

(51) International Patent Classification:
A61M 5/145 (2006.01) *A61M 5/315* (2006.01)(21) International Application Number:
PCT/EP2010/063842(22) International Filing Date:
21 September 2010 (21.09.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09171134.1 23 September 2009 (23.09.2009) EP(71) Applicant (for all designated States except US):
SANOFI-AVENTIS DEUTSCHLAND GMBH
[DE/DE]; Brüningstraße 50, 65929 Frankfurt (DE).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **PLUMPTRE, David** [GB/GB]; 36 Shire Way, Doritwich Spa, Worcestershire WR9 7RQ (GB). **TERRY, Warren** [ZA/GB]; 4 Glendower Approach, Warwick CV34 6ET (GB). **VEASEY, Robert** [GB/GB]; 31 Lonsdale Road, Lillington, Leamington Spa, Warwickshire CV32 7EP (GB). **JONES, Matthew** [GB/GB]; 8 The Furr Marsh, Warwick, Warwickshire CV34 6DL (GB). **CLAUGHTON,****Timothy Giles** [GB/GB]; c/o Sanofi-Aventis, London Road, Holmes Chapel, Crewe Cheshire CW4 8BE (GB).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

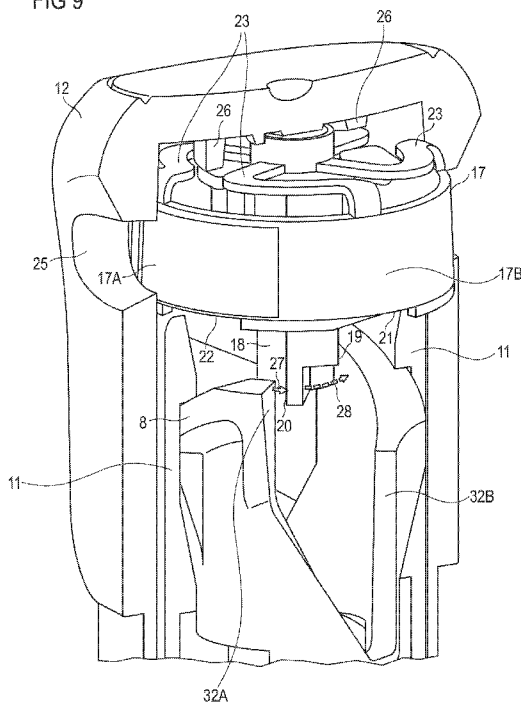
Published:

— with international search report (Art. 21(3))

[Continued on next page]

(54) Title: ASSEMBLY AND INDICATOR FOR A DRUG DELIVERY DEVICE

FIG 9



(57) Abstract: An assembly for a drug delivery device (1), comprising a housing (2) having a proximal end and a distal end, a piston rod (8) and an indicator (13). The piston rod (8) is adapted to be displaced distally with respect to the housing (2) away from a proximal start position and towards a distal end position for delivering a drug (31). The indicator (13) is adapted for indicating at least two different operation conditions of the assembly, the indicator (13) being moveable with respect to the housing (2) from a first indication position for a first condition of the assembly into a second indication position for a second condition of the assembly. The piston rod (8) and the indicator (13) are configured to mechanically interact for converting movement of the piston rod (8) into movement of the indicator (13). A first detent (21) is provided which is configured to releasably secure the indicator (13) in the first indication position such that movement into the second indication position is allowed. A second detent (22) is provided which is configured to secure the indicator (13) in the second indication position such that movement into the first indication position is prevented.



— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) **Date of publication of the international search report:**
23 June 2011

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2010/063842

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/145 A61M5/315
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2008/154616 A1 (BECTON DICKINSON CO [US]; CAIZZA RICHARD [US]; ODELL ROBERT [US]) 18 December 2008 (2008-12-18) paragraphs [0052] - [0065] paragraphs [0070] - [0077] -----	1,2,5,15
A	US 6 030 363 A (KRIESEL MARSHALL S [US]) 29 February 2000 (2000-02-29) column 11 - column 12; figures 20,25 -----	1-15
A	US 2007/112299 A1 (SMIT KAREN L [US] ET AL) 17 May 2007 (2007-05-17) paragraphs [0047] - [0056] paragraphs [0099] - [0100] -----	1-15
A	US 2007/197976 A1 (JACOBS ALEXANDER T [US] ET AL JACOBS ALEXANDER THOMAS [US] ET AL) 23 August 2007 (2007-08-23) paragraph [0026] - paragraph [0041] -----	1-15



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

25 January 2011

Date of mailing of the international search report

26/04/2011

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Rivera Pons, Carlos

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2010/063842

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-15

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-15

1. An assembly for a drug delivery device (1), comprising:
 - a housing (2) having a proximal end and a distal end,
 - a piston rod (8) which is adapted to be displaced distally with respect to the housing (2) away from a proximal start position and towards a distal end position for delivering a drug (31),
 - an indicator (13) for indicating at least two different operation conditions of the assembly, the indicator (13) being moveable with respect to the housing (2) from a first indication position for a first condition of the assembly into a second indication position for a second condition of the assembly, wherein
 - the piston rod (8) and the indicator (13) are configured to mechanically interact for converting movement of the piston rod (8) into movement of the indicator (13), and wherein
 - a first detent (21) is provided which is configured to releasably secure the indicator (13) in the first indication position such that movement into the second indication position is allowed, and
 - a second detent (22) is provided which is configured to secure the indicator (13) in the second indication position such that movement into the first indication position is prevented.

2. claim: 16

- An indicator (13) for a drug delivery device (1), the indicator (13) comprising an inner member (18) and an outer indication element (17), the outer indication element (17) providing an indication surface (17A, 17B) and being resiliently connected to the inner member (18) by at least one flexible member (23), wherein the indicator (13) comprises at least one first detent (21) and at least one second detent (22), the first detent (21) being adapted to enable rotation of the indicator (13) in a first direction and the second (22) detent being adapted to prevent rotation of the indicator (13) in the direction opposite to the first direction.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2010/063842

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2008154616	A1	18-12-2008	
		AU 2008261631 A1	18-12-2008
		AU 2008261699 A1	18-12-2008
		CA 2691356 A1	18-12-2008
		CA 2691359 A1	18-12-2008
		CN 101772360 A	07-07-2010
		CN 101808686 A	18-08-2010
		EP 2170441 A1	07-04-2010
		EP 2167175 A2	31-03-2010
		JP 2010528826 T	26-08-2010
		JP 2010529892 T	02-09-2010
		KR 20100043183 A	28-04-2010
		KR 20100047213 A	07-05-2010
		US 2009076450 A1	19-03-2009
		WO 2008154630 A2	18-12-2008
		ZA 200909134 A	29-09-2010

US 6030363	A	29-02-2000	
		US 5876377 A	02-03-1999
		US 5993421 A	30-11-1999

US 2007112299	A1	17-05-2007	
		WO 2006130491 A2	07-12-2006

US 2007197976	A1	23-08-2007	
		AU 2005231731 A1	20-10-2005
		BR PI0509269 A	04-09-2007
		CA 2557897 A1	20-10-2005
		EA 200601801 A1	27-04-2007
		EP 1732629 A2	20-12-2006
		IL 177829 A	30-11-2010
		JP 2007530241 T	01-11-2007
		KR 20060131946 A	20-12-2006
		NZ 549099 A	28-05-2010
		WO 2005097233 A2	20-10-2005
