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(54) **Title:** CARTRIDGE INSERTION ASSEMBLY FOR DRUG DELIVERY SYSTEM

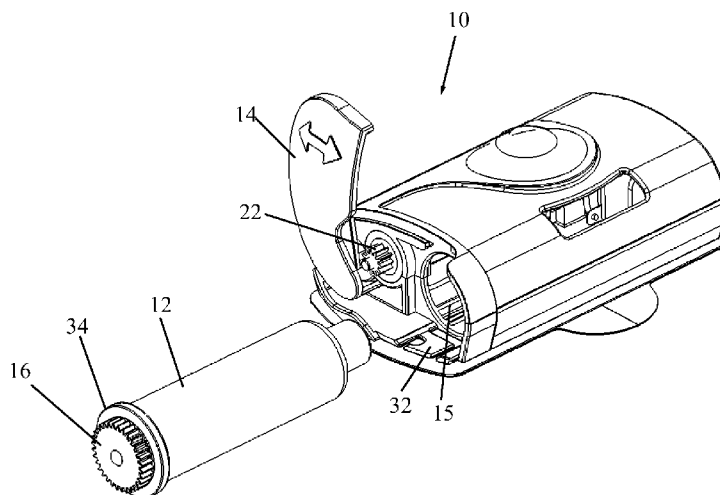


FIG. 2

(57) **Abstract:** A cartridge insertion assembly including apparatus (10) with a pathway (15) formed therein, and a cartridge (12) insertable into the pathway (15), the cartridge (12) including a cartridge coupling element (16) connectable to an activation mechanism (18) disposed in the apparatus (10) operative to cause a substance contained in the cartridge (12) to be metered out of the cartridge (12), characterised by a door (14) pivoted to the apparatus (10) that includes a door coupling element (20) arranged with respect to the cartridge (12) such that when the door (14) is in a fully closed position, the door coupling element (20) couples the cartridge coupling element (16) with a coupling element (22) of the activation mechanism (18).

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CARTRIDGE INSERTION ASSEMBLY FOR DRUG DELIVERY SYSTEM

FIELD OF THE INVENTION

The present invention generally relates to drug delivery systems, e.g., external drug pumps, and particularly to an assembly for inserting a cartridge, which contains a substance to be administered to a patient, into the drug delivery system.

BACKGROUND OF THE INVENTION

External drug pumps are typically used to deliver to patients substances which contain large molecules which cannot be digested when administered orally, such as insulin. Typically, the pump is adhered to the abdomen or chest or other of the patient and delivers the substance to the patient via a cannula that is inserted into the patient subcutaneously, although the invention described below is not limited to needle administration of substances.

SUMMARY OF THE INVENTION

The present invention seeks to provide an improved assembly for inserting a cartridge, which contains a substance to be administered to a patient, into a drug pump (or any kind of drug delivery system), as is described more in detail hereinbelow. It is noted that the term "cartridge" encompasses any kind of reservoir or container (disposable or not) for a substance that is to be administered to a patient, such as but not limited to, a vial, ampoule, bottle, pre-filled syringe and the like, and is not limited to any size or shape.

There is thus provided in accordance with an embodiment of the present invention a cartridge insertion assembly including apparatus with a pathway formed therein, a cartridge insertable into the pathway, the cartridge including a cartridge coupling element connectable to an activation mechanism disposed in the apparatus operative to cause a substance contained in the cartridge to be metered out of the cartridge, and a door pivoted to the apparatus that includes a door coupling element arranged with respect to the cartridge such that when the door is in a fully closed position, the door coupling element couples the cartridge coupling element with a coupling element of the activation mechanism.

In accordance with an embodiment of the present invention a locking latch is cantilevered from a base of the apparatus, wherein when the cartridge is fully inserted in the apparatus, the locking latch abuts against a rim of the cartridge, thereby locking the cartridge in the pathway.

In accordance with an embodiment of the present invention when the cartridge is fully inserted in the apparatus, the cartridge abuts against a cartridge stopper disposed in the apparatus.

In accordance with an embodiment of the present invention the cartridge includes a septum at an end opposite to the cartridge coupling element, and the apparatus includes a hollow needle, wherein when the cartridge is fully inserted in the apparatus, the needle punctures the septum.

In accordance with an embodiment of the present invention the door includes a closure member on an inside surface thereof, the closure member including one or more inclined ramp members, wherein closing the door causes the ramp members to slide and push against the cartridge coupling element so as to push the cartridge fully into the apparatus.

In accordance with an embodiment of the present invention the door is formed with one or more ribs, which when the door is fully closed, the ribs are received in one or more corresponding grooves formed in the apparatus.

In accordance with an embodiment of the present invention the closure member includes a hub, wherein when the door is fully closed, the hub is fixedly received in a snap member.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

Fig. 1 is a simplified illustration of apparatus for administering a substance to a subject, in accordance with an embodiment of the present invention;

Fig. 2 is a simplified illustration of the apparatus of Fig. 1, showing a door of a cartridge insertion assembly in the open position and a cartridge poised for insertion into the apparatus;

Fig. 3 is a simplified illustration of the cartridge partially inserted into the apparatus;

Fig. 4 is a simplified illustration of the cartridge partially inserted into the apparatus, showing components of the cartridge insertion assembly;

Fig. 5 is a simplified illustration of the cartridge fully inserted into the apparatus up to a cartridge stopper of the cartridge insertion assembly, with the door still open;

Fig. 6 is a simplified illustration of the cartridge fully inserted into the apparatus and locked in place;

Fig. 7 is a simplified illustration of a locking latch that locks the cartridge in place;

Fig. 8 is a simplified illustration of the inside of the door of the cartridge insertion assembly;

Fig. 9 is a simplified illustration of partially closing the door of the cartridge insertion assembly;

Fig. 10 is a simplified illustration of the door fully closed, but only showing the inner components of the door (e.g., coupling elements) and not the outside surface of the door itself; and

Fig. 11 is a simplified illustration of the door fully closed, showing a snap that snaps the door to the body of the apparatus.

