	1	4000	4000
Pages:				
Claims:				
Miscellaneous-Filing:				
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
RCE- 1st Request	1801	1	1200	1200
Total in USD (\$)				5340

Electronic Acknowledgement Receipt

EFS ID:	27221251
Application Number:	15156616
International Application Number:	
Confirmation Number:	1083
Title of Invention:	PEN-TYPE INJECTOR
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Customer Number:	98548
Filer:	David M. Frischkorn
Filer Authorized By:	
Attorney Docket Number:	10-1188-US-CON8
Receipt Date:	14-OCT-2016
Filing Date:	17-MAY-2016
Time Stamp:	16:04:03
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$5340
RAM confirmation Number	3104
Deposit Account	132490
Authorized User	Frischkorn, David

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 CFR 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 CFR 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 CFR 1.19 (Document supply fees)
 Charge any Additional Fees required under 37 CFR 1.20 (Post Issuance fees)
 Charge any Additional Fees required under 37 CFR 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	TrackOne Request	10-1188-US-CON8_Track_One.pdf	114187 c65e26b6bc9a493c9523b2febbb45b92eff7b96a	no	2

Warnings:

Information:

2	Request for Continued Examination (RCE)	10-1188-US-CON8_RCE.pdf	1350135 6889c447d32e79a7eacd34a7ffa8e3ba7df7ce65	no	3
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Warnings:

Information:

3		10-1188-US-CON8_Response.pdf	148530 b1a464c2017b114bf845584771bcb393de04b3f2	yes	7
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Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment after Notice of Allowance (Rule 312)	1	1
Claims	2	6
Applicant Arguments/Remarks Made in an Amendment	7	7

Warnings:

Information:

4	Information Disclosure Statement (IDS) Form (SB08)	10-1188-US-CON8_IDS.pdf	1036590 6e442dced4af3d8037832665866e1297db71327b	no	8
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Warnings:

Information:

5	Foreign Reference	EP0937477A2.pdf	1031089 b1e938d3bf7ca1a25420820edcdfa8023c9c5014	no	22
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Warnings:					
Information:					
6	Foreign Reference	EP1855743B1.pdf	139136	no	14
			e5877e21135fb3c76f0c860b3e0b007a2311dab		
Warnings:					
Information:					
7	Foreign Reference	WO0110484A1.pdf	721481	no	22
			f0287841454822b1a7165badbe2d5b7d110c29ac		
Warnings:					
Information:					
8	Foreign Reference	WO02053214A1.pdf	1767864	no	45
			7219f945aba36a0706c4bd6d041f3676a0f400f1		
Warnings:					
Information:					
9	Foreign Reference	WO02092153A2.pdf	4823896	no	98
			eb4be481f8373c6e84c4ad3aac2989263ce2ab3a		
Warnings:					
Information:					
10	Foreign Reference	WO03080160A1.pdf	2590721	no	59
			315d76d1555c88cf0ba20a8f90c5fd86f314a21c		
Warnings:					
Information:					
11	Foreign Reference	WO9625965A1.pdf	1219019	no	33
			0149180d0625a58aeaaae5d9ccf638b308d67337		
Warnings:					
Information:					
12	Foreign Reference	WO2011051366A2.pdf	1568042	no	42
			46fead21e0a7219662597e5222f4025401e4e5d4		
Warnings:					
Information:					

13	Fee Worksheet (SB06)	fee-info.pdf	33886	no	2
			4ccd81304a1d9fdc8bf574e435bb6261921af452		

Warnings:

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Total Files Size (in bytes):	16544576
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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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

First Named Inventor:	Robert Frederick Veasey	Nonprovisional Application Number (if known):	15/156,616
Title of Invention:	PEN-TYPE INJECTOR		

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

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.
2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

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

- i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.
 ---OR---
 (b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.
- ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, or the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

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

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

Signature /David M. Frischkorn/	Date October 14, 2016
Name (Print/Typed) David M. Frischkorn	Practitioner Registration Number 32833

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

*Total of _____ forms are submitted.

Privacy Act Statement

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

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

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.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/156,616	Filing Date 05/17/2016	<input type="checkbox"/> To be Mailed
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ENTITY: LARGE SMALL MICRO

APPLICATION AS FILED – PART I

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	
<input type="checkbox"/> 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 \$ =	
<input type="checkbox"/> 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).			
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

	(Column 1)	(Column 2)	(Column 3)	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT	10/14/2016	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		
	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0	X \$80 = 0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X \$420 = 0
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))					
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

	(Column 1)	(Column 2)	(Column 3)	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))					
<input type="checkbox"/> 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
DENISE T. LILES

This collection of information is required by 37 CFR 1.16. 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, 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.



