



- (51) International Patent Classification:  
A61M 5/19 (2006.01) A61M 5/20 (2006.01)
- (21) International Application Number:  
PCT/EP2012/058260
- (22) International Filing Date:  
4 May 2012 (04.05.2012)
- (25) Filing Language:  
English
- (26) Publication Language:  
English
- (30) Priority Data:  
11165121.2 6 May 2011 (06.05.2011) EP
- (71) Applicant (for all designated States except US): **SANOFI-AVENTIS DEUTSCHLAND GMBH** [DE/DE]; Brüningstrasse 50, 65929 Frankfurt am Main (DE).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): **HARMS, Michael** [DE/DE]; c/o Sanofi-Aventis Deutschland GmbH, 65926 Frankfurt am Main (DE).
- (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, QA, RO, RS, RU, RW, 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, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, 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, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Declarations under Rule 4.17:**

— of inventorship (Rule 4.17(iv))

**Published:**

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

(54) Title: NEEDLE HUB AND NEEDLE

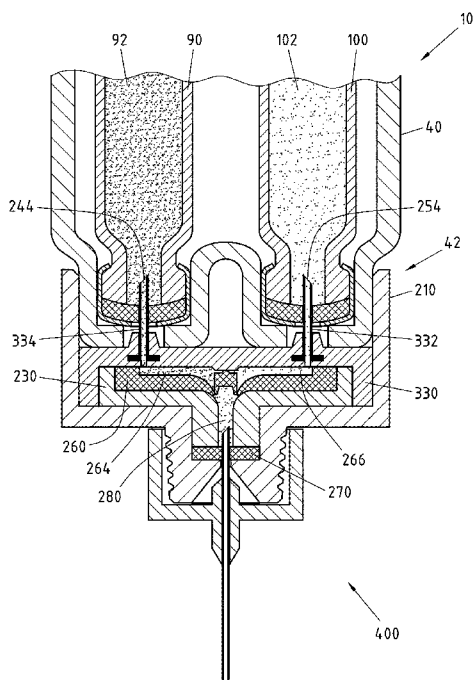


Fig.18

(57) Abstract: The invention is related to an apparatus comprising a needle hub (320; 330) comprising at least one channel configured to guide a liquid, especially a liquid drug component, a needle (300; 310; 322; 332, 334) comprising a cannula (302; 312; 323; 333, 335) configured to guide the liquid and a plate (304, 314; 324; 336, 338) fixedly connected to one end of the cannula (302; 312; 323; 333, 335), wherein the plate (304, 314; 324; 336, 338) is configured to interact with the needle hub (320; 330) for fixing the needle (300; 310; 322; 332, 334) to the needle hub (320; 330). The invention further is related to an apparatus comprising a cannula (302; 312; 323; 333, 335) configured to guide a liquid, especially a liquid drug component, and a plate (304, 314; 324; 336, 338) fixