Doc Code: TRACK1.REQ

**Document Description: TrackOne Request** 

filed with the application.

PTO/AIA/424 (04-14)

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:								
THE ABOVE-ID	APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.							
37 CFR becaus and exa	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.							
indeper	<ol> <li>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.</li> </ol>							
3. The app	3. The applicable box is checked below:							
I. Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)								
	<ul> <li>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.     </li> </ul>							
	(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. Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

inventor, or the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each

- 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/	<sub>Date</sub> May 17, 2016
Name (Print/Typed) David M. Frischkorn	Practitioner 32,833
Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for Submit multiple forms if more than one signature is required.*	or signature requirements and certifications.
*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:

- 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-		10-1188-U	S-CON8					
			pplication Number		0-00110			_		
			Applicatio	11114						_
Title of Invention	Title of Invention   IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR									
bibliographic data arrar This document may be	nged in a format specified by	the Un nd subi	ited States Pat mitted to the C	tent ar	id Trademark O	ffice as outline	ed. The following form contains ed in 37 CFR 1.76. e Electronic Filing System (EF			e
Secrecy Orde	er 37 CFR 5.2:									
	f the application associate Paper filers only. Application						der a Secrecy Order pur	sua	ant	:0
Inventor Infor		ations	tilat lali uli	<u>uei c</u>	eciecy Orde	i may not b	e med electromodily.)			
Inventor 1							Remove			
Legal Name										
Prefix Given Nar	ne	Mi	ddle Name	<u>;</u>		Family Na	ame	5	Suf	fiχ
Robert		Fr	ederick			Veasey		İΤ		•
Residence Inform	nation (Select One)	US	Residency	•	Non US Res	sidency	Active US Military Service	e		
City Warwickshir	e		Country of R	Resid	ence <sup>i</sup>		GB			7
l-							_	_		_
Mailing Address of	f Inventor:									_
Address 1	35 Hitchman Ro	oad, Le	eamington Sp	oa						
Address 2										_
City Warv	vickshire				State/Prov	rince				
Postal Code	CV31 3QH			Cot	intry i	GB				
Inventor 2							Remove			_
Legal Name										_
Prefix Given Nar	ne	Mi	iddle Name			Family Na	ame	Ţ	Suf	Fix
Robert		<b>1</b>				Perkins		$\mathbf{H}$		₹
	nation (Select One)	US	Residency	(1)	Non US Res		Active US Military Service	<b>⊥</b> ⊥⊥ e		ш
City Warwickshire Country of Residence i GB										
Mailing Address of Inventor:										
Address 1 67 Erica Drive, Learnington Spa										
Address 2	J. 2.198 31119,		g.o opu					_		_
	vickshire				State/Prov	ince				
Postal Code	CV31 2RW			Cor	intry i	GB	l			
	11-151-111					_	Remove			_
Inventor 3 Legal Name								—		

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Application Data She	10-1188-US-CON	18						
Application Bata one		Applicatio	n Number					
Title of Invention IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR								
Prefix Given Name		Middle Name	i	Family Name		Suffix		
→ David		Aubrey		Plumptre		<b>-</b>		
Residence Information (S	Select One)	JS Residency	Non US Res	sidency Acti	ve US Military Service			
City Worcestershire		Country of R	tesidence <sup>i</sup>	GВ				
,				,-				
Mailing Address of Invento	)r: 							
Address 1	36 Shire Way, Droi	twich Spa						
Address 2								
City Worcestershire			State/Prov	/ince				
Postal Code	WR9 7RQ		Country	GB				
All Inventors Must Be Lis generated within this form be			rmation blocks	may be	Add			
Correspondence In	formation:							
Enter either Customer Nu For further information se			pondence Inforn	nation section b	elow.			
☐ An Address is being p	provided for the	corresponder	nce Information	of this application	on.			
Customer Number	98548							
Email Address	PSGDOCKET@N	ІВНВ.СОМ		Add	Email Remove	Email		
Application Inform	ation:							
Title of the Invention	IMPROVEMENTS	S IN AND RELA	TING TO A PEN-T	YPE INJECTOR				
Attorney Docket Number	10-1188-US-CON	18	Small Ent	ntity Status Claimed 🔲				
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 to application papers including a specific provided in the appropriate section. For the purposes of a filing date unreference to the previously filed a	ecification and any dr on(s) below (i.e., "Dor nder 37 CFR 1.53(b),	rawings are being mestic Benefit/Na the description a	g filed. Any domesti itional Stage Informa nd any drawings of 1	c benefit or foreign p ation" and "Foreign F the present applicati	oriority information mustriority Information").			
Application number of the previ filed application	ously Filing	date (YYYY-MM-	DD)	Intellectual	Property Authority or C	ountry		

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Application D	ata Sheet 37 CFR 1.76	Attorney Docket Number	10-1188-US-CON8					
Application D	ata Sileet St CFK 1.76	Application Number						
Title of Invention IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR								
Publication	Publication Information:							
Request Earl	y Publication (Fee required a	t time of Request 37 CFR 1.2	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:

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 custom Number will be used for the Representative Information during processing.  Please Select One:  Customer Number  US Patent Practitioner  Limited Recognition (37 CFR 11.9)									
	Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer								
	Please Select One:	Customer Number	US Patent Practitioner	Limited Recognition (37 CFR 11.9)					
Customer Number 98548	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.

			r	_	pplication Number lield			
Prior Applicati	on Status	Pending		▼			Ren	nove
Application N	lumber	Conti	nuity Type		Prior Application Number Filing or 371(c) Da (YYYY-MM-DD)			
		Continuation of	of	3	14946203		2015-11-19	
Prior Applicat	on Status	Patented		<b>-</b>			Ren	nove
Application Number	Cont	inuity Type	Prior Applicati Number	on	Filing Date (YYYY-MM-DD)	Pat	tent Number	Issue Date (YYYY-MM-DD)
14946203	Continuat	ion of	of 14635573		2015-03-02	9233211		2016-01-12
Prior Applicat	on Status	Patented		3	•		Ren	nove
Application Number	Cont	inuity Type	Prior Applicati Number	on	Filing Date (YYYY-MM-DD)	Pat	tent Number	Issue Date (YYYY-MM-DD)
14635573	Continuat	ion of	on of 13919251		2013-06-17 9011391 2		2015-04-21	
Prior Applicat	on Status	Patented		3			Ren	nove
Application Number	Cont	inuity Type	Prior Applicati Number	on	Filing Date (YYYY-MM-DD)	Pat	tent Number	Issue Date (YYYY-MM-DD)
13919251	Division o	f 🔻	13040198		2011-03-03	85	12297	2013-08-20

PTO/AIA/14 (11-15)

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

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Application Data Sheet 37 CFR 1.76				Attorney D	cket Number	10-1188-US-CON8				
Application	ala Siic	ersi cirk	1.70	Application	Number					
Title of Invention	IMPRO	ELATING TO	ΑI	PEN-TYPE INJE	CTOR					
		<b>5</b>								
Prior Application	on Status	Patented		▼	ı				Ren	nove
Application Number	Cont	NIIITV I VNA I		ior Application Number		Filing Da (YYYY-MM-		Pat	ent Number	Issue Date (YYYY-MM-DD)
13040198	Continuat	ion of	1148	33546		2006-07-11		79	18833	2011-04-05
Prior Application	on Status	Abandoned		•					Ren	nove
Application Number Continuity			Туре		Prior Applicati	on Num	ber		or 371(c) Date YY-MM-DD)	
11483546 Continuation of			•	•	10790225			2004-03-02		
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the <b>Add</b> button.										

## **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)<sup>1</sup> 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 <sup>i</sup>	Filing Date (YYYY-MM-DD)	Access Code <sup>i</sup> (if applicable)
0304822.0	GB	2003-03-03	
Additional Foreign Priority  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
П	16, 2013.
ш	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.

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 Da	ta Shoot 27 CED 1 76	Attorney Docket Number	10-1188-US-CON8				
Application Data Sheet 37 CFR 1.76		Application Number					
Title of Invention	IMPROVEMENTS IN AND RE	ELATING 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 <u>must opt-out</u> 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 <u>DOES NOT</u> 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.

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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.

Application Da	ita Sheet 37 CED 1 76	Attorney Docket Number	10-1188-US-CON8			
Application Data Sheet 37 CFR 1.76		Application Number				
Title of Invention	IMPROVEMENTS IN AND RE	D RELATING TO A PEN-TYPE INJECTOR				

## **Applicant Information:**

Providing assignment information in to have an assignment recorded by the		for compliance with any req	uirement of part 3 of Title 37 of CFR		
Applicant 1			Remove		
If the applicant is the inventor (or the real The information to be provided in this said 1.43; or the name and address of the alwho otherwise shows sufficient propriet applicant under 37 CFR 1.46 (assigned proprietary interest) together with one identified in this section.	section is the name and address assignee, person to whom the in etary interest in the matter who i e, person to whom the inventor	s of the legal representative oventor is under an obligation s the applicant under 37 CF is obligated to assign, or pe	who is the applicant under 37 CFR on to assign the invention, or person R 1.46. If the applicant is an around the arou		
<ul> <li>Assignee</li> </ul>	Legal Representative ur	nder 35 U.S.C. 117	Joint Inventor		
Person to whom the inventor is obli	gated to assign.	Person who shows sufficient proprietary interest			
If applicant is the legal representat	ive, indicate the authority to	file the patent application	, the inventor is:		
			▼		
Name of the Deceased or Legally	Incapacitated Inventor:				
If the Applicant is an Organization check here.					
Organization Name SANOFI-AVENTIS DEUTSCHLAND GMBH					
Mailing Address Information Fo	or Applicant:				
Address 1 Brüningstrasse 50, 65929					
Address 2					
City Frank	rfurt am Main	State/Province			
Country DE		Postal Code			
Phone Number		Fax Number			
Email Address					
Additional Applicant Data may be g	generated within this form by	selecting the Add button	. 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.

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76		Attorney Doo	ket Number	10-1188-	10-1188-US-CON8			
		Application N	lumber					
Title of Invention IMPROVEMENTS IN AND RELATING TO A PEN-TYPE INJECTOR								
Assignee 1								
Complete this section application publication publication as an application application put	n. An assignee licant. For an a	e-applicant identifie	d in the "Applica	ant Information	n" section will	appear on th	e patent app	olication
F						Г	Remove	
If the Assignee or	Non-Applica	nt Assignee is an	Organization	check here.				
Prefix Given Name		Middle Name F		Family Name		Suffix		
	<b>-</b>							•
Mailing Address Ir	nformation F	or Assignee inc	_ cluding Non- <i>l</i>	Applicant As	ssignee:			
Address 1								
Address 2	-							
City				State/Prov	/ince			
Country i				Postal Code				
Phone Number				Fax Numb	Fax Number			
Email Address				•	•			
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.  Add								
Signature: Remove								
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	nature /David M. Frischkorn/		Date (Y	Date (YYYY-MM-DD) 2016-05-17				
First Name Dav	id M.	Last Name	Frischkorn		Registra	ation Numbe	r 32833	
Additional Signature may be generated within this form by selecting the Add button.  Add								

PTO/AIA/14 (11-15)

Approved for use through 04/30/2017. OMB 0651-0032

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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.