NOTICE OF ALLOWANCE AND FEE(S) DUE

98548 7590 11/02/2016
McDonnell Boehnen Hulbert & Berghoff LLP
Sanofi - Aventis
300 South Wacker Drive
Chicago, IL 60606

Table with 2 columns: EXAMINER (MENDEZ, MANUEL A), ART UNIT (3763), PAPER NUMBER (1083)

DATE MAILED: 11/02/2016

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.

15/156,616 05/17/2016 Robert Frederick Veasey 10-1188-US-CON8 1083
TITLE OF INVENTION: PEN-TYPE INJECTOR

Table with 7 columns: APPLN. TYPE, ENTITY STATUS, ISSUE FEE DUE, PUBLICATION FEE DUE, PREV. PAID ISSUE FEE, TOTAL FEE(S) DUE, DATE DUE

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)

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.

98548 7590 11/02/2016
McDonnell Boehnen Hulbert & Berghoff LLP
 Sanofi - Aventis
 300 South Wacker Drive
 Chicago, IL 60606

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.
15/156,616	05/17/2016	Robert Frederick Veasey	10-1188-US-CON8	1083

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	02/02/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
MENDEZ, MANUEL A	3763	604-209000

<p>1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).</p> <p><input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</p> <p><input type="checkbox"/> "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.</p>	<p>2. For printing on the patent front page, list</p> <p>(1) The names of up to 3 registered patent attorneys or agents OR, alternatively, _____ 1</p> <p>(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. _____ 2</p> <p>_____ 3</p>
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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

<p>4a. The following fee(s) are submitted:</p> <p><input type="checkbox"/> Issue Fee</p> <p><input type="checkbox"/> Publication Fee (No small entity discount permitted)</p> <p><input type="checkbox"/> Advance Order - # of Copies _____</p>	<p>4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)</p> <p><input type="checkbox"/> A check is enclosed.</p> <p><input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.</p> <p><input type="checkbox"/> 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).</p>
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5. **Change in Entity Status** (from status indicated above)

Applicant certifying micro entity status. See 37 CFR 1.29

Applicant asserting small entity status. See 37 CFR 1.27

Applicant changing to regular undiscounted fee status.

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.

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.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____



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

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
15/156,616 05/17/2016 Robert Frederick Veasey 10-1188-US-CON8 1083

98548 7590 11/02/2016
McDonnell Boehnen Hulbert & Berghoff LLP
Sanofi - Aventis
300 South Wacker Drive
Chicago, IL 60606

EXAMINER

MELENDEZ, MANUEL A

ART UNIT PAPER NUMBER

3763

DATE MAILED: 11/02/2016

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.

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.

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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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.

Notice of Allowability	Application No. 15/156,616	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 RCE filed on 10/14/2016.
 A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. The allowed claim(s) is/are 1-30. 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. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Examiner's Amendment/Comment |
| 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>10/14/2016</u> | 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 7. <input type="checkbox"/> Other _____. |
| 4. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ . | |

/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 Request for Continued Examination (RCE) filed on 10/14/2016. The pending claims of this application [claims 1-30] were allowed by the examiner on 9/21/2016. In relation to the amendment to independent claim 1, the examiner has reviewed all the references submitted in the Information Disclosure Statement (IDS) filed with the RCE [10/14/2016] and considers amended claim 1 to be allowable over the prior art submitted in the IDS. Based on the above information, claims 1-30 are 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. Nathan R. Price can be reached on 571-270-5421. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Art Unit: 3763

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

Search Notes 	Application/Control No. 15156616	Applicant(s)/Patent Under Reexamination VEASEY ET AL.
	Examiner MANUEL MENDEZ	Art Unit 3763

CPC- SEARCHED		
Symbol	Date	Examiner
a61m5/31551, a61m5/31533, a61m5/31535, a61m5/31536, a61m5/31541, a61m5/31546, a61m5/31585	8/7/2016	mm
a61m2005/2407, a61m2205/581, a61m2205/582	8/7/2016	mm
updated	9/12/2016	mm
updated	10/27/2016	mm


CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
604	208-211, 68	8/7/2016	mm
128	digest 12 and 13	8/7/2016	mm
	updated	9/12/2016	mm
	updated	10/27/2016	mm

SEARCH NOTES		
Search Notes	Date	Examiner

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
a61m	5/31585	9/12/2016	mm
	updated	10/27/2016	mm


	/ MANUEL MENDEZ/ Primary Examiner, Art Unit 3763
--	---

Issue Classification 	Application/Control No. 15156616	Applicant(s)/Patent Under Reexamination VEASEY ET AL.	
	Examiner MANUEL MENDEZ	Art Unit 3763	

CPC						
Symbol					Type	Version
A61M		5		31551	F	2013-01-01
A61M		5		31565	A	2013-01-01
A61M		5		31578	A	2013-01-01
A61M		5		24	I	2013-01-01
A61M		5		31535	I	2013-01-01
A61M		5		31541	I	2013-01-01
A61M		5		3156	A	2013-01-01
A61M		5		31575	A	2013-01-01
A61M		5		31585	I	2013-01-01
A61M		2005		2407	A	2013-01-01
A61M		2205		581	A	2013-01-01
A61M		2205		582	A	2013-01-01
A61M		5		31533	I	2013-01-01
A61M		5		31536	I	2013-01-01
A61M		5		31546	I	2013-01-01
A61M		5		31528	I	2013-01-01
A61M		5		31563	I	2013-01-01
A61M		5		31568	I	2013-01-01
A61M		5		3157	I	2013-01-01
A61M		5		31593	I	2013-01-01
A61M		5		32	I	2013-01-01
A61M		2005		3126	A	2013-01-01


CPC Combination Sets				
Symbol	Type	Set	Ranking	Version

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	30	
/MANUEL MENDEZ/ Primary Examiner.Art Unit 3763	10/27/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1 and 2

Issue Classification 	Application/Control No. 15156616	Applicant(s)/Patent Under Reexamination VEASEY ET AL.
	Examiner MANUEL MENDEZ	Art Unit 3763

US ORIGINAL CLASSIFICATION					INTERNATIONAL CLASSIFICATION									
CLASS		SUBCLASS			CLAIMED					NON-CLAIMED				
604		209			A	6	1	M	5 / 315 (2006.01.01)					
CROSS REFERENCE(S)														
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)													

NONE			Total Claims Allowed:	
			30	
(Assistant Examiner)		(Date)	O.G. Print Claim(s)	O.G. Print Figure
/MANUEL MENDEZ/ Primary Examiner. Art Unit 3763		10/27/2016	1	1 and 2
(Primary Examiner)		(Date)		

Issue Classification 	Application/Control No. 15156616	Applicant(s)/Patent Under Reexamination VEASEY ET AL.
	Examiner MANUEL MENDEZ	Art Unit 3763

<input checked="" type="checkbox"/> Claims renumbered in the same order as presented by applicant		<input type="checkbox"/> CPA		<input checked="" type="checkbox"/> T.D.		<input type="checkbox"/> R.1.47									
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		17												
	2		18												
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	12		28												
	13		29												
	14		30												
	15														
	16														

NONE		Total Claims Allowed:	
		30	
(Assistant Examiner)	(Date)	O.G. Print Claim(s)	O.G. Print Figure
/MANUEL MENDEZ/ Primary Examiner. Art Unit 3763	10/27/2016	1	1 and 2
(Primary Examiner)	(Date)		

Doc code: IDS

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2016. OMB 0651-0031
 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	15156616
	Filing Date	2016-05-17
	First Named Inventor	Robert Frederick Veasey
	Art Unit	3763
	Examiner Name	MENDEZ, MANUEL A.
	Attorney Docket Number	10-1188-US-CON8

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	0533575		1895-02-05	Wilkins	
	2	2717597		1955-09-13	Hein, Jr.	
	3	2722931		1955-11-08	May	
	4	3815785		1974-06-11	Gilmont	
	5	4592745		1986-06-03	Rex, et al.	
	6	4863072		1989-09-05	Perler	
	7	5030209		1991-07-09	Wanderer, et al.	
	8	5328486		1994-07-12	Woodruff	

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

Application Number		15156616
Filing Date		2016-05-17
First Named Inventor	Robert Frederick Veasey	
Art Unit		3763
Examiner Name	MENDEZ, MANUEL A.	
Attorney Docket Number		10-1188-US-CON8

9	5547131	1996-08-20	Brace
10	5582598	1996-12-10	Chanoch
11	5728075	1998-03-17	Levander
12	5957896	1999-09-28	Bendek, et al.
13	5961495	1999-10-05	Walters, et al.
14	6001089	1999-12-14	Burroughs, et al.
15	6059755	2000-05-09	Michel
16	6277099	2001-08-21	Strowe, et al.
17	6277101	2001-08-21	Kirchhofer, et al.
18	6383167	2002-05-07	Kirchhofer, et al.
19	6936032	2005-08-30	Bush, Jr., et al.