DETAILED DESCRIPTION OF EMBODIMENTS

Reference is now made to Figs. 1 and 2, which illustrate apparatus 10 for administering a substance (e.g., insulin) to a subject, in accordance with a non-limiting embodiment of the present invention. Typically, apparatus 10 includes a cartridge 12 (Fig. 2) that contains the substance to be administered to a subject. Fig. 2 illustrates a door 14 of a cartridge insertion assembly in the open position and cartridge 12 poised for insertion into a pathway 15 in apparatus 10.

As seen in Fig. 2, cartridge 12 includes a cartridge coupling element 16 (e.g., a gear) for coupling (e.g., meshing) with an activation mechanism 18 (seen in Fig. 4, which typically includes a motor, a battery and a control unit) that causes the substance contained in cartridge 12 to be metered out of cartridge 12 for eventual administration to the patient. (In some embodiments, cartridge coupling element 16 is assembled to an end of a driving screw.) The way in which the activation mechanism works to meter the substance out of cartridge 12 is not pertinent to this invention. By way of example, the activation mechanism may work as in an external drug pump of the type described in US Patent Applications 20090093792 and 20090093793 or PCT Patent Application PCT/IL2008/001312 (published as WO 2009/044401), the disclosures of which are incorporated herein by reference. However, the invention is not limited to such a drug pump, and may be used for any kind of suitable administration of substances, not just by needle puncture into the patient, but also transdermally (wherein the substance is metered by apparatus 10 to a transdermal patch), by spray (wherein the substance is metered by apparatus 10 to a spray nozzle), micro needles array and others.

It is noted that although cartridge 12 is typically a one-use item, the electronics, batteries and motor and other elements of the system can be used more than once if desired.

As seen in Fig. 3, in accordance with a non-limiting embodiment of the present invention, door 14 includes a door coupling element 20 (e.g., a gear, but could also be any other coupling element for transmitting rotary motion, such as a friction wheel) for effecting coupling (e.g., meshing) between the cartridge coupling element 16 and a coupling element 22 (Fig. 2) of the activation mechanism 18, as will be described more in detail below.

Reference is now made to Fig. 4, which illustrates the cartridge 12 partially inserted into apparatus 10, showing components of the cartridge insertion assembly. Cartridge 12 has a septum 24 at an end opposite to cartridge coupling element 16. The septum 24 is pierced by a hollow needle 26 so that contents of cartridge 12 flow out of cartridge 12 into needle 26 and from needle 26 to an exit port (not shown) for eventual administration to the patient. A cartridge stopper 28, which may be made of a rigid material (e.g., plastic) or more preferably a resilient material (e.g., an elastomer or silicone), is provided for arresting movement of cartridge 12 during insertion into apparatus 10 and preventing over-insertion of cartridge 12. Cartridge stopper 28 also prevents the torque, which is generated by the activation mechanism 18 to rotate the driving screw of the cartridge, from rotating cartridge 12. The cartridge stopper 28 abuts against a shoulder 30 of cartridge 12. Fig. 5 shows cartridge 12 fully inserted into apparatus 10 up to cartridge stopper 28 with door 14 still open.

Reference is now made to Figs. 6 and 7. The cartridge insertion assembly of apparatus 10 includes a locking latch 32 which is cantilevered from a base 33 (Fig. 7) of the apparatus 10. While inserting cartridge 12 into apparatus 10, a rim 34 near cartridge coupling element 16 depresses and slides over locking latch 32. When cartridge 12 is fully inserted into apparatus 10, rim 34 moves past locking latch 32 and locking latch 32 springs back and abuts against rim 34, thereby locking cartridge 12 in place. The user cannot remove cartridge 12 from apparatus 10.

Reference is now made to Fig. 8, which illustrates the inside of door 14. The door coupling element 20 mentioned above is in the middle of the inside of door 14. On one side of element 20 is a hinge member 36 that pivotally connects (e.g., by snap fit) into a corresponding socket 38 (seen in Fig. 10) in the body of apparatus 10. On the other side of element 20 is a closure member 40, which is formed with a central hub 42 and one or

more ramp members 44 (in the illustrated embodiment, two inclined ramp members 44 extend on either side of hub 42). Even if the user has not fully inserted cartridge 12 into apparatus 10, the act of closing door 14 (see Fig. 9) causes the ramp members 44 to slide and swipe against cartridge coupling element 16. The inclined surfaces of ramp members 44 gently push and wedge cartridge coupling element 16 to seat fully into apparatus 10 so that septum 24 is pierced by hollow needle 26 as described above with reference to Figs. 4 and 5.

After the cartridge 12 is locked in place, ramp members 44 keep pushing against the driving screw to create priming of the drug pump, wherein contents of the cartridge 12 overflow and pressurize into the needle 26 and drip out therefrom. This priming process reduces the breaking force (the initial force to remove the plunger after a long storage time) and removes air bubbles from the fluid path.

The inside of door 14 is formed with one or more ribs 46, which when door 14 is fully closed, are received in one or more corresponding grooves 48 (Fig. 10) formed at the end of the housing of apparatus 10. Ribs 46 seated in grooves 48 provide resistance to axial pull-out forces that may be acting on cartridge 12 and door 14 during operation of apparatus 10.

Fig. 10 illustrates door 14 fully closed. Door coupling element 20 couples between cartridge coupling element 16 of the cartridge and coupling element 22 of the activation mechanism, so that the activation mechanism can now cause the substance contained in the cartridge to be metered out of the cartridge for eventual administration to the patient.

Reference is now made to Fig. 11. When door 14 is fully closed, hub 42 of closure member 40 snaps and is fixedly received in a snap member 50 (curved snap member) so that door 14 is properly secured to the body of apparatus 10.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the present invention includes both combinations and subcombinations of the features described hereinabove as well as modifications and variations thereof which would occur to a person of skill in the art upon reading the foregoing description and which are not in the prior art.