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. 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.
- 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 CooperationTreaty.
- 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
- 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 does 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 pentype 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 dispose 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 though the opening 18 in the insert 16, thereby to advance the piston 10 in the cartridge

8. Once the dialed dose has been dispensed, the dose dial sleeve 70 is prevented from further rotation by contact of a plurality of members 110 (Figure 14) extending from the dose dial grip 76 with a corresponding plurality of stops 112 formed in the main housing 4 (Figures 15 and 16). In the illustrated embodiment, the members 110 extend axially from the dose dial grip 76 and have an inclined end surface. The zero dose position is determined by the abutment of one of the axially extending edges of the members 110 with a corresponding stop 112.

#### **CLAIMS**

- 1. A 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 movement of the button caused by distally applied pressure to the head initiates dose 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;

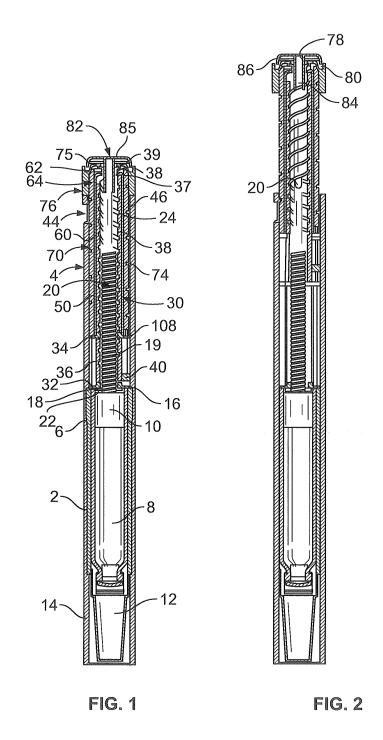
and the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.

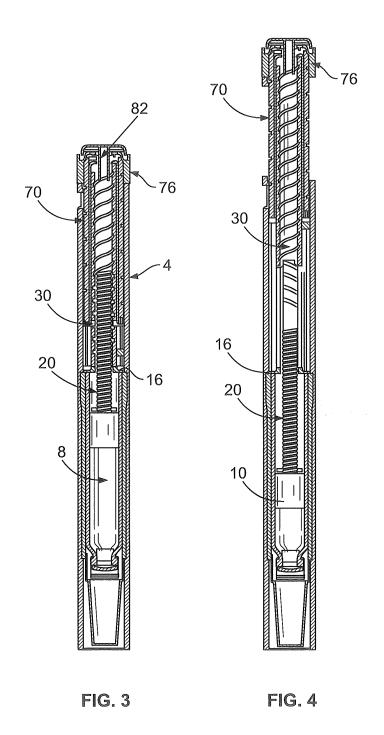
- 22. The drug delivery device of claim 21 where the piston rod has a circular cross-section.
  - 23. The drug delivery device of claim 21 further comprising a clutch.
- 24. The drug delivery device of claim 24 where the clutch provides audible and tactile feedback indicative of unit doses of medicament.
- 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 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. 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.





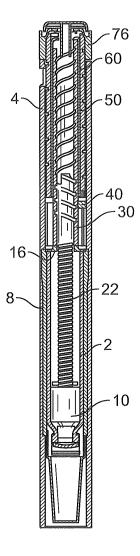


FIG. 5

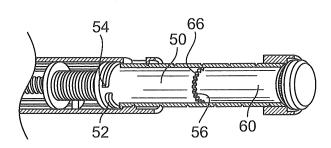


FIG. 6

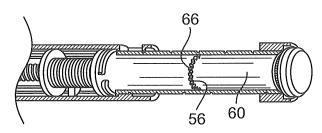


FIG. 7

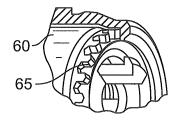


FIG. 8

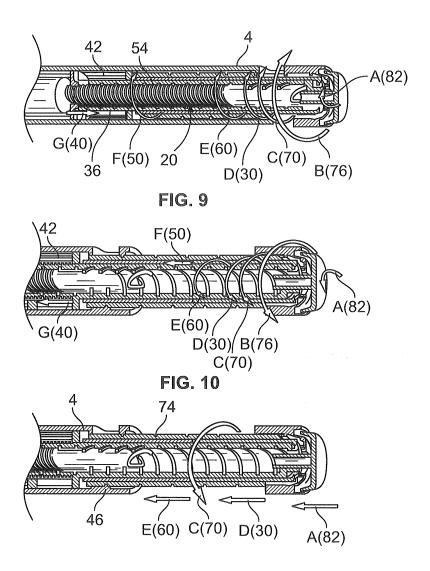
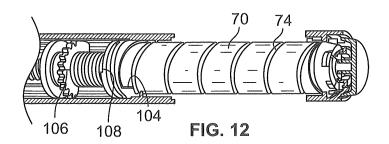
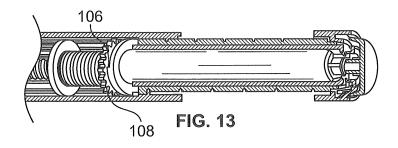


FIG. 11





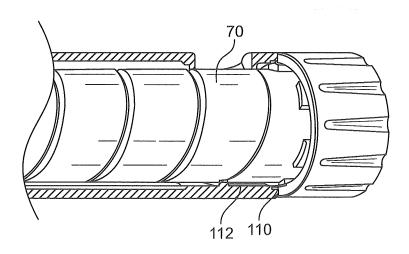


FIG. 14

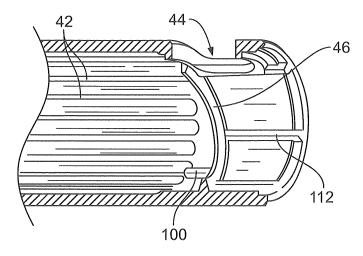


FIG. 15

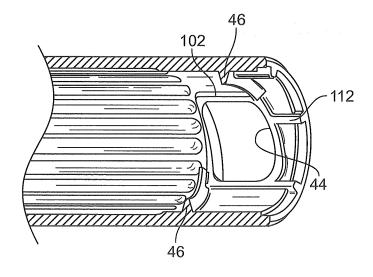


FIG. 16

PTO/AIA/01 (06-12)

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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				
As the below named inventor, I hereby declare that:					
This declar					
	United States application or PCT international application number 13/919,251  filed on June 17, 2013				
The above-identified application was made or authorized to be made by me.					
I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.					
I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.					
	WARNING:				
Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.					
LEGAL NA	AME OF INVENTOR				
Inventor:	Robert Frederick Veasey  Date (Optional): 6 3 15				
Note: An appli been previous	cation data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have ly filed. Use an additional PTO/AIA/01 form for each additional inventor.				

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,

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

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 displays a valid OMB control number.

## 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				
As the below named inventor, I hereby declare that:					
This declaration The attached application, or is directed to:					
	United States application or PCT international application number 13/919,251  filed on June 17, 2013				
The above-identified application was made or authorized to be made by me.					
I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.					
I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.					
	WARNING:				
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LEGAL NA	ME OF INVENTOR				
Inventor: F	Robert Perkins  Date (Optional): II MAIL 2015				
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.					

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PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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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				
As the belo	w named inventor, I hereby declare that:				
This declard is directed t	The attached application or				
The above-i	dentified application was made or authorized to be made by me.				
I believe tha	t I am the original inventor or an original joint inventor of a claimed invention in the application.				
	I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.				
	WARNING:				
Petilioner/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 redecting 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 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.					
LEGAL NA	ME OF INVENTOR				
Inventor: _ Signature:	David Aubrey Plumptre  Date (Optional): 6   3   15				
	cation data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have ly filed. Use an additional PTO/AIA/01 form for each additional inventor.				

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

under 37 C	voke all previous powers FR 3.73(c).	of attorney	given in the a	pplication identified in th	ne attached statement
I hereby ap	point:				**************************************
<b>V</b> Pra	ctitioners associated with Custon	ner Number:	00540		
OF	₹		98548	***************************************	
Pra	ctitioner(s) named below (if more	than ten pat	ent practitioners are	e to be named, then a custon	ner number must be used):
å	Name	Ren	istration	Name	Registration
<b></b>	1.450.000		lumber	1401110	Number
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any and all pa	or agent(s) to represent the und tent applications a ssigned <u>only</u> t	o the unders	ore the United State Igned according to	es Patent and Trademark On the USPTO assignment reco	rds or assignments docu ments
}=====================================	s form in accordance with 37 CF	000000000000000000000000000000000000000	000000000000000000000000000000000000000		22/20/20/20/20/20/20/20/20/20/20/20/20/2
Please change	the correspondence address fo	the applicat	ion identified in the	attached statement under 37	CFR 3.73(c) to:
√ The	address associated with Custom	er Number:	98548		
OR				TYVAYAXITKEHENKAAAAAAAAAAAAAAAAAAAAAA	
Firm or	al Name				
Address				**************************************	
Gity		***************************************			
Country		***************************************			
	***************************************				
Telepho	ne	***************************************	E	mail	
Assignee Nam	Assignee Name and Address: Sanofi-Aventis Deutschland GmbH Brüningstrasse 50, D65929 Frankfurt am Main, Germany				
Filed in each	s form, together with a state application in which this for ners appointed in this form, a	m is used.	The statement us	nder 37 CFR 3.73(c) may t	se completed by one of
Tin	e individual who∮e∫signature	SIGNATU and title is	RE of Assignee supplied below is	of Record authorized to act on beha	alf of the assignee
Signature	Ma WA-	i.V.	MYN	Date Septemb	er 24, 2012
Name	Dr. Michael Bankma	ann D	)ieter Breuer	Telephone 0049-	69-305-5794
Title	Prokurist	Autho	orized/Signat	ory	

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.D. 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

	Application Number		
	Filing Date		2016-05-17
INFORMATION DISCLOSURE	First Named Inventor	Robert	t Frederick Veasey
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit		
(1100 to Submission ander of of K 1.00)	Examiner Name		
	Attorney Docket Number		10-1188-US-CON8

				U.S.I	PATENTS	Remove
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	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	

( Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		2016-05-17
First Named Inventor Rober		rt 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	

( Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		2016-05-17
First Named Inventor Rober		rt 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	

( Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		2016-05-17
First Named Inventor	Robei	rt Frederick Veasey
Art Unit		
Examiner Name		
Attorney Docket Numb	er	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	

( Not for submission under 37 CFR 1.99)

Application Number		
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First Named Inventor Rober		t 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.			
If you wish to add additional U.S. Patent citation information p			n information pl	ease click the Add button.		Add		
			U.S.P	ATENT APPLIC	CATION PUBLICATIONS		Remove	
Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Releva		Lines where es or Relevant

( Not for submission under 37 CFR 1.99)

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

			11	
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.	