**INFORMATION DISCLOSURE
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Art Unit	3763
Examiner Name	MENDEZ, MANUEL A.
Attorney Docket Number	10-1188-US-CON8

20	7195616	2007-03-27	Diller, et al.
21	7361161	2008-04-22	Bainton
22	7771400	2010-08-10	Nielsen
23	7905867	2011-03-15	Veasey, et al.
24	7918833	2011-04-05	Veasey, et al.
25	8021345	2011-09-20	Veasey, et al.
26	8512297	2013-08-20	Veasey, et al.
27	8608709	2013-12-17	Moller, et al.
28	8679069	2014-03-25	Veasey, et al.
29	9233211	2016-01-12	Veasey, et al.

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

U.S.PATENT APPLICATION PUBLICATIONS

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

Application Number	15156616
Filing Date	2016-05-17
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	MENDEZ, MANUEL A.
Attorney Docket Number	10-1188-US-CON8

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	20010034507		2001-10-25	Kirchhofer, et al.	
	2	20020165499		2002-11-07	Slate, et al.	
	3	20030050609		2003-03-13	Sams	
	4	20070123829		2007-05-31	Aitterbury, et al.	
	5	20090275916		2009-11-05	Harms, et al.	
	6	20100042054		2010-02-18	Elahi, et al.	
	7	20120053528		2012-03-01	Bollenbach, et al.	

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

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	0937477	EP	A2	1999-08-25	BECTON DICKINSON CO		

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

Application Number	15156616
Filing Date	2016-05-17
First Named Inventor	Robert Frederick Veasey
Art Unit	3763
Examiner Name	MENDEZ, MANUEL A.
Attorney Docket Number	10-1188-US-CON8

2	1855743	EP	B1	2008-12-17	NOVO NORDISK AS
3	96/25965	WO	A1	1996-08-29	SMITH MARK TIMOTHY
4	01/010484	WO	A1	2001-02-15	BECTON DICKINSON CO
5	02/053214	WO	A1	2002-07-11	NOVO NORDISK AS
6	02/092153	WO	A2	2002-11-21	LILLY CO ELI
7	03/080160	WO	A1	2003-10-02	LILLY CO ELI
8	2011/051366	WO	A2	2011-05-05	SANOFI AVENTIS DEUTSCHLAND

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

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1		

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

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

Application Number	15156616	
Filing Date	2016-05-17	
First Named Inventor	Robert Frederick Veasey	
Art Unit	3763	
Examiner Name	MENDEZ, MANUEL A.	
Attorney Docket Number	10-1188-US-CON8	

EXAMINER SIGNATURE

Examiner Signature	/MANUEL A MENDEZ/	Date Considered	10/27/2016
--------------------	-------------------	-----------------	------------

*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	15156616		
Filing Date	2016-05-17		
First Named Inventor	Robert Frederick Veasey		
Art Unit	3763		
Examiner Name	MENDEZ, MANUEL A.		
Attorney Docket Number	10-1188-US-CON8		

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	/David M. Frischkorn/	Date (YYYY-MM-DD)	2016-10-14
Name/Print	David M. Frischkorn	Registration Number	32833

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

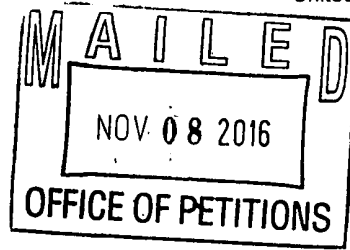
The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection 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 records.
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.