CLAIMS

What is claimed is:

1. A cartridge insertion assembly comprising:
apparatus (10) with a pathway (15) formed therein; and
a cartridge (12) insertable into said pathway (15), said cartridge (12) comprising a cartridge coupling element (16) connectable to an activation mechanism (18) disposed in said apparatus (10) operative to cause a substance contained in said cartridge (12) to be metered out of said cartridge (12);
characterised by a door (14) pivoted to said apparatus (10) that comprises a door coupling element (20) arranged with respect to said cartridge (12) such that when said door (14) is in a fully closed position, said door coupling element (20) couples said cartridge coupling element (16) with a coupling element (22) of said activation mechanism (18).
2. The cartridge insertion assembly according to claim 1, further comprising a locking latch (32) cantilevered from a base (33) of said apparatus (10), wherein when said cartridge (12) is fully inserted in said apparatus (10), said locking latch (32) abuts against a rim (34) of said cartridge (12), thereby locking said cartridge (12) in said pathway (15).
3. The cartridge insertion assembly according to claim 1, wherein when said cartridge (12) is fully inserted in said apparatus (10), said cartridge (12) abuts against a cartridge stopper (28) disposed in said apparatus (10).
4. The cartridge insertion assembly according to claim 1, wherein said cartridge (12) comprises a septum (24) at an end opposite to said cartridge coupling element (16), and said apparatus (10) comprises a hollow needle (26), wherein when said cartridge (12) is fully inserted in said apparatus (10), said needle (26) punctures said septum (24).
5. The cartridge insertion assembly according to claim 1, wherein said door (14) comprises a closure member (40) on an inside surface thereof, said closure member (40) comprising one or more inclined ramp members (44), wherein closing said door (14) causes said ramp members (44) to slide and push against said cartridge coupling element (16) so as to push said cartridge (12) fully into said apparatus (10).
6. The cartridge insertion assembly according to claim 1, wherein said door (14) is formed with one or more ribs (46), which when said door (14) is fully closed, said ribs (46) are received in one or more corresponding grooves (48) formed in said apparatus (10).

7. The cartridge insertion assembly according to claim 1, wherein said door (14) comprises a closure member (40) on an inside surface thereof, said closure member (40) comprising a hub (42), wherein when said door (14) is fully closed, said hub (42) is fixedly received in a snap member (50).

8. The cartridge insertion assembly according to claim 1, wherein said coupling elements (16, 20) comprise gears.

9. The cartridge insertion assembly according to claim 1, further comprising a locking latch (32) cantilevered from a base (33) of said apparatus (10), wherein when said cartridge (12) is fully inserted in said apparatus (10), said locking latch (32) abuts against a rim (34) of said cartridge (12), thereby locking said cartridge (12) in said pathway (15), and wherein said door (14) comprises a closure member (40) on an inside surface thereof, said closure member (40) comprising one or more inclined ramp members (44), wherein closing said door (14) causes said ramp members (44) to slide and push against said cartridge coupling element (16) so as to push said cartridge (12) fully into said apparatus (10), and wherein said door (14) comprises a closure member (40) on an inside surface thereof, said closure member (40) comprising a hub (42), wherein when said door (14) is fully closed, said hub (42) is fixedly received in a snap member (50).

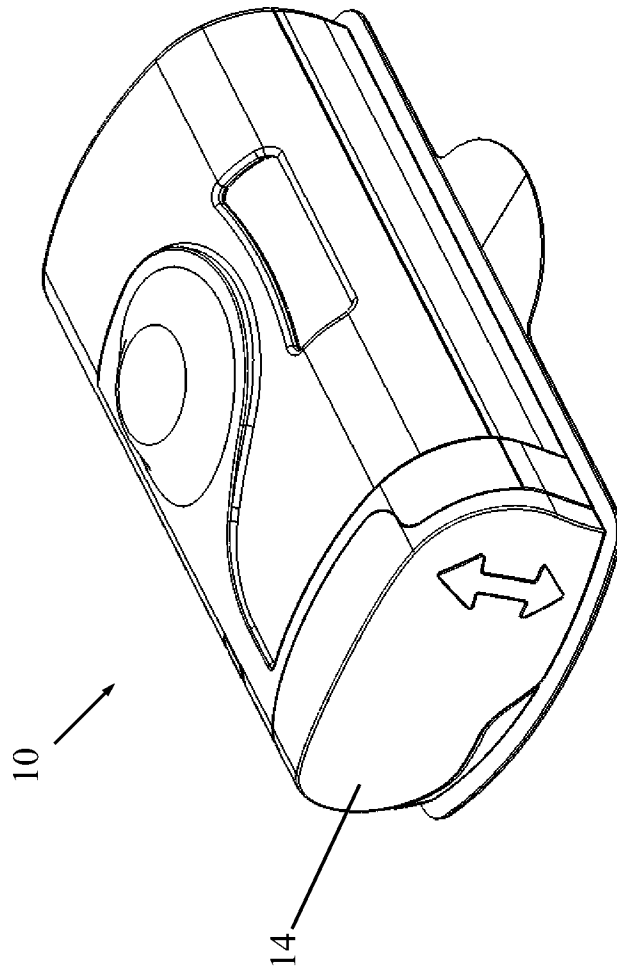


FIG. 1

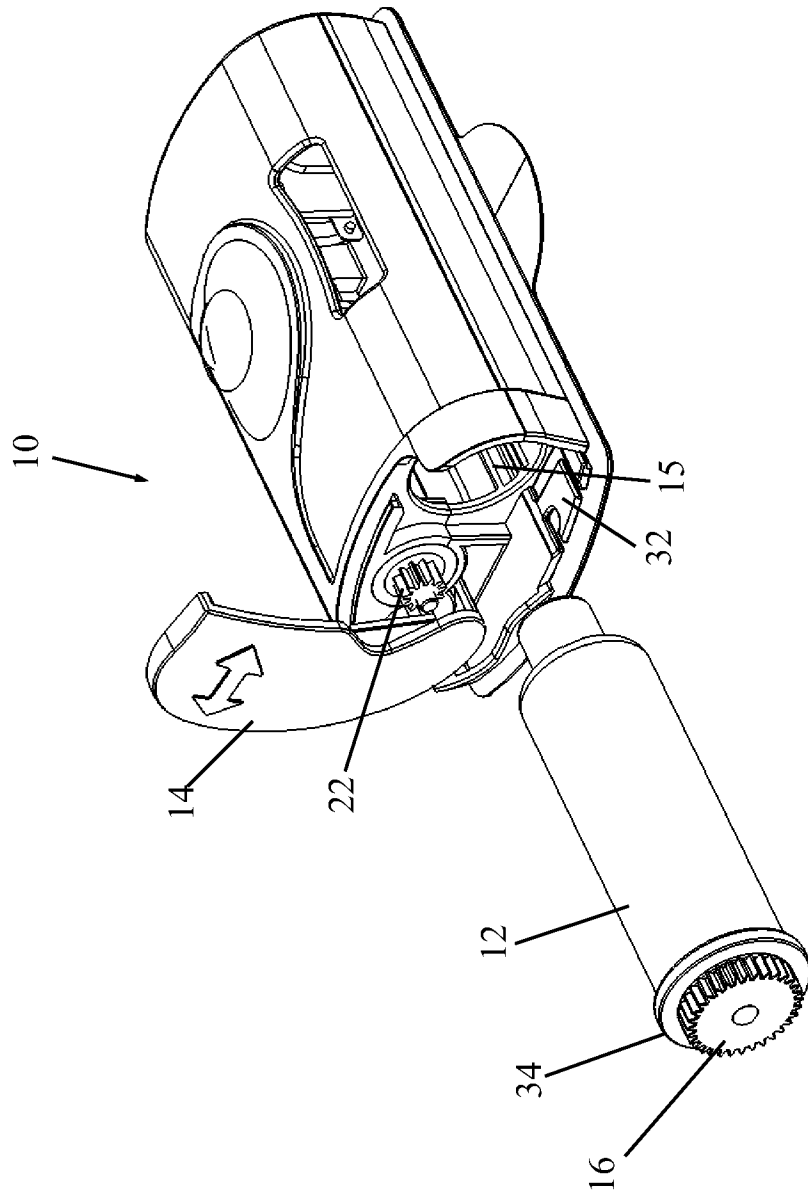


FIG. 2