( Not for submission under 37 CFR 1.99)

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

			-			-		
12	2	20040267207		2004-12-30	Veasey et al.			
13	3	20040267208		2004-12-30	Veasey et al.			
14	4	20050004529		2005-01-06	Veasey et al.			
15	5	20050019400		2005-01-27	Deveney et al.			
16	6	20050033244		2005-02-10	Veasey et al.			
17	7	20050055011		2005-03-10	Enggaard			
18	8	20050113765		2005-05-26	Veasey et al.			
19	9	20050205083		2005-09-22	Staniforth et al.			
20	0	20050209570		2005-09-22	Moller			
21	1	20050268915		2005-12-08	Wassenaar et al.			
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FOREIGN PATENT DOCUMENTS Remove								

( Not for submission under 37 CFR 1.99)

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

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> İ	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T5
	1	3609555	DE		1987-09-24	Pomer		
	2	D673482	EP		1998-04-29	Sams		
	3	D937471	EP		1999-08-25	Becton, Dickinson & Co.		
	4	D937476	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	D5-337179	JP		1993-12-21	Balkwill		
	9	D6-296691	JP		1994-10-25	Michel et al.		
	10	2111019	RU		1998-05-20	Khvorostov		

( Not for submission under 37 CFR 1.99)

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

				-					
	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 Add									
NON-PATENT LITERATURE DOCUMENTS Remove									
Examiner Initials*	No		nal, serial, symp	osium,	catalog, etc), d	the article (when appropi late, pages(s), volume-is			T5
	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 First Named Inventor Robert Frederick Veasey Art Unit Examiner Name Attorney Docket Number 10-1188-US-CON8

:	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	specif	S. Reissue Patent Application No. 11/121,331, "Injection Syringe", Filed May 3, 2005, including copies of as-filed pecification, drawings, abstract, and claims, as well as the reissue declaration and a copy of list of documents found 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).									
If you wish	to ad	d add	litional non-patent literature document citation information please click the Add button Add								
			EXAMINER SIGNATURE								
Examiner S	miner 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.											
Standard ST.	3). <sup>3</sup> Fo	or Japa	O Patent Documents at <a href="https://www.uspro.gov">www.uspro.gov</a> or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO anese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document appropriate symbols as indicated on the document under WIPO Standard ST 16 if possible. <sup>5</sup> Applicant is to place a check mark here								

EFS Web 2.1.17

English language translation is attached.

( Not for submission under 37 CFR 1.99)

Application Number				
Filing Date		2016-05-17		
First Named Inventor	Robei	rt 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.

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

INFORMATION DISCLOSURE	Application Number		
	Filing Date		2016-05-17
	First Named Inventor Robert		rt Frederick Veasey
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit		
(Not for Submission under or of K 1.55)	Examiner Name		
	Attorney Docket Number		10-1188-US-CON8

				U.S.I	PATENTS	Remove
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	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.	

( Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		2016-05-17
First Named Inventor	Robe	rt Frederick Veasey
Art Unit		
Examiner Name		
Attorney Docket Numb	er	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.

( Not for submission under 37 CFR 1.99)

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

	2074070	2000 00 40		
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.	
	0.12000	2000 10 10	Tions of the	
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.	

( Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		2016-05-17
First Named Inventor	Robe	rt 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	2001-0 <del>9</del> -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.	

( Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		2016-05-17
First Named Inventor Rober		rt 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	_

( Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		2016-05-17
First Named Inventor	Robe	rt 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 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	B512297		2013-08-20	Veasey et al.			
	69	2722931		1955-11-08	May			
	70	2717597		1955-09-13	Hein, Jr.			
If you wisl	h to add	additional U.S. Paten	t citatio	n information pl	ease click the Add button.		Add	
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( Not for submission under 37 CFR 1.99)

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

Examiner Initial*	Cite No	Foreig Numb	gn Document per <sup>3</sup>	Country Code <sup>2</sup> İ	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T5	
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Examiner	Signa	ture					Date Considered			
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Standard ST  4 Kind of doo	Γ.3). <sup>3</sup> F cument l	or Japar by the ap	nese patent docume	nts, the indication of	the year	of the reign of the	r office that issued the docume Emperor must precede the ser dard ST.16 if possible. <sup>5</sup> Applic	rial number of the patent doc	ument.	

( Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		2016-05-17
First Named Inventor	Robei	rt Frederick Veasey
Art Unit		
Examiner Name		
Attorney Docket Numb	er	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.

X 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

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  court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement
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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 A	\pp	lication Fee	Transmi	ttal		
Application Number:						
Filing Date:						
Title of Invention:	IMI	PROVEMENTS IN AN	ID RELATING TO	) A PEN-TYPE INJEC	ETOR	
First Named Inventor/Applicant Name:	Ro	bert Frederick Vease	еу			
Filer:	Da	vid M. Frischkorn				
Attorney Docket Number: 10-1188-US-CON8						
Filed as Large Entity						
Filing Fees for Track I Prioritized Examination - Nonpr	ovis	ional Applicatio	n under 35 U	SC 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:								
	Tot	al in USD	(\$)	6540				

Electronic Ack	knowledgement 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: File Size(Bytes)/ Multi **Document Pages Document Description File Name** Part /.zip Number **Message Digest** (if appl.) 136695 10-1188-US-2 1 TrackOne Request no CON8\_TrackOne\_Request.PDF 198b6cb5ef77dfe09f3fafb5d67e3d6bf792i f26 Warnings: Information: 1823837 9 2 **Application Data Sheet** 10-1188-US-CON8\_ADS.PDF no f78b0b85ddb7c2ee6ecc802457083c0026 94ba0 Warnings: Information: 121862 3 10-1188-US-CON8\_Spec.pdf 16 yes fa4003916f82db8572e678badeeb13e49e 2ad2b Multipart Description/PDF files in .zip description **Document Description** Start **End** Specification 1 10 Claims 11 15 Abstract 16 16 Warnings: Information: 558914 Drawings-only black and white line 10-1188-US-CON8\_Drawings. 4 7 no drawings PDF 7fd86377c4005bab6ebc6152f02ca4f97e c3d5 Warnings: Information: 268101 10-1188-US-5 Oath or Declaration filed 3 no CON8\_Declarations.PDF 91e1f4327becf6332f1f993a7bae6e9e8bc0 b0d7 Warnings: Information: 181881 6 Power of Attorney 10-1188-US-CON8\_POA.PDF no 1

Warnings:					
Information	:				
7	Transmittal Letter	10-1188-US-	91256	no	2
	CON8_IDS_Transmittal.pdf		ec7197613c4eac89b2f4d92e415696a21c72 0aab		
Warnings:					
Information	:				
8	Information Disclosure Statement (IDS)	10-1188-US-CON8_IDS_1.PDF	1009890	no	12
	Form (SB08)		95010830e446f5f1fb4ab9d3c9d4c777c294 a9f0		
Warnings:					
Information	:				
9	Information Disclosure Statement (IDS)	10-1188-US-CON8_IDS_2.PDF	1008818	no	10
	Form (SB08)		d0f89b167d366cee46cdce4ae1412374e6a 5f7e4		
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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.

	PAT	ENT APPL		N FEE DE titute for Form		ION RECORI	D		tion or Docket Num 6,616	ber
	APP	LICATION A	S FILE[		umn 2)	SMALL	ENTITY	OR	OTHER SMALL	
FOR NUMBER FILED NUMBER EXTRA						RATE(\$)	FEE(\$)	1	RATE(\$)	FEE(\$)
BASIC FEE (37 CFR 1.16(a), (b), or (c)) N/A N/A				I/A	N/A		1	N/A	280	
SEA	RCH FEE FR 1.16(k), (i), or (m))	N	I/A	١	I/A	N/A		1	N/A	600
XΑ	MINATION FEE FR 1.16(o), (p), or (q))	N	I/A	N	I/A	N/A		1	N/A	720
OT.	AL CLAIMS FR 1.16(i))	30	minus 2	20= *	10			OR	x 80 =	800
NDE	PENDENT CLAIN	MS 2	minus 3	3 = *				1	x 420 =	0.00
APP	LICATION SIZ	E sheets of p \$310 (\$15 50 sheets	oaper, the 5 for sma or fractio	and drawings e e application siz all entity) for eac n thereof. See CFR 1.16(s).	ze fee due is ch additional					0.00
<b>V</b> IUL	TIPLE DEPENDE	NT CLAIM PRE	SENT (37	' CFR 1.16(j))				1		0.00
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	Total (37 CFR 1.16(i))	*	Minus	**	-	х =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	х =	
{	Application Size Fe	e (37 CFR 1.16(s))	)		•					
	FIRST PRESENTA	TION OF MULTIP	LE DEPENI	DENT CLAIM (37 C	FR 1.16(j))			OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
_		(Column 1)		(Column 2)	(Column 3)			,		
ء ا ۾		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONA FEE(\$)
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<u> </u>	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fe	ee (37 CFR 1.16(s)						]		
	FIRST PRESENTA	TION OF MULTIP	LE DEPENI	DENT CLAIM (37 C	CFR 1.16(j))			OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
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PFIZER, INC. v. SANOFI-AVENTIS DEUTSCHLAND GMBH



## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS PO. Box 1450

Alexandria, Virginia 22313-1450 www.uspto.gov

 APPLICATION NUMBER
 FILING or 371(c) DATE
 GRP ART UNIT
 FIL FEE REC'D
 ATTY.DOCKET.NO
 TOT CLAIMS IND CLAIMS

 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 <a href="http://www.uspto.gov">http://www.uspto.gov</a> 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

page 1 of 4

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 page 2 of 4

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

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

#### **NOT GRANTED**

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page 3 of 4



## United States Patent and Trademark Office

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
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 - Aventi 300 South Wac	s				
Chicago, IL 60	506		ART UNIT	PAPER NUMBER	
			3763		
			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.



## UNITED STATES PATENT AND TRADEMARK OFFICE

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

Doc Code: TRACK1.GRANT

	Prior	n Granting Request for ritized Examination nck I or After RCE)	Application No.:15/156,616
1.	THE REQI	JEST FILED <u>May 17, 2016</u>	IS <b>GRANTED</b> .
	The above A.  B.	• • • • • • • • • • • • • • • • • • • •	
2.			ergo prioritized examination. The application will be course of prosecution until one of the following occurs:
	A.	filing a petition for extension of	f time to extend the time period for filing a reply;
	В.	filing an amendment to amend	the application to contain more than four independent
		claims, more than thirty total c	claims, or a multiple dependent claim;
	C.	filing a request for continued ex	xamination;
	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;	
	Н.	completion of examination as de	fined in 37 CFR 41.102; or
	l.	abandonment of the application.	
	Telephone	inquiries with regard to this decisi	ion should be directed to Vanitha Elgart at 571-272-7395.
			ns Examiner, Office of Petitions

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

Office of	Petitions: De	ecision C	Count Sheet		Mailing Month	
Application	on No.	15	5156616	<b>    </b>		*
		-	no slashes or commas ling+last 5 numbers", Ex		6 5/12345, enter 5151234	5
Deciding	Official:	ELG	ART, VANITH	<b>HA</b>		
Count (1) - F	Palm Credit	15/15	66,616 FINANCE WORK NEEDED Select Check Box for YES	S	# G R A N T *	d.
Decision Typ	oe: 643 - Track C	 One request			* 6 4 3 *	
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Decision:	n/a		FINANCE WORK NEEDED	S		
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Count (3)						
Decision: 1	n/a		FINANCE WORK NEEDED	S		
Decision Typ	e: NONE					
Notes:						
	Initials of Approving	Official (if re	quired)		ore than 3 decisions, attach count sheet & mark this box	
Printed on:			C	Office of Petitions	s Internal Document - Ver. 5	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.

 <u>X</u>	GRANTED
	DISMISSED
	DENIED

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
15/156,616	05/17/2016	Robert Frederick Veasey	10-1188-US-CON8	1083	
	7590 08/10/201 ehnen Hulbert & Bergh	-	EXAM	INER	
Sanofi - Aventi 300 South Wac	s	MENDEZ, MANUEL A			
Chicago, IL 60	506		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.