McDonnell Boehnen Hulbert & Berghoff LLP
Sanofi - Aventis
300 South Wacker Drive
Chicago IL 60606



Doc Code: TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.: 15/156,616
<p>1. THE REQUEST FILED. <u>October 14, 2016</u> IS GRANTED.</p> <p>The above-identified application has met the requirements for prioritized examination</p> <p>A. <input type="checkbox"/> for an original nonprovisional application (Track I). B. <input checked="" type="checkbox"/> for an application undergoing continued examination (RCE).</p> <p>2. The above-identified application will undergo prioritized examination. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:</p> <p>A. filing a <u>petition for extension of time</u> to extend the time period for filing a reply; B. filing an <u>amendment to amend the application to contain more than four independent claims, more than thirty total claims</u>, or a multiple dependent claim; C. filing a <u>request for continued examination</u>; D. filing a notice of appeal; E. filing a request for suspension of action; F. mailing of a notice of allowance; G. mailing of a final Office action; H. completion of examination as defined in 37 CFR 41.102; or I. abandonment of the application.</p> <p>Telephone inquiries with regard to this decision should be directed to Brian W. Brown at 571-272-5338.</p> <p>/Brian W. Brown/ [Signature]</p> <p>Petitions Examiner, Office of Petitions (Title)</p>	

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.

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.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

98548 7590 11/02/2016
McDonnell Boehnen Hulbert & Berghoff LLP
Sanofi - Aventis
300 South Wacker Drive
Chicago, IL 60606

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.
15/156,616	05/17/2016	Robert Frederick Veasey	10-1188-US-CON8	1083

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	02/02/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
MENDEZ, MANUEL A	3763	604-209000

<p>1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).</p> <p><input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</p> <p><input type="checkbox"/> "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.</p>	<p>2. For printing on the patent front page, list</p> <p>(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,</p> <p>(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.</p> <p>1 <u>McDonnell Boehnen</u></p> <p>2 <u>Hulbert & Berghoff LLP</u></p> <p>3 _____</p>
---	--

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

<p>4a. The following fee(s) are submitted:</p> <p><input checked="" type="checkbox"/> Issue Fee</p> <p><input type="checkbox"/> Publication Fee (No small entity discount permitted)</p> <p><input type="checkbox"/> Advance Order - # of Copies _____</p>	<p>4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)</p> <p><input type="checkbox"/> A check is enclosed.</p> <p><input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.</p> <p><input checked="" type="checkbox"/> The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number <u>13-2490</u> (enclose an extra copy of this form).</p>
--	---

5. Change in Entity Status (from status indicated above)

Applicant certifying micro entity status. See 37 CFR 1.29

Applicant asserting small entity status. See 37 CFR 1.27

Applicant changing to regular undiscounted fee status.

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.

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.

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 /David M. Frischkorn/ Date November 11, 2016

Typed or printed name David M. Frischkorn Registration No. 32, 833

Electronic Patent Application Fee Transmittal

Application Number:	15156616
Filing Date:	17-May-2016
Title of Invention:	PEN-TYPE INJECTOR
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Filer:	David M. Frischkorn
Attorney Docket Number:	10-1188-US-CON8

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:	27476188
Application Number:	15156616
International Application Number:	
Confirmation Number:	1083
Title of Invention:	PEN-TYPE INJECTOR
First Named Inventor/Applicant Name:	Robert Frederick Veasey
Customer Number:	98548
Filer:	David M. Frischkorn
Filer Authorized By:	
Attorney Docket Number:	10-1188-US-CON8
Receipt Date:	11-NOV-2016
Filing Date:	17-MAY-2016
Time Stamp:	13:21:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$960
RAM confirmation Number	111416INTEFSW00009545132490
Deposit Account	132490
Authorized User	David Frischkorn

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

Mylan Exhibit - 1009

0187

Mylan v. Sanofi

37 CFR 1.19 (Document supply fees)
 37 CFR 1.20 (Post Issuance fees)
 37 CFR 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	Issue Fee Payment (PTO-85B)	10-1188-US-CON8_IssueFee.pdf	1577765 e2a597d7e201b63ef380728df430b79f057820dd	no	1

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30301 7fa364860671875e7548d47c5a8f2f6be9f414f7	no	2
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Warnings:

Information:

Total Files Size (in bytes):	1608066
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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.



APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/156,616	12/27/2016	9526844	10-1188-US-CON8	1083

98548 7590 12/07/2016
 McDonnell Boehnen Hulbert & Berghoff LLP
 Sanofi - Aventis
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ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

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

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

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

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

SANOFI-AVENTIS DEUTSCHLAND GMBH, Frankfurt am Main, GERMANY;
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