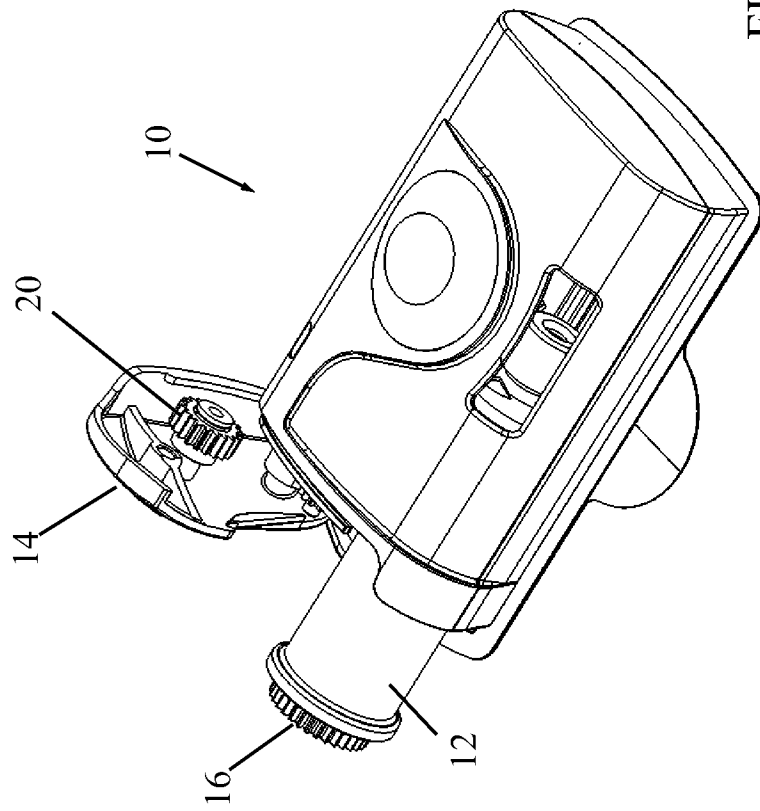


FIG. 3

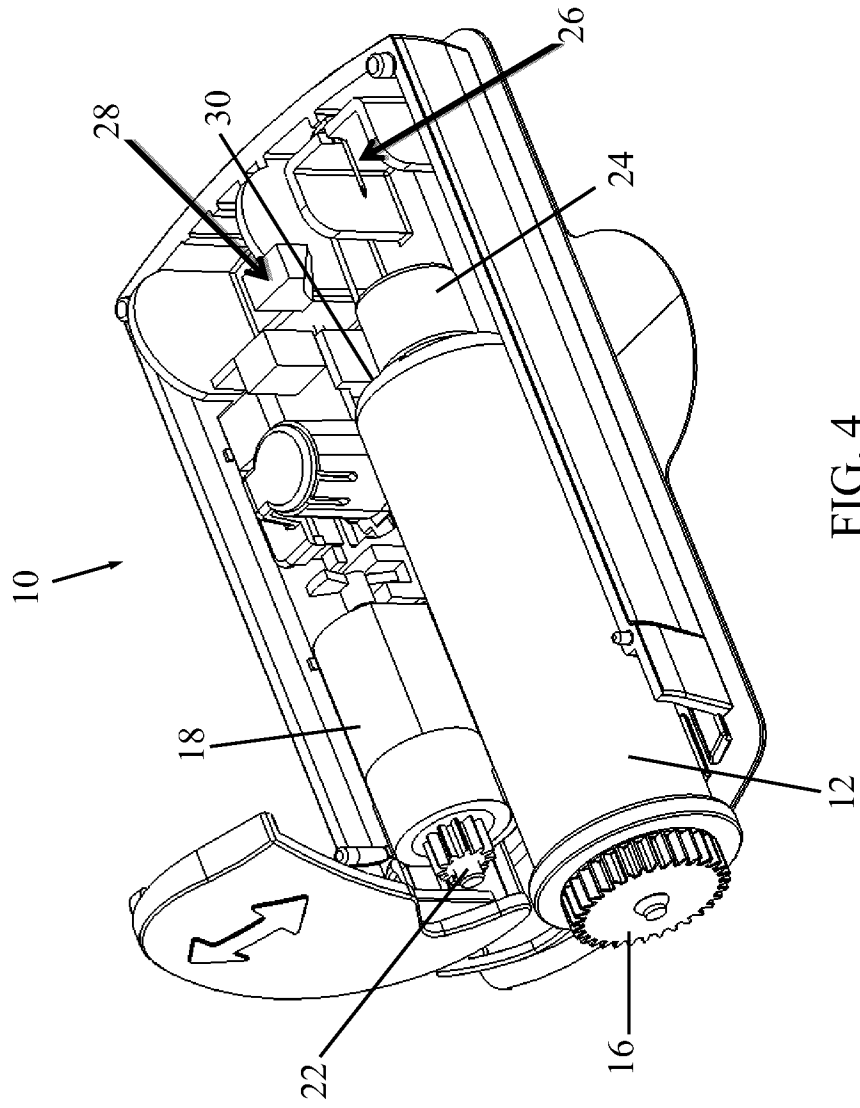
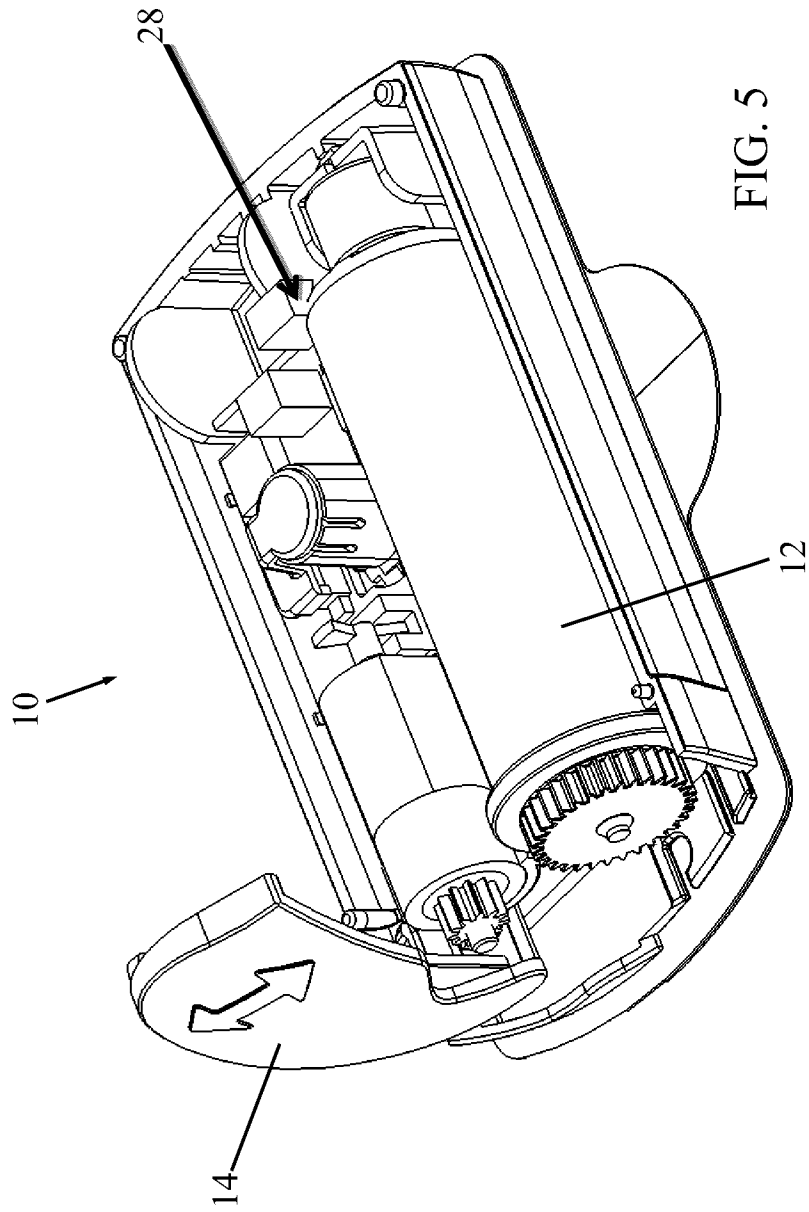