	<b>Application No.</b> 15/156,616	Applicant(s) VEASEY ET					
Office Action Summary	Examiner MANUEL MENDEZ	Art Unit 3763	AIA (First Inventor to File) Status No				
The MAILING DATE of this communication app	pears on the cover sheet with the	corresponden	ce address				
Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPL' THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period or - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be till will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	mely filed In the mailing date of ED (35 U.S.C. § 133	f this communication.				
Status							
1) Responsive to communication(s) filed on A declaration(s)/affidavit(s) under <b>37 CFR 1.1</b>							
· <del>_</del>	action is non-final.						
<ul> <li>3) An election was made by the applicant in respect.</li> <li>4) Since this application is in condition for alloward closed in accordance with the practice under E</li> </ul>	n have been incorporated into this nce except for formal matters, pro	s action. osecution as t					
Disposition of Claims*							
5a) Of the above claim(s) is/are withdray 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/o * If any claims have been determined allowable, you may be elementary.	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. any claims have been determined allowable, you may be eligible to benefit from the Patent Prosecution Highway program at a ricipating intellectual property office for the corresponding application. For more information, please see						
Application Papers							
<ul> <li>10) The specification is objected to by the Examine</li> <li>11) The drawing(s) filed on 5/17/2016 is/are: a) Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct</li> </ul>	accepted or b)  objected to by drawing(s) be held in abeyance. Se	e 37 CFR 1.85	(a).				
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) Notice of References Cited (PTO-892)	3) Interview Summary Paper No(s)/Mail D						
<ol> <li>Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/S Paper No(s)/Mail Date <u>5/17/2016, 5/17/2016, and 5/17/2016</u>.</li> </ol>	SB/08b) 4) Other:	<u></u> .					

U.S. Patent and Trademark Office PTOL-326 (Rev. 11-13)

DL-326 (Rev. 11-13) Office Action Summary

Application/Control Number: 15/156,616 Page 2

Art Unit: 3763

## **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).

Application/Control Number: 15/156,616 Page 3

Art Unit: 3763

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

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

Application/Control Number: 15/156,616 Page 5

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.

Application/Control Number: 15/156,616 Page 6

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

## Application/Control No. Applicant(s)/Patent Under Reexamination 15/156,616 VEASEY ET AL. Notice of References Cited Art Unit Examiner Page 1 of 1 MANUEL MENDEZ 3763 **U.S. PATENT DOCUMENTS** Document Number Date Name **CPC Classification** US Classification Country Code-Number-Kind Code MM-YYYY US-7,918,833 B2 04-2011 Veasey; Robert Frederick A61M5/31546 604/209 Α US-В С US-D US-US-Ε US-F US-G US-Н US-US-US-Κ US-US-Μ FOREIGN PATENT DOCUMENTS Document Number Date Name **CPC Classification** Country Country Code-Number-Kind Code MM-YYYY Ν 0 Ρ Q R s Т NON-PATENT DOCUMENTS Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) U

\*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.

U.S. Patent and Trademark Office

PTO-892 (Rev. 01-2001) **Notice of References Cited**  Part of Paper No. 20160807



## UNITED STATES PATENT AND TRADEMARK OFFICE

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

## **BIB DATA SHEET**

## **CONFIRMATION NO. 1083**

SERIAL NUM	BER	FILING or DATI	2371(c)		CLASS	GR	OUP ART	UNIT	ATTC	RNEY DOCKET NO.
15/156,61	6	05/17/2			604		3763		10-1188-US-CON8	
		RULI	E							
APPLICANTS		IS DEUTSCH	HLAND GN	/IВН, F	rankfurt am Mair	n, GE	RMANY;			
Robert Fr Robert Pe David Aul	INVENTORS  Robert Frederick Veasey, Warwickshire, UNITED KINGDOM;  Robert Perkins, Warwickshire, UNITED KINGDOM;  David Aubrey Plumptre, Worcestershire, UNITED KINGDOM;									
** CONTINUING DATA **********************************										
UNITED	KINGDO	OM 0304822.	0 03/03/20	003						
** <b>IF REQUIRE</b> 06/01/201		EIGN FILING	LICENS	E GRA	ANTED **					
Foreign Priority claime 35 USC 119(a-d) cond Verified and			☐ Met af Allowa	ter nce	STATE OR COUNTRY		HEETS WINGS	TOT.		INDEPENDENT CLAIMS
M	MENDEZ/ Examiner's		Initials		UNITED KINGDOM		7	30	)	2
ADDRESS						•				
McDonne Sanofi - A 300 Soutl Chicago, UNITED S	Aventis h <b>W</b> acke IL 6060	6	& Berghoff	LLP						
TITLE										
PEN-TYP	E INJE	CTOR								
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							☐ Other			
							☐ Credi	t		

BIB (Rev. 05/07).

Receipt date: 05/17/2016 15156616 - GAU: 3763

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

Mation Disclosure Statement (IDS) Filed

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.

	Application Number		
INFORMATION BIOOLOGUES	Filing Date		2016-05-17
INFORMATION DISCLOSURE	First Named Inventor	Robert	t Frederick Veasey
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit		
(Not for submission under 57 of K 1.55)	Examiner Name	•	
	Attorney Docket Number		10-1188-US-CON8

				U.S.I	PATENTS	Remove	
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Releva	Columns,Lines where nt Passages or Relevant 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		

D.	eceipt date: 05/17/2016				<del>15156616 -</del>	Carr.	2762
7	ecerpt date. 00/1//2010	Application Number			10100010 -	· GAO.	3,03
		Filing Date		2016-05-17			
	INFORMATION DISCLOSURE	First Named Inventor	Robei	ert Frederick Veasey			
	STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit					
	(Not for submission under 57 of it 1.55)	Examiner Name					

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	

3				<del>15156616 -</del>	C13.77	2762
Receipt date: 05/17/2016	Application Number			10100010 -	· GAU:	3763
	Filing Date		2016-05-17			
	First Named Inventor	Robei	rt Frederick Veasey			
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit					
	Examiner Name					

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	

Ю	eceipt date: 05/17/2016				<del>15156616 -</del>	Carr.	2762
Σ.	eceipt date. 03/17/2010	Application Number			13136616 -	GAU.	2,03
		Filing Date		2016-05-17			
	INFORMATION DISCLOSURE	First Named Inventor	Robe	rt Frederick Veasey			
	( Not for submission under 37 CFR 1.99)	Art Unit	•				
	(Not for Submission under or or it 1.33)	Examiner Name					

10-1188-US-CON8

Attorney Docket Number

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	

Danaint data: 05/17/2016				<del>- 15156616 -</del>	773.77	2762
Receipt date: 05/17/2016	Application Number			13136616 -	GALU:	3/63
INFORMATION DISCLOSURE	Filing Date		2016-05-17			
	First Named Inventor	Robe	pert Frederick Veasey			
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit					
(Not for Submission under or STR 1.33)	Examiner Name					
	Attorney Docket Numb	er	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.P.	ATENT APPLIC	CATION PUBLICATIONS		Remove
Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Releva	Columns,Lines where nt Passages or Relevant s Appear

Descript dat	A . A E /17 /2016				<del>15156616 -</del>	CATT. 2765
Receipt date: 05/17/2016		Application Number			13130010 -	GRU. 3702
		Filing Date		2016-05-17		
INFORMATION DISCLOSURE	First Named Inventor	Robe	rt Frederick Veasey			
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)		Art Unit				
( NOT IOI SUL	inission under or or it 1.33)	Examiner Name				

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.	

Receipt date: 05/17/2016				<del>- 15156616 - G</del>	ATT	2762
Receipt date. 05/1/2010	Application Number			10100010 - @	RO.	3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Filing Date		2016-05-17			
	First Named Inventor Robert Fi		rt Frederick Veasey			
	Art Unit					
(Not for Submission under or of it 1.55)	Examiner Name					
	Attorney Docket Numb	er	10-1188-US-CON8			

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.	
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.	
16 20050033244 2005-02-10 Veasey et al.  17 20050055011 2005-03-10 Enggaard  18 20050113765 2005-05-26 Veasey et al.	
16 20050033244 2005-02-10 Veasey et al.  17 20050055011 2005-03-10 Enggaard	
16 20050033244 2005-02-10 Veasey et al.	
15   20050019400   2005-01-27   Deveney et al.	
14 20050004529 2005-01-06 Veasey et al.	
13 20040267208 2004-12-30 Veasey et al.	
12 20040267207 2004-12-30 Veasey et al.	

3				<del>- 15156616 - (</del>	22.22	2262
Receipt date: 05/17/2016	Application Number			13136616 - (	sau:	3763
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INFORMATION DISCLOSURE	First Named Inventor	Robe	rt Frederick Veasey			
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit					
(Not lot submission under or of N 1.33)	Examiner Name					
	Attorney Docket Numb	er	10-1188-US-CON8			

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> İ	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T5
	1	3609555	DE		1987-09-24	Pomer		
	2	D673482	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		

Receipt date: 05/17/2016	T		T	<del>15156616 - (</del>	GAU:	3763
	Application Number					
INFORMATION DISCLOSURE	Filing Date					
	First Named Inventor Robert		rt Frederick Veasey			
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit					
(Not lot Submission under or or it isset)	Examiner Name					
	Attorney Docket Numb	er	10-1188-US-CON8			

	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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Examiner Initials*	Cite No.		nal, serial, symp	osium,	catalog, etc), d	he article (when appropi ate, pages(s), volume-is		T⁵
	1		abstract, and claim	ns, as w	ell as the reissue	", Filed May 21, 2003, included the copy of a copy of		

Receipt date: 05/17/2016				<del>15156616 -</del>	C73.77.	2762
Receipt date: 03/17/2016	Application Number			10100010	- GAU:	3/63
	Filing Date		2016-05-17			
INFORMATION DISCLOSURE	First Named Inventor	Robei	rt Frederick Veasey			
( Not for submission under 37 CFR 1.99)	Art Unit					
(Not lot Submission under of or N 1.55)	Examiner Name					
	Attorney Docket Numb	er	10-1188-US-CON8			

	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 n image file wrapper in PAIR as of January 23, 2008.						
	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 n image file wrapper in PAIR as of January 23, 2008.						
	4	J.S. Reissue Patent Application No. 11/640,610, "Injection Syringe", Filed specification, drawings, abstract, and claims, as well as the reisstround 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	n No. 10/790,866 (11 pag	es).			
If you wis	h to ac	d additional non-patent literature document citation information	please click the Add bu	utton Add			
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Examiner	Examiner Signature /MANUEL A MENDEZ/ Date Considered 08/07/2016						

\*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.

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

D	eceipt date: 05/17/2016				<del>15156616 -</del>	Carr.	2765
Receipt date: 05/17/2016		Application Number			13130010 -	GEO.	570.
		Filing Date		2016-05-17			
	INFORMATION DISCLOSURE	First Named Inventor	Robe	rt Frederick Veasey			
	STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit					
	(Not 101 Submission under 01 Of K 1.55)	Examiner Name					
		Attorney Docket Numb	er	10-1188-US-CON8			

CERTI	FICA	TION	STA	TEMENT

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.

X 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 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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- 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.

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## 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

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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

Receipt date: 05/17/2016 15156616 - GAU: 3763

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-15)

Approved for use through 07/31/2016. OMB 0651-0031

Mation Disclosure Statement (IDS) Filed

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

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	Application Number		
	Filing Date		2016-05-17
INFORMATION DISCLOSURE	First Named Inventor	First Named Inventor Robert Frederick Veasey	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		
(Not for Submission under 57 Of K 1.55)	Examiner Name	•	
	Attorney Docket Number		10-1188-US-CON8

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	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.	