FIG. 4



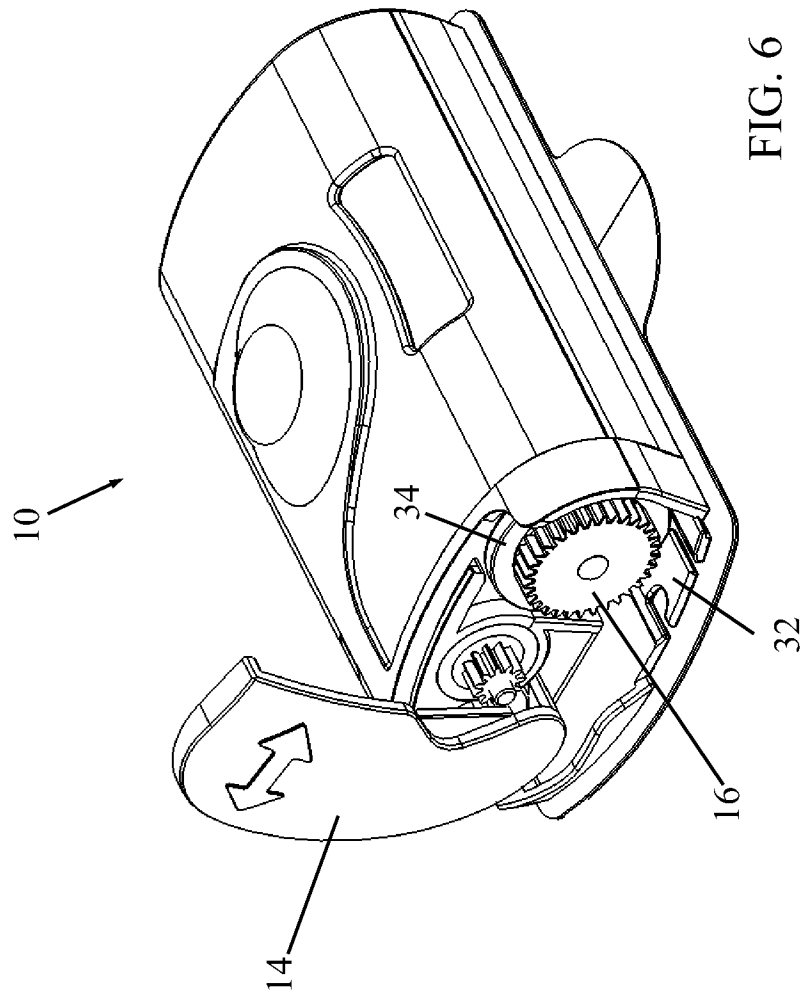


FIG. 6

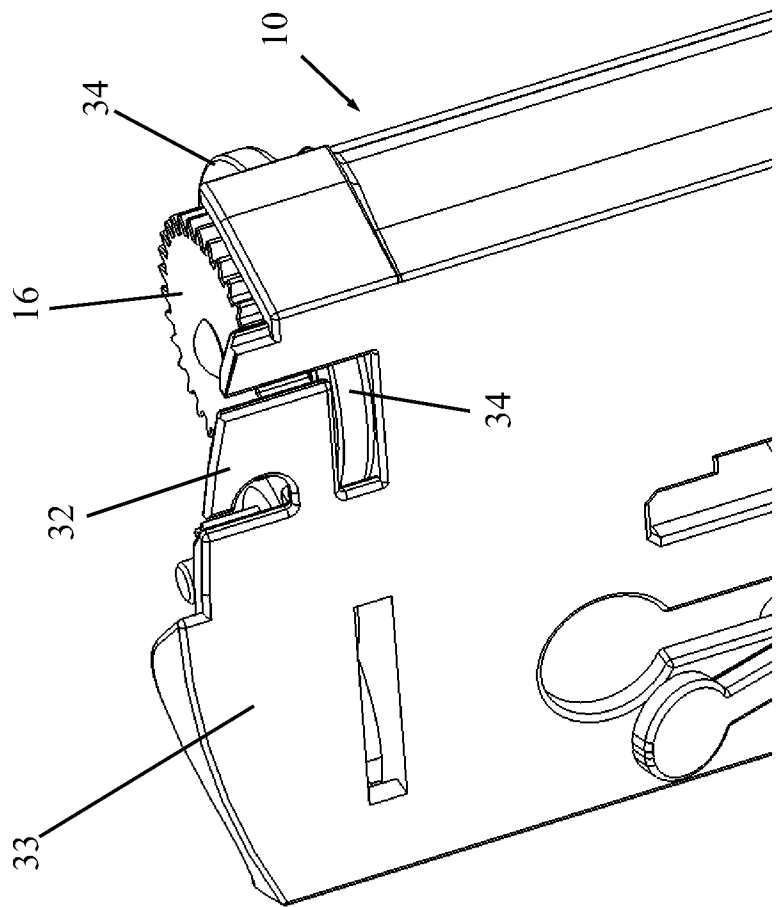


FIG. 7