Descri	eipt date: 05/17/2016				<del>15156616 -</del>	CATT.	2762
rec	eipt date. 03/1//2010	Application Number			10100010	- GAO.	3,03
		Filing Date		2016-05-17			
	NFORMATION DISCLOSURE	First Named Inventor	Robe	rt Frederick Veasey			
	STATEMENT BY APPLICANT Not for submission under 37 CFR 1.99)	Art Unit					
	not for Submission under or Of It 1.55)	Examiner Name					

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.	

Descri	eipt date: 05/17/2016				<del>15156616 -</del>	CATT.	2762
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	not for Submission under or Of It 1.55)	Examiner Name					

20	6074372	2000-06-13	Hansen
21	6083197	2000-07-04	Umbaugh
22	<b>6110149</b>	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	Виrroughs 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.

Descri	eipt date: 05/17/2016				<del>15156616 -</del>	CATT.	2762
rec	eipt date. 03/1//2010	Application Number			10100010	- GAO.	3,03
		Filing Date		2016-05-17			
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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.	

Descri	eipt date: 05/17/2016				<del>15156616 -</del>	CATT.	2762
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	not for Submission under or Of It 1.55)	Examiner Name					

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	

٥	eceipt date: 05/17/2016				<del>15156616 -</del>	CATT.	2762
.,	ecerpt date. 03/1//2010	Application Number			10100010 -	GAO.	5765
		Filing Date		2016-05-17			
	INFORMATION DISCLOSURE	First Named Inventor	Robei	rt Frederick Veasey			
	STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit					
	(Not 10) Submission under 07 Of K 1.55)	Examiner Name					

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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				Filing Date			2016-05-17			
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		BY APPLICA		Art Unit						
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	64	7133329		2006-11-07	Skyggebje	ergeta	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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**FOREIGN PATENT DOCUMENTS** 

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Danaint data: 05/17/2016				<del>- 15156616 -</del>	773.77	2762
Receipt date: 05/17/2016	Application Number			13136616 -	GALU:	3/63
INFORMATION DISCLOSURE	Filing Date		2016-05-17			
	First Named Inventor	Robe	t Frederick Veasey			
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit					
(Not for Submission under or STR 1.33)	Examiner Name					
	Attorney Docket Numb	er	10-1188-US-CON8			

Examiner Initial*	Cite No	Foreign Numbe	n Document r <sup>3</sup>	Country Code <sup>2</sup> İ	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T5
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Examiner	Signa	ture	/MANUEL	A MENDEZ/			Date Considered	08/07/2016	
*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.									
Standard ST	F.3). <sup>3</sup> F cument l	or Japane by the app	se patent docume propriate symbols a	nts, the indication of	the year	of the reign of the	r office that issued the docume Emperor must precede the sei dard ST.16 if possible. <sup>5</sup> Applid	rial number of the patent docu	ument.

D	eceipt date: 05/17/2016				<del>15156616 -</del>	Carr.	2765
Ε.	ecerpt date. 03/1//2010	Application Number			13130010 -	GEO.	570.
	Filing Date		2016-05-17				
	INFORMATION DISCLOSURE	First Named Inventor	Robe	rt Frederick Veasey			
	STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit					
	(Not 101 Submission under 01 Of K 1.55)	Examiner Name					
		Attorney Docket Numb	er	10-1188-US-CON8			

CERTIFIC	ATION	STATE	MENT
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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.

X 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.** 

Receipt date: 05/17/2016 15156616 - GAU: 3763

## **Privacy Act Statement**

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

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

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

**PATENT** 

## 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

movement of the button caused by distally applied pressure to the head initiates dose 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 wi	mitted with Payment no								
File Listing:									
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)				
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	Document Description	Start	End							
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1							
	Specification	2	2							
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	Applicant Arguments/Remarks Made in an Amendment	8	8							
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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.

Doc Code: DIST.E.FILE Document Description: Electronic	Terminal Disclaimer - Filed		PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce			
Electronic Petition Request	TERMINAL DISCLAIMER TO ( "PRIOR" PATENT	DBVIATE A DO	DUBLE PATENTING REJECTION OVER A			
Application Number	15156616					
Filing Date	17-May-2016					
First Named Inventor	Robert Veasey	Robert Veasey				
Attorney Docket Number	10-1188-US-CON8					
Title of Invention	PEN-TYPE INJECTOR					
Filing of terminal disclaimer do	es not obviate requirement for re	esponse unde	r 37 CFR 1.111 to outstanding			
This electronic Terminal Disclain	mer is not being used for a Joint	Research Agre	eement.			
Owner		Percent Interest				
SANOFI-AVENTIS DEUTSCHLAND GM	<b>ЛВН</b>	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)

#### 7918833

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;
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- 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.

0	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.								
Appl	pplicant claims the following fee status:								
0	Small Entity								
0	Micro Entity								
•	Regular Undiscounted								
belie the l	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.								
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	Registration Number 32833	3							
0	A sole inventor								
0	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								
0	A joint inventor; all of whom are signing this request								
Signature /David M. Frischkorn/									
Nar	me	David M. Frischkorn							

<sup>\*</sup>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-	17-May-2016						
Title of Invention:	PEN-TYPE INJECTOR							
First Named Inventor/Applicant Name:	st Named Inventor/Applicant Name: Robert Frederick Veasey							
Filer:	Da	vid 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:				
	Tot	al 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
This patent is subject to a terminal disclaimer
DISAPPROVED
Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web
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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)

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.)					
			33407							
1	Electronic Terminal Disclaimer-Filed	e Terminal-Disclaimer.pdf	a1c42ec8835ee2cb7fca7cac7f159c3fa08ca 53d	no	2					
Warnings:	Warnings:									
Information:										
			30231							
2	Fee Worksheet (SB06)	Fee Worksheet (SB06) fee-info.pdf		no	2					
Warnings:										
Information:	Information:									
		6	3638							

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

#### **New Applications Under 35 U.S.C. 111**

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

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

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

### New International Application Filed with the USPTO as a Receiving Office

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

PTO/SB/06 (09-11)
Approved for use through 1/31/2014, OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE id to a collection of information unless it displays a valid OMB control number.

U.S. Patent and Tracemark Reduction Act of 1995 no persons are required to respond to a collection of information unless it distallars a valid OMR control number

P	PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						n or Docket Number 5/156,616	Filing Date 05/17/2016	To be Mailed	
	ENTITY:   LARGE   SMALL   MICRO									
	APPLICATION AS FILED – PART I									
			(Column 1	)	(Column 2)					
	FOR		NUMBER FIL	.ED	NUMBER EXTRA		RATE (\$)	F	EE (\$)	
	BASIC FEE (37 CFR 1.16(a), (b),	or (c))	N/A		N/A		N/A			
	SEARCH FEE (37 CFR 1.16(k), (i), (	or (m))	N/A		N/A		N/A			
	EXAMINATION FE (37 CFR 1.16(o), (p),		N/A		N/A		N/A			
	TAL CLAIMS CFR 1.16(i))		min	us 20 = *			X \$ =			
	EPENDENT CLAIM CFR 1.16(h))	S	mi	inus 3 = *			X \$ =			
	APPLICATION SIZE (37 CFR 1.16(s))	FEE .	of paper, the a for small entity	ation and drawing application size for the form each addition of the second of the sec	ee due is \$310 ( onal 50 sheets o	\$155 or				
	MULTIPLE DEPEN	IDENT CLAII	M PRESENT (3	7 CFR 1.16(j))						
* If	the difference in colu	umn 1 is less	than zero, ente	r "0" in column 2.			TOTAL			
		(Column	1)	APPLICAT	ION AS AMEN		ART II			
LN:	09/01/2016	CLAIMS REMAININ AFTER AMENDMI		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EX	TRA	RATE (\$)	ADDITIC	DNAL FEE (\$)	
AMENDMENT	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0		x \$80 =		0	
Ä	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0		x \$420 =		0	
AM	Application Si	ize Fee (37 C	CFR 1.16(s))							
	FIRST PRESEN	NTATION OF M	IULTIPLE DEPENI	DENT CLAIM (37 CFF	R 1.16(j))					
							TOTAL ADD'L FE		0	
		(Column	1)	(Column 2)	(Column 3	·)				
		CLAIMS REMAINI AFTEF AMENDMI	NG R	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EX	TRA	RATE (\$)	ADDITIO	DNAL FEE (\$)	
ENT	Total (37 CFR 1.16(i))	*	Minus	ww	=		X \$ =			
ENDM	Independent (37 CFR 1.16(h))	*	Minus	***	=		X \$ =			
NEN	Application Size Fee (37 CFR 1.16(s))									
AM	FIRST PRESEN	NTATION OF M	MULTIPLE DEPENI	DENT CLAIM (37 CFF	R 1.16(j))					
							TOTAL ADD'L FE			
** If	the entry in column f the "Highest Numbe If the "Highest Numb e "Highest Number P	er Previously per Previousl	Paid For" IN TH y Paid For" IN T	IIS SPACE is less HIS SPACE is less	than 20, enter "20' s than 3, enter "3".		LIE /FLORENCE F			

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.



## United States Patent and Trademark Office

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

APPLICATION NUMBER

FILING OR 371(C) DATE

FIRST NAMED APPLICANT

ATTY. DOCKET NO./TITLE 10-1188-US-CON8

15/156.616

05/17/2016

Robert Frederick Veasey

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

page 1 of 1

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

## NOTICE OF ALLOWANCE AND FEE(S) DUE

98548 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

DATE MAILED: 09/21/2016

3763

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

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. 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.

Page 1 of 3

#### PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

o: <u>Mail</u> Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 or <u>Fax</u> (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) Certificate of Mailing or Transmission 09/21/2016 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. McDonnell Boehnen Hulbert & Berghoff LLP Sanofi - Aventis 300 South Wacker Drive (Depositor's name) Chicago, IL 60606 (Signature APPLICATION NO. FILING DATE FIRST NAMED INVENTOR CONFIRMATION NO. ATTORNEY DOCKET 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 UNDISCOUNTED \$960 12/21/2016 \$960 \$0 \$0 nonprovisional CLASS-SUBCLASS EXAMINER ART UNIT MENDEZ, MANUEL A 3763 604-209000 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) The names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. or agents OR, alternatively, (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. ☐ "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. 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. (B) RESIDENCE: (CITY and STATE OR COUNTRY) (A) NAME OF ASSIGNEE Please check the appropriate assignee category or categories (will not be printed on the patent): 🔲 Individual 🚨 Corporation or other private group entity 🚨 Government 4a. The following fee(s) are submitted: 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) ☐ Issue Fee A check is enclosed. Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. Advance Order - # of Copies \_ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. ☐ Applicant certifying micro entity status. See 37 CFR 1.29 ☐ Applicant asserting small entity status. See 37 CFR 1.27 <u>NOTE:</u> If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status. Applicant changing to regular undiscounted fee status. <u>NOTE:</u> 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.

Page 2 of 3

PTOL-85 Part B (10-13) Approved for use through 10/31/2013.

Authorized Signature

Typed or printed name

OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Date

Registration No.



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR CONFIRMATION NO. 15/156,616 05/17/2016 Robert Frederick Veasey 10-1188-US-CON8 1083 EXAMINER 7590 09/21/2016 McDonnell Boehnen Hulbert & Berghoff LLP MENDEZ, MANUEL A Sanofi - Aventis PAPER NUMBER ART UNIT 300 South Wacker Drive Chicago, IL 60606 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.
- 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.