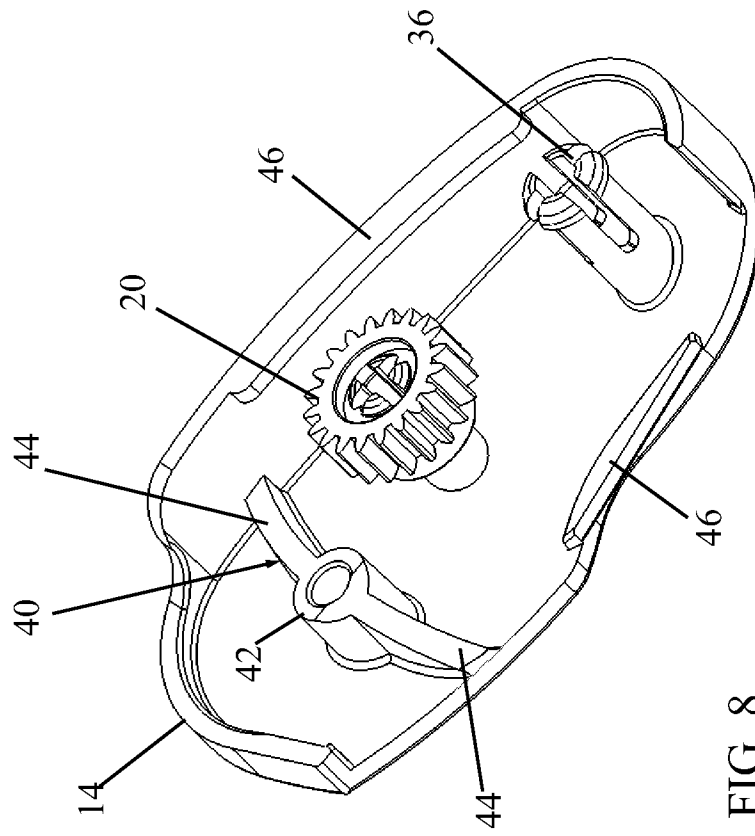


FIG. 8

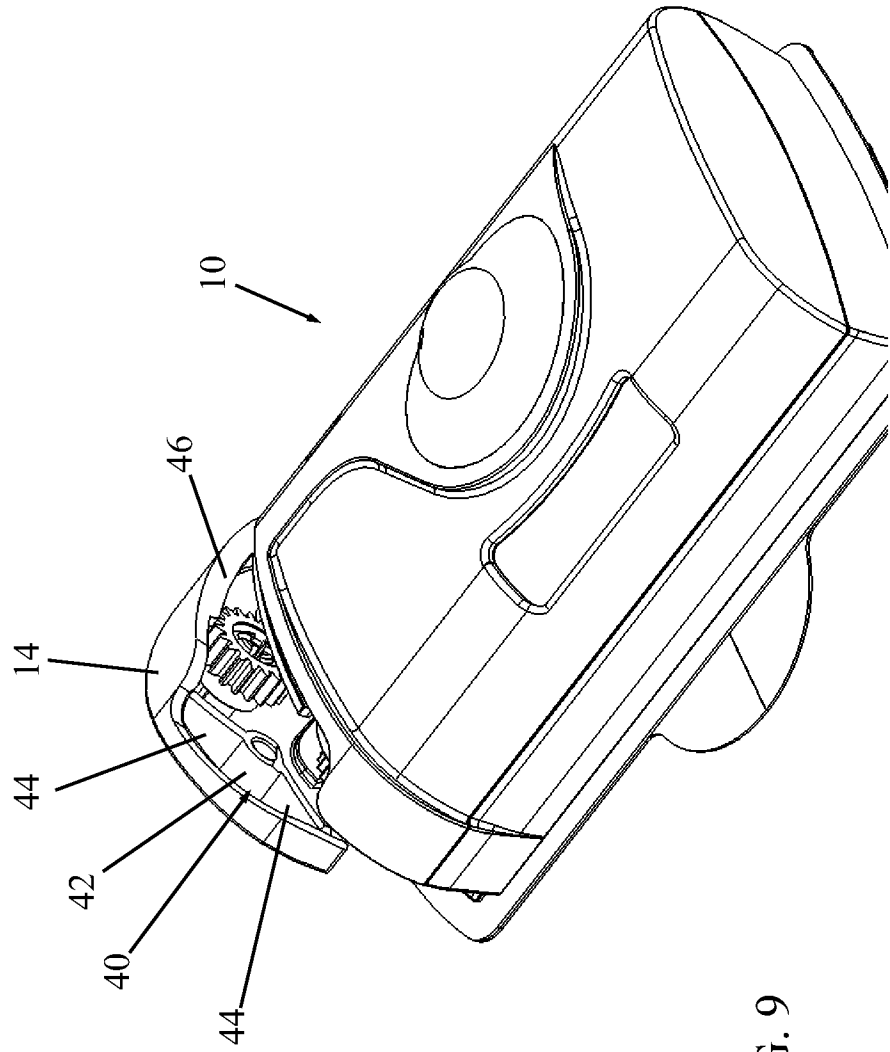
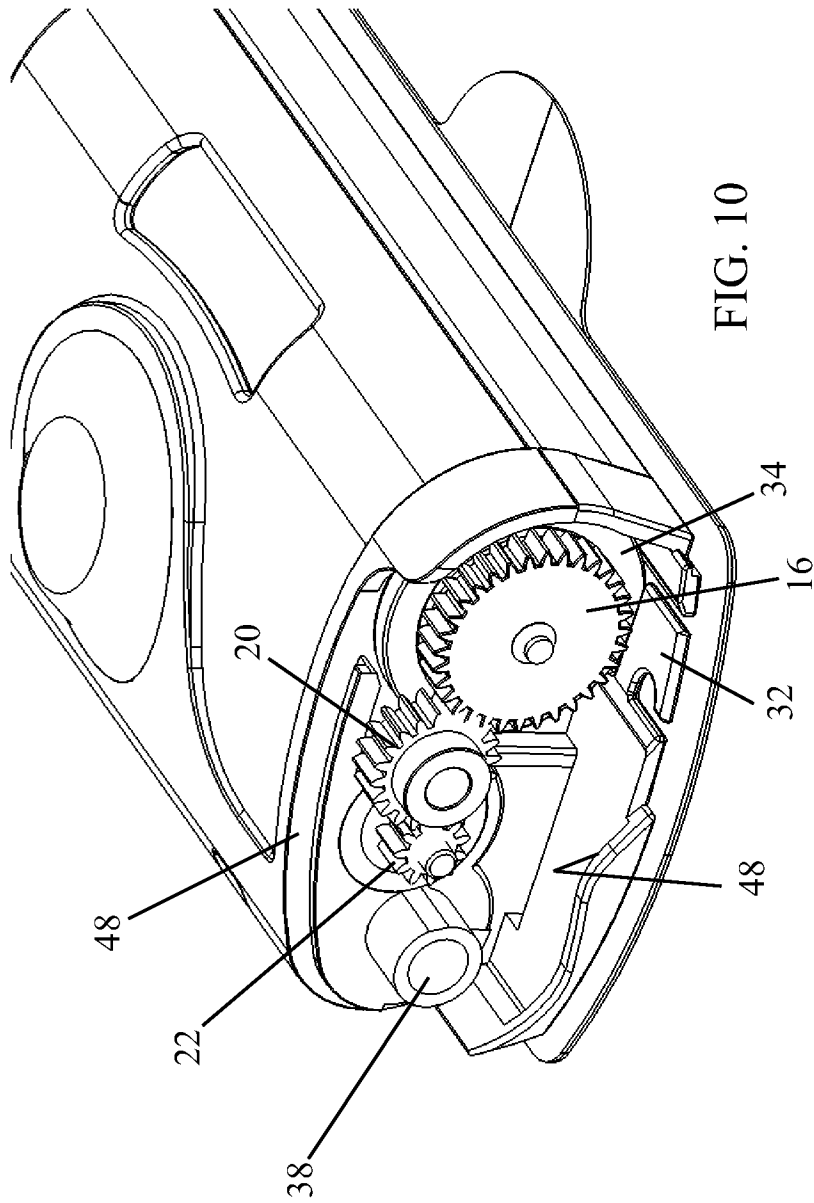


FIG. 9



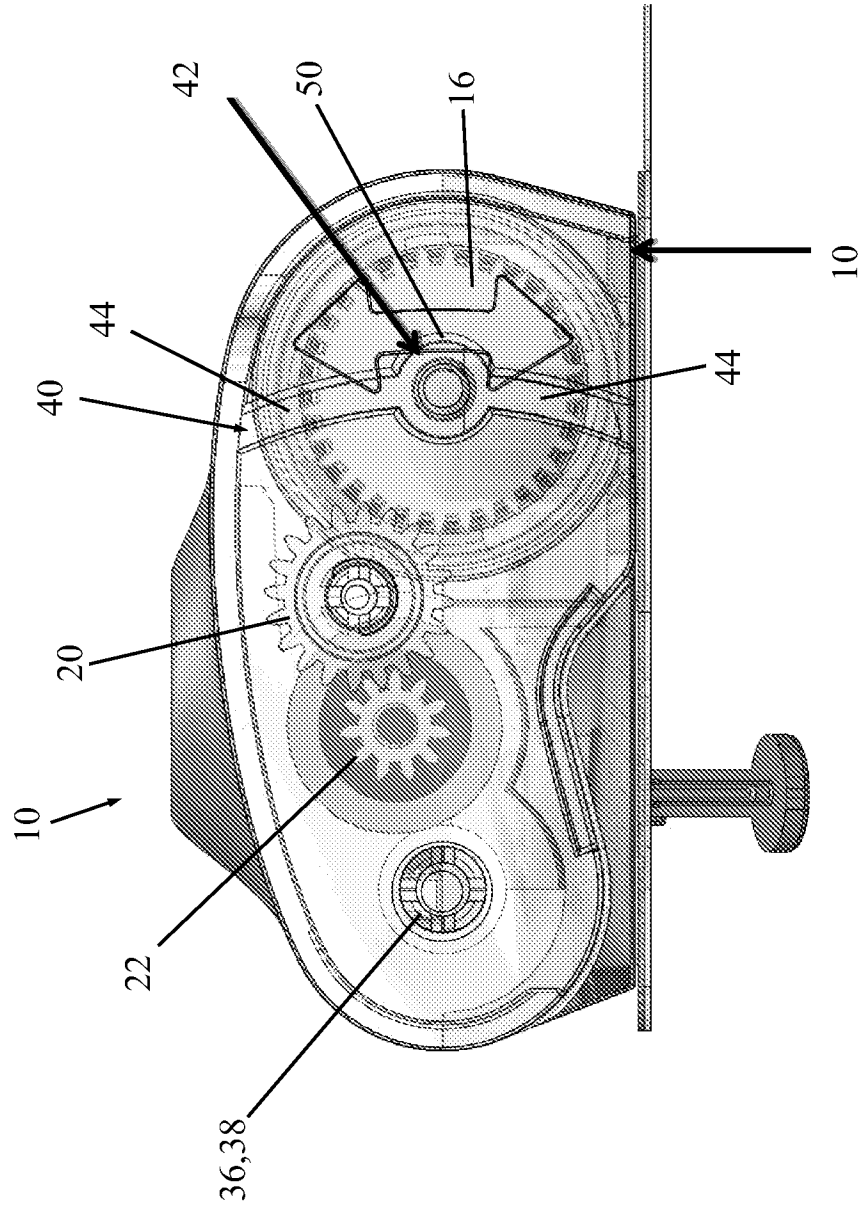


FIG. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/048556

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61M5/142 A61M5/145
 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	US 4 300 554 A (HESSBERG SIGFRIED ET AL) 17 November 1981 (1981-11-17) column 5, line 65 - column 6, line 30	1
A	US 2009/143735 A1 (DE POLO MARCO C [US] ET AL) 4 June 2009 (2009-06-04) paragraphs [0022] - [0030]	1
A	US 5 954 697 A (SRISATHAPAT CHAD [US] ET AL) 21 September 1999 (1999-09-21) the whole document	1
A	US 2009/093792 A1 (GROSS YOSSI [IL] ET AL) 9 April 2009 (2009-04-09) cited in the application the whole document	1

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	"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
"E" earlier document but published on or after the international filing date	"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
"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)	"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.
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 3 January 2011	Date of mailing of the international search report 12/01/2011
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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 Manschot, Jan
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2010/048556

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
US 4300554	A	17-11-1981	DE 2906830 B1	21-08-1980
			DK 73480 A	23-08-1980
			EP 0016343 A1	01-10-1980
			FI 800518 A	23-08-1980
			JP 1418852 C	14-01-1988
			JP 55146165 A	14-11-1980
			JP 62025390 B	02-06-1987
			NO 800468 A	25-08-1980
US 2009143735	A1	04-06-2009	EP 2217306 A1	18-08-2010
			WO 2009068251 A1	04-06-2009
US 5954697	A	21-09-1999	NONE	
US 2009093792	A1	09-04-2009	CN 101868273 A	20-10-2010
			EP 2195052 A2	16-06-2010
			WO 2009044401 A2	09-04-2009
			US 2009093793 A1	09-04-2009