	<b>Application No.</b> 15/156,616	Applicant(s) VEASEY ET	
Notice of Allowability	Examiner MANUEL MENDEZ	Art Unit 3763	AIA (First Inventor to File) Status No

	1 110				
The MAILING DATE of this communication appears on the All claims being allowable, PROSECUTION ON THE MERITS IS (OR REM herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other a NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. Tof the Office or upon petition by the applicant. See 37 CFR 1.313 and MPE	AINS) CLOSED in this application. If not included appropriate communication will be mailed in due course. <b>THIS</b> his application is subject to withdrawal from issue at the initiative				
1. A declaration(s)/affidavit(s) under <b>37 CFR 1.130(b)</b> was/were filed	_				
An election was made by the applicant in response to a restriction recrequirement and election have been incorporated into this action.					
3. The allowed claim(s) is/are <u>1-30</u> . As a result of the allowed claim(s), y <b>Highway</b> program at a participating intellectual property office for the http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inc	corresponding application. For more information, please see				
<ul> <li>4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.0 Certified copies: <ul> <li>a)  All</li> <li>b)  Some</li> <li>*c)  None of the:</li> <li>1.  Certified copies of the priority documents have been recent and t</li></ul></li></ul>	eived. eived in Application No. <u>10/790,225</u> . nave been received in this national stage application from the				
noted below. Failure to timely comply will result in ABANDONMENT of this application.  THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.					
. 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)) sho	ould 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  6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGIC attached Examiner's comment regarding REQUIREMENT FOR THE D	AL MATERIAL must be submitted. Note the				
Attachment(s)  1. ☐ Notice of References Cited (PTO-892)  2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date  3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material  4. ☐ Interview Summary (PTO-413), Paper No./Mail Date	<ul> <li>5. ☑ Examiner's Amendment/Comment</li> <li>6. ☑ Examiner's Statement of Reasons for Allowance</li> <li>7. ☐ Other</li> </ul>				
/MANUEL MENDEZ/ Primary Examiner, Art Unit 3763					

U.S. Patent and Trademark Office PTOL-37 (Rev. 08-13) 20160912

**Notice of Allowability** 

Part of Paper No./Mail Date

Application/Control Number: 15/156,616 Page 2

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.

Application/Control Number: 15/156,616 Page 3

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

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

=	Rejected	- ÷	Cancelled Restricted	N I	Non-Elected Interference	А О	Appeal Objected		
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Final	Original	09/12/2016							
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U.S. Patent and Trademark Office Part of Paper No. : 20160912

Doc code: RCEX Approved for use through 07/31/2016. OMB 0651-0031 Doc description: Request for Continued Examination (RCE)

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.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL (Submitted Only via EFS-Web) Application Filing **Docket Number** Art 15156616 2016-05-17 10-1188-US-CON8 3763 Number Unit Date (if applicable) First Named Examiner Robert Frederick Veasey MENDEZ, MANUEL A. Inventor Name 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 Patent Practitioner Signature Applicant Signature

PTO/SB/30EFS (07-14)

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

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.

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.

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

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

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

**PATENT** 

## 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.

6

**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

7

	Application Number		15156616	
	Filing Date		2016-05-17	
INFORMATION DISCLOSURE	First Named Inventor Robert		ert Frederick Veasey	
STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	Art Unit		3763	
( Not 101 Submission ander of of K 1.00)	Examiner Name		DEZ, MANUEL A.	
	Attorney Docket Number	er	10-1188-US-CON8	

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	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	Мау	
	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	

( Not for submission under 37 CFR 1.99)

Application Number		15156616	
Filing Date		2016-05-17	
First Named Inventor	Robe	rt 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	5001089	1999-12-14	Burroughs, et al.	
15	5059755	2000-05-09	Michel	
16	5277099	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.	

EFS Web 2.1.17

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

20	0	7195616		2007-03-27	Diller, et al.			
21	1	7361161		2008-04-22	Bainton			
22	2	7771400		2010-08-10	Nielsen			
23	3	7905867		2011-03-15	Veasey, et al.			
24	4	7918833		2011-04-05	Veasey, et al.			
25	5	8021345		2011-09-20	Veasey, et al.			
26	6	8512297		2013-08-20	Veasey, et al.			
27	7	8608709		2013-12-17	Moller, et al.			
28	8	8679069		2014-03-25	Veasey, et al.			
29	9	9233211		2016-01-12	Veasey, et al.			
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Application Number		15156616
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First Named Inventor	Robe	rt Frederick Veasey
Art Unit		3763
Examiner Name	MENDEZ, MANUEL A.	
Attorney Docket Number		10-1188-US-CON8

Examiner Initial*	Cite N		Publication Number	Kind Code <sup>1</sup>	Publica Date	ition	Name of Pate of cited Docu	entee or Applicant ment	Relev	s,Columns,Lines where vant Passages or Relevant es Appear	Ċ
	1		20010034507		2001-10	)-25	Kirchhofer, et al.				
	2		20020165499		2002-11	-07	Slate, et al.				
	3		20030050609		2003-03	<b>-13</b>	Sams				
	4		20070123829		2007-05	i-31	Atterbury, et al.				
	5		20090275916		2009-11	-05	Harms, et al.				
	6		20100042054		2010-02	!-18	Elahi, et al.				
	7		20120053528		2012-03	i-01	Bollenbach, et	al.			
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Examiner Initial*			reign Document mber <sup>3</sup>	Country Code <sup>2</sup> i	country Kind		Publication	Name of Patented Applicant of cited Document		Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	<u> </u>
	1	093	7477	EP		A2	1999-08-25 BECTON DICKINSO		ON		

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

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

( 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.

X 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.** 

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- 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.

Application Number: 15156616   Filing Date: 17449-2016   Title of Invention: PEN-TYPE INJECTOR   First Named Inventor/Applicant Name: RODERTYPE INJECTOR   Filer: David M. Frischkors   Attorney Docket Number: 10-1188-US-CONB   Filed as Large Entity Flee Code Quantity Amount Sub-Total in Using Number Subscitute   Basic Filing:   REQUEST FOR PRICRITIZED EXAMINATION 1817 1 4000 4000   Pages:   Claims:   Claims:   Miscellaneous-Filing:   PROCESSING FEE, EXCEPT PROV. APPLS. 1830 1 140 140   Petition:	Electronic Patent Application Fee Transmittal					
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)  Peacription Pee Code Quantity Amount Sub-Total in USD(s)  Basic Filing:  REQUEST FOR PRIORITIZED EXAMINATION 1817 1 4000 4000  Pages:  Claims:  Miscellaneous-Filing: PROCESSING FEE, EXCEPT PROV. APPLS. 1830 1 140 140 140 140 140 140 140 140 140 140	Application Number:	15	156616			
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)  Pescription Fee Code Quantity Amount Sub-Total in USD(s)  Basic Filing:  REQUEST FOR PRIORITIZED EXAMINATION 1817 1 4000 4000  Pages:  Claims:  Miscellaneous-Filing:  PROCESSING FEE, EXCEPT PROV. APPLS. 1830 1 140 140  Petition:	Filing Date:	17-	-May-2016			
Filer: David M. Frischkorn  Attorney Docket Number: 10-1188-US-CON8  Filed as Large Entity  Filing Fees for Utility under 35 USC 111(a)  Pescription Fee Code Quantity Amount Sub-Total in USD(s)  REQUEST FOR PRIORITIZED EXAMINATION 1817 1 4000 4000  Pages:  Claims:  Miscellaneous-Filing:  PROCESSING FEE, EXCEPT PROV. APPLS. 1830 1 140 140  Petition:	Title of Invention:	PEI	N-TYPE INJECTOR			
Attorney Docket Number:  Filed as Large Entity  Filing Fees for Utility under 35 USC 111(a)  Pescription  Fee Code Quantity Amount USD(\$)  Basic Filing:  REQUEST FOR PRIORITIZED EXAMINATION  1817 1 4000 4000  Pages:  Claims:  Miscellaneous-Filing:  PROCESSING FEE, EXCEPT PROV. APPLS.  1830 1 140 140 140 140 140 140 140 140 140	First Named Inventor/Applicant Name:	d Inventor/Applicant Name: Robert Frederick Veasey				
Filed as Large Entity  Filing Fees for Utility under 35 USC 111(a)  Pee Code Quantity Amount Sub-Total in USD(s)  Basic Filing:  REQUEST FOR PRIORITIZED EXAMINATION 1817 1 4000 4000  Pages:  Claims:  Miscellaneous-Filing:  PROCESSING FEE, EXCEPT PROV. APPLS. 1830 1 140 140  Petition:	Filer:	David M. Frischkorn				
Filing Fees for Utility under 35 USC 111(a)  Description Fee Code Quantity Amount USD(5)  Basic Filing:  REQUEST FOR PRIORITIZED EXAMINATION 1817 1 4000 4000  Pages:  Claims:  Miscellaneous-Filing:  PROCESSING FEE, EXCEPT PROV. APPLS. 1830 1 140 140  Petition:	Attorney Docket Number: 10-1188-US-CON8					
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Basic Filing:  REQUEST FOR PRIORITIZED EXAMINATION 1817 1 4000 4000  Pages:  Claims:  PROCESSING FEE, EXCEPT PROV. APPLS. 1830 1 140 140  Petition:	Filing Fees for Utility under 35 USC 111(a)					
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	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
	Tot	al 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)

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Request for Continued Examination (RCE)  Warnings: Information:    10-1188-US-CON8_RCE.pdf							
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3 10-1188-US-CON8_Response. pdf site in .zip description  Multipart Description/PDF files in .zip description  Document Description Start I  Amendment after Notice of Allowance (Rule 312) 1  Claims 2  Applicant Arguments/Remarks Made in an Amendment 7  Warnings:							
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7	Foreign Reference	WO0110484A1.pdf	f0287841454822b1a7165badbe2d5b7d11 0c29ac	no	22
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9	Foreign Reference	WO02092153A2.pdf	eb4be481f8373c6e84c4ad3aac2989263ce 2ab3a	no	98
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10	Foreign Reference	WO03080160A1.pdf	315d76d1555c88cf0ba20a8f90c5fd86f314 a21c	no	59
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11	Foreign Reference	WO9625965A1.pdf	0149180d0625a58aeaaae5d9ccf638b308d 67337	no	33
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		Total Files Size (in bytes)	16	544576	

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.

Doc Code: TRACK1.REQ

**Document Description: TrackOne Request** 

	onphon: Huokono Koquost			PTO/AIA/424 (04-14)			
c	CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)						
First Named Inventor:	Robert Frederick Veasey	Nonprovisional Application N known):	lumber (if	15/156,616			
Title of Invention:	PEN-TYPE INJECTOR						
	EREBY CERTIFIES THE FOLLOWINDENTIFIED APPLICATION.	G AND REQUESTS PR	IORITIZED	EXAMINATION FOR			
37 CFF becaus and ex	ocessing fee set forth in 37 CFR 1 R 1.17(c) have been filed with the is se that fee, set forth in 37 CFR 1.1 amination fee are filed with the red y required excess claims fees or a	request. The publicati 8(d), is currently \$0. T quest or have been alr	on fee requ The basic fi eady been	uirement is met iling fee, search fee, paid. I understand			
<ol> <li>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.</li> </ol>							
3. The ap	3. The applicable box is checked below:						
I. Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)							
<ul> <li>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     </li> </ul>							
	e application is an original nonproves certification and request is being	isional plant applicatio					
invento	cuted inventor's oath or declaration or, or the application data sheet menth the application.						
II.	Request for Continued Examina	ation - Prioritized Ex	<u>amination</u>	under § 1.102(e)(2)			
<ul> <li>i. A request for continued examination has been filed with, or prior to, this form.</li> <li>ii. If the application is a utility application, this certification and request is being filed via EFS-Web.</li> <li>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.</li> <li>iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.</li> <li>v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).</li> </ul>							
/Davi	d M. Frischkorn/		Octo	phor 14, 2016			

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 Submit multiple forms if more than one signature is required.*	or signature requirements and certifications.
*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:

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

PTO/SB/06 (09-11)
Approved for use through 1/31/2014, OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE id to a collection of information unless it displays a valid OMB control number.

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				APPLICA	ATION AS FIL	ED – PAR	RTI		
			(Column 1	)	(Column 2)				
	FOR		NUMBER FIL	.ED	NUMBER EXTRA		RATE (\$)	FEE	≣ (\$)
	BASIC FEE (37 CFR 1.16(a), (b),	or (c))	N/A		N/A		N/A		
	SEARCH FEE (37 CFR 1.16(k), (i), (	or (m))	N/A		N/A		N/A		
	EXAMINATION FE (37 CFR 1.16(o), (p),		N/A		N/A		N/A		
	TAL CLAIMS CFR 1.16(i))		min	us 20 = *			X \$ =		
	EPENDENT CLAIM CFR 1.16(h))	IS	mi	nus 3 = *			X \$ =		
	APPLICATION SIZE (37 CFR 1.16(s))	FEE 1	of paper, the a for small entity	ation and drawing application size for the size of the size for each addition of the size	ee due is \$310 ( onal 50 sheets o	\$155 or			
	MULTIPLE DEPEN	IDENT CLAIN	M PRESENT (3)	7 CFR 1.16(j))					
* If	the difference in colu	umn 1 is less	than zero, ente	r "0" in column 2.			TOTAL		
		(Column	1)	APPLICATI	ION AS AMEN		ART II		
LN:	10/14/2016	CLAIMS REMAININ AFTER AMENDME		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EX	TRA	RATE (\$)	ADDITION	IAL FEE (\$)
ME	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0		x \$80 =	(	0
AMENDMENT	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0		x \$420 =	(	0
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** If	the entry in column the "Highest Numbo If the "Highest Numb Highest Number P	er Previously er Previously	Paid For" IN TH y Paid For" IN T	IIS SPACE is less HIS SPACE is less	than 20, enter "20' s than 3, enter "3".		LIE DENISE T. LIL		

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.

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

#### NOTICE OF ALLOWANCE AND FEE(S) DUE

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

MENDEZ, MANUEL A

ART UNIT PAPER NUMBER

DATE MAILED: 11/02/2016

3763

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

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.

Page 1 of 3

#### PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Note: A certificate of mailing can only be used for domestic mailings of the

or <u>Fax</u> (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 CORRESPOND	ENCE ADDRESS (Note: Use BI	ock 1 for any change of address)	pap	ers. Each additional	paper, such as an assignme of mailing or transmission.		
98548 McDonnell Bo Sanofi - Aventis 300 South Wack	ehnen Hulbert & 1	<sub>V2016</sub> Berghoff LLP		Cert	ificate of Mailing or Trans is Fee(s) Transmittal is being ith sufficient postage for firs Stop ISSUE FEE address O (571) 273-2885, on the da	mission g deposited with the United st class mail in an envelope above, or being facsimile tte indicated below.	
Chicago, IL 606						(Depositor's name)	
omengs, in ooo						(Signature)	
						(Date)	
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	2	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
15/156,616	05/17/2016		Robert Frederick Veasey		10-1188-US-CON8	1083	
TITLE OF INVENTION	: PEN-TYPE INJECTO	R					
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	
EXAM	IINER	ART UNIT	CLASS-SUBCLASS	7			
MENDEZ, M		3763	604-209000	_			
1. Change of corresponde		n of "Fee Address" (37	2. For printing on the p	oatent front page, list	i		
CFR 1.363).			(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,				
Address form PTO/SI	ondence address (or Cha B/122) attached.	inge of Correspondence					
"Fee Address" ind PTO/SB/47; Rev 03-0 Number is required.	ication (or "Fee Address )2 or more recent) attach	" Indication form ed. Use of a Customer	(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.				
3. ASSIGNEE NAME A	ND RESIDENCE DATA	A TO BE PRINTED ON	THE PATENT (print or ty	pe)			
PLEASE NOTE: Unl	less an assignee is ident h in 37 CFR 3.11. Com	ified below, no assignee	data will appear on the p	atent. If an assigne	e is identified below, the de	ocument has been filed for	
(A) NAME OF ASSI			(B) RESIDENCE: (CITY	=			
Please check the appropr	iate assignee category or	categories (will not be pr	rinted on the patent): $\Box$	Individual 🖵 Cor	rporation or other private gro	oup entity 📮 Government	
4a. The following fee(s)	are submitted:	4	<del></del>		y previously paid issue fee:		
Issue Fee	are submitted.	7,	A check is enclosed.	изе птэс теаррту ап	y previously paid issue ice	shown above)	
	No small entity discount p		Payment by credit card. Form PTO-2038 is attached.				
☐ Advance Order - #	of Copies		The director is hereby overpayment, to Depo	authorized to chargosit Account Number	e the required fee(s), any det r(enclose a	ficiency, or credits any n extra copy of this form).	
5. Change in Entity Sta  Applicant certifying	tus (from status indicate ng micro entity status. Se	*	NOTE: Absent a valid ce	ertification of Micro	Entity Status (see forms PTC	D/SB/15A and 15B) issue	
					Entity Status (see forms PTC not be accepted at the risk of er micro entity status, check		
☐ Applicant asserting small entity status. See 37 CFR 1.27			to be a notification of los	s of entitlement to m	nicro entity status.		
Applicant changing to regular undiscounted fee status.			NOTE: Checking this bo entity status, as applicable		a notification of loss of enti	tlement to small or micro	
NOTE: This form must b	oe signed in accordance v	with 37 CFR 1.31 and 1.3	3. See 37 CFR 1.4 for sign	ature requirements a	and certifications.		
Authorized Signature				Date			
					0.		
Typed or printed name				Registration IV	·		

Page 2 of 3

PTOL-85 Part B (10-13) Approved for use through 10/31/2013.

OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE



#### UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR CONFIRMATION NO. 15/156,616 05/17/2016 Robert Frederick Veasey 10-1188-US-CON8 1083 EXAMINER 7590 11/02/2016 McDonnell Boehnen Hulbert & Berghoff LLP MENDEZ, MANUEL A Sanofi - Aventis PAPER NUMBER ART UNIT 300 South Wacker Drive Chicago, IL 60606 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.

#### **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.
- 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.

Applicatio		<b>pplicant(s)</b> EASEY ET A	L.
Notice of Allowability  Examiner MANUEL N	1	763	AIA (First Inventor to File) Status No

L	L L
The MAILING DATE of this communication appears on the All claims being allowable, PROSECUTION ON THE MERITS IS (OR REM herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other a NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. Tof the Office or upon petition by the applicant. See 37 CFR 1.313 and MPE	AINS) CLOSED in this application. If not included appropriate communication will be mailed in due course. <b>THIS</b> his application is subject to withdrawal from issue at the initiative
1. This communication is responsive to <u>RCE filed on 10/14/2016</u> .	
A declaration(s)/affidavit(s) under 37 CFR 1.130(b) was/were filed	d on
2.  An election was made by the applicant in response to a restriction requirement and election have been incorporated into this action.	uirement set forth during the interview on; the restriction
3. The allowed claim(s) is/are <u>1-30</u> . As a result of the allowed claim(s), y <b>Highway</b> program at a participating intellectual property office for the http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inc	corresponding application. For more information, please see
<ul> <li>4.  Acknowledgment is made of a claim for foreign priority under 35 U.S. Certified copies:</li> <li>a)  All b)  Some *c)  None of the:</li> <li>1.  Certified copies of the priority documents have been recent copies of the priority docum</li></ul>	eived. eived in Application No. <u>10/790,225</u> .
International Bureau (PCT Rule 17.2(a)).  * Certified copies not received:  Applicant has THREE MONTHS FROM THE "MAILING DATE" of this cornoted below. Failure to timely comply will result in ABANDONMENT of the THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.	
5. $\square$ CORRECTED DRAWINGS ( as "replacement sheets") must be subm	itted.
including changes required by the attached Examiner's Amendre Paper No./Mail Date	
Identifying indicia such as the application number (see 37 CFR 1.84(c)) sho each sheet. Replacement sheet(s) should be labeled as such in the header	
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGIC attached Examiner's comment regarding REQUIREMENT FOR THE D	
Attachment(s)  1. ☐ Notice of References Cited (PTO-892)  2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 10/14/2016  3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material  4. ☐ Interview Summary (PTO-413), Paper No./Mail Date	<ul> <li>5. ☐ Examiner's Amendment/Comment</li> <li>6. ☑ Examiner's Statement of Reasons for Allowance</li> <li>7. ☐ Other</li> </ul>
/MANUEL MENDEZ/ Primary Examiner, Art Unit 3763	

U.S. Patent and Trademark Office PTOL-37 (Rev. 08-13) 20161027

Notice of Allowability

Part of Paper No./Mail Date

Application/Control Number: 15/156,616 Page 2

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.

Application/Control Number: 15/156,616 Page 3

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.	Applicant(s)/Patent Under Reexamination
15156616	VEASEY ET AL.
Examiner	Art Unit
MANUEL MENDEZ	3763

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

CPC COMBINATION SETS - SEARC	CHED	
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

U.S. Patent and Trademark Office Part of Paper No. :

# Issue ClassificationApplication/Control No.<br/>15156616Applicant(s)/Patent Under Reexamination<br/>VEASEY ET AL.ExaminerArt UnitMANUEL MENDEZ3763

СРС					
Symbol				Туре	Version
A61M	5		31551	F	2013-01-01
A61M	5		31565	Α	2013-01-01
A61M	5		31578	Α	2013-01-01
A61M	5		24	1	2013-01-01
A61M	5		31535	T	2013-01-01
A61M	5	1	31541	1	2013-01-01
A61M	5		3156	А	2013-01-01
A61M	5		31575	А	2013-01-01
A61M	5		31585	1	2013-01-01
A61M	2005		2407	А	2013-01-01
A61M	2205		581	Α	2013-01-01
A61M	2205		582	А	2013-01-01
A61M	5		31533	1	2013-01-01
A61M	5	1	31536	T	2013-01-01
A61M	5	1	31546	1	2013-01-01
A61M	5	1	31528	T	2013-01-01
A61M	5	1	31563	1	2013-01-01
A61M	5	1	31568	1	2013-01-01
A61M	5	1	3157	1	2013-01-01
A61M	5	1	31593	1	2013-01-01
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A61M	2005		3126	Α	2013-01-01

CPC Combination Sets									
Symbol			Туре	Set	Ranking	Version			

NONE	Total Clain	ns 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		

U.S. Patent and Trademark Office Part of Paper No.

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

	US ORIGINAL CLASSIFICATION							INTERNATIONAL CLASSIFICATION							
	CLASS SUBCLASS						CLAIMED NON-CLAIMED							LAIMED	
604	604 209				Α	6	1	М	5 / 315 (2006.01.01)						
	CROSS REFERENCE(S)														
CLASS	CLASS SUBCLASS (ONE SUBCLASS PER BLOCK)														
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NONE	Total Clain	ns Allowed:	
(Assistant Examiner)	(Date)	3	0
/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

U.S. Patent and Trademark Office Part of Paper No.

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

₫	Claims re	numbere	d in the sa	☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47											
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Origina
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	16														

NONE	Total Claims Allowed:		
(Assistant Examiner)	(Date)	3	0
/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

U.S. Patent and Trademark Office Part of Paper No.

Receipt date: 10/14/2016 15156616 - GAU: 3763

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

Mation Disclosure Statement (IDS) Filed

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.

	Application Number		15156616		
	Filing Date		2016-05-17		
INFORMATION DISCLOSURE	First Named Inventor	Rober	t Frederick Veasey		
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		3763		
(Not lot submission under or of N 1.33)	Examiner Name	MEND	DEZ, MANUEL A.		
	Attorney Docket Numb	er	10-1188-US-CON8		

				U.S.I	PATENTS	Remove
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	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	Мау	
	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	

Receipt date: 10/14/2016

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	1	5728075	1998-03-17	Levander	
12	2	5957896	1999-09-28	Bendek, et al.	
13	3	5961495	1999-10-05	Walters, et al.	
14	1	6001089	1999-12-14	Burroughs, et al.	
15	ō	6059755	2000-05-09	Michel	
16	6	6277099	2001-08-21	Strowe, et al.	
17	7	6277101	2001-08-21	Kirchhofer, et al.	
18	3	6383167	2002-05-07	Kirchhofer, et al.	
19	9	6936032	2005-08-30	Bush, Jr., et al.	

Application Number 15156616 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

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Attorney Docket Number

10-1188-US-CON8

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	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 wis	If you wish to add additional U.S. Patent citation information please click the Add button.							
U.S.PATENT APPLICATION PUBLICATIONS							Remove	

Receipt date: 10/14/2016 15156616 - GAU: 3763 15156616 **Application Number** Filing Date 2016-05-17 **INFORMATION DISCLOSURE** First Named Inventor Robert Frederick Veasey STATEMENT BY APPLICANT Art Unit 3763 ( Not for submission under 37 CFR 1.99) **Examiner Name** MENDEZ, MANUEL A. Attorney Docket Number 10-1188-US-CON8

Examiner Initial*	Cite N	lo	Publication Number	Kind Code <sup>1</sup>	Publica Date	ition	Name of Patentee or Applicant of cited Document		Relev	s,Columns,Lines where vant Passages or Relevant es Appear	t		
	1		20010034507		2001-10	)-25	Kirchhofer, et al.						
	2		20020165499		2002-11	-07	Slate, et al.		Slate, et al.				
	3		20030050609		2003-03	s-13	Sams						
	4		20070123829		2007-05	i-31	Atterbury, et al.						
	5		20090275916		2009-11	-05	Harms, et al.						
	6		20100042054		2010-02	2-18	Elahi, et al.						
	7		20120053528		2012-03	3-01	Bollenbach, et al.						
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Examiner Initial*			reign Document mber <sup>3</sup>	Country Code <sup>2</sup> i		Kind Code <sup>4</sup>	Publication Date	Name of Patente Applicant of cited Document		where Relevant Passages or Relevant Figures Appear	5		
	1	093	37477	EP		A2	1999-08-25	BECTON DICKINS CO	ON				

Receipt date: 10/14/2016				<del>15156616 -</del>	CATT.	2762
Necespt date. 10/14/2010	Application Number		15156616	10100010 -	GEAC .	5,05
INFORMATION BIOOLOGUES	Filing Date	Filing Date				
INFORMATION DISCLOSURE STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99)	First Named Inventor	First Named Inventor Robert Free				
	Art Unit	Art Unit				
(Not lot Submission under or or K 1.50)	Examiner Name	Examiner Name MENDEZ, MANUEL A.				
	Attorney Docket Numb	Attorney Docket Number		10-1188-US-CON8		·

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	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 wisl	h to ad	d additional Foreign Pa	atent Document	citation	information ple	ease click the Add buttor	Add				
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Examiner Initials* Cite No Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.							<b>T</b> 5				
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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 /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.							
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 <a href="https://www.USPTO.GOV">www.USPTO.GOV</a> or MPEP 901.04. 2 Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). 3 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 4 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 5 Applicant is to place a check mark here if English language translation is attached.							

Receipt date: 10/14/2016

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.

CFRT			

10-1188-US-CON8

Attorney Docket Number

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.

X 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.** 

Receipt date: 10/14/2016 15156616 - GAU: 3763

#### **Privacy Act Statement**

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

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

- 1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.
- 2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 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.



#### UNITED STATES PATENT AND TRADEMARK OFFICE

LLP

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

Decision Granting Request for

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

Doc Code: TRACK1.GRANT

Commissioner for Patents

	Prior	itized Examination ck I or After RCE)	Application No.: 15/156,616					
1.	THE R	EQUEST FILED. October 14,	2016 IS GRANTED.					
	The above-identified application has met the requirements for prioritized examination  A.							
2.			indergo prioritized examination. The application will be course of prosecution until one of the following occurs:					
	A.	filing a petition for extension of	f time to extend the time period for filing a reply;					
	B.	filing an amendment to amend	the application to contain more than four independent					
		claims, more than thirty total c	laims, or a multiple dependent claim;					
	C.	filing a request for continued e	xamination;					
	D.	filing a notice of appeal;						
	E.	filing a request for suspension of	action;					

Telephone inquiries with regard to this decision should be directed to Brian W. Brown at 571-272-5338.

Petitions Examiner, Office of Petitions

(Title)

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

/Brian W. Brown/

[Signature]

F.

G.

H.

I.

mailing of a notice of allowance;

abandonment of the application.

completion of examination as defined in 37 CFR 41.102; or

mailing of a final Office action;

#### 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 <u>Fax</u> (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 CORRESPOND	ENCE ADDRESS (Note: Use Bi	ock 1 for any change of address)	Feeí	's) Transmittal. Thi:	s certificat	e cannot be used fo	or any other accompanying of the or formal drawing, must
98548 McDonnell Bo Sanofi - Aventis 300 South Wack	ehnen Hulbert & l	/2016 Berghoff LLP	I hes State addr trans	Cert reby certify that thi es Postal Service w ressed to the Mail smitted to the USPT	ificate of a s Fee(s) T ith sufficient Stop ISS O (571) 2	Mailing or Transuransmittal is being ent postage for first UE FEE address : 73-2885, on the day	nission deposited with the United t class mail in an envelope above, or being facsimile te indicated below.
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				***************************************	nanananananananan	***************************************	(Signature)
			0000000	***************************************	***************************************	***************************************	(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR		ATTORNE	Y DOCKET NO.	CONFIRMATION NO.
15/156,616	05/17/2016		Robert Frederick Veasey		***************************************	8-US-CON8	1083
TITLE OF INVENTION		R	ROBERT PROGRAMME		10 110	o os com	7003
APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE	FEE T	OTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0		\$960	02/02/2017
EXAM	UNER	ART UNIT	CLASS-SUBCLASS				
MENDEZ, I	MANUEL A	3763	604-209000	à.			
1. Change of correspond CFR 1.363).	ence address or indicatio	n of "Fee Address" (37	2. For printing on the p			1 MaTann	oll Dookson
	ondence address (or Cha B/122) attached.	nge of Correspondence	<ol> <li>The names of up to or agents OR, alternative</li> </ol>	vely,	•		ell Boehnen
"Fee Address" ind	ication (or "Fee Address )2 or more recent) attach	" Indication form	(2) The name of a singl registered attorney or a 2 registered patent attor listed, no name will be	igent) and the name rneys or agents. If r	s of up to	***************************************	t & Berghoff LLP
*		A TO BE PRINTED ON T	THE PATENT (print or typ	oe)	******	***************************************	***************************************
		ified below, no assignee oletion of this form is NO					ocument has been filed for
(A) NAME OF ASSI			(B) RESIDENCE: (CITY				
SANOFI-A	VENTIS DEUT	SCHLAND GMBF	I FRANKFUI	RT AM MAI	N, GE	ERMANY	
Please check the appropr	iate assignee category or	categories (will not be pr	inted on the patent):	Individual 🔕 Co	rporation o	or other private gro	up entity Government
4a. The following fee(s)	are submitted:	46	. Payment of Fee(s): (Plea	ise first reapply an	y previou	sly paid issue fee s	hown above)
Issue Fee Publication Fee (1)	No small entity discount p	permitted)	A check is enclosed.  Payment by credit care	d. Form PTO-2038	is attached	I.	
	of Copies		The director is hereby overpayment, to Depo				iciency, or credits any nextra copy of this form).
5. Change in Entity Sta	tus (from status indicate	d above)					
Applicant certifying	ng micro entity status. Se	e 37 CFR 1.29	NOTE: Absent a valid cer fee payment in the micro	rtification of Micro entity amount will	Entity Sta	tus (see forms PTO opted at the risk of	0/SB/15A and 15B), issue application abandonment.
Applicant assertin	g small entity status. See	37 CFR 1.27	NOTE: If the application to be a notification of loss				ng this box will be taken
Applicant changing	g to regular undiscounte	d fee status.	NOTE: Checking this box entity status, as applicable	s will be taken to be	,		lement to small or micro
NOTE: This form must b	e signed in accordance v	vith 37 CFR 1.31 and 1.33	3. See 37 CFR 1.4 for signs	ature requirements a	ınd certific	ations.	
Authorized Signature	/David M.	Frischkorn	/	DateNO	vembe	er 11, 20	16
Typed or printed nam	e David M.	Frischkorn		Registration N	o. <u>32,</u>	833	
			Page 2 of 3		mananananananan	***************************************	

Page 2 of 3

PTOL-85 Part B (10-13) Approved for use through 10/31/2013.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE OMB 0651-0033

Electronic Patent Application Fee Transmittal							
Application Number:	15156616						
Filing Date:	17-	-May-2016					
Title of Invention:	PEN-TYPE INJECTOR						
First Named Inventor/Applicant Name:	Ro	bert Frederick Veas	еу				
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:				
	Tot	al in USD	(\$)	960

Electronic Acl	knowledgement 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)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

#### **File Listing:**

<u> </u>									
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)				
	Issue Fee Payment (PTO-85B)  10-1188-US-CON8_IssueFe pdf		1577765	no	1				
1			e2a597d7e201b63ef380728df430b79f0578 20dd						
Warnings:									
Information:									
			30301						
2	Fee Worksheet (SB06)	fee-info.pdf	7fa364860671875e7548d47cSa8f2f6be9f4 14f7	no	2				
Warnings:									
Information:									
Total Files Size (in bytes)			1608066						

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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.

#### United States Patent and Trademark Office

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

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 300 South Wacker Drive Chicago, IL 60606

#### **ISSUE NOTIFICATION**

The projected patent number and issue date are specified above.

#### **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**

(application filed on or after May 29, 2000)

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

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

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

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

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

SANOFI-AVENTIS DEUTSCHLAND GMBH, Frankfurt am Main, GERMANY; Robert Frederick Veasey, Warwickshire, UNITED KINGDOM; Robert Perkins, Warwickshire, UNITED KINGDOM; David Aubrey Plumptre, Worcestershire, UNITED KINGDOM;

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IR103 (Rev. 10/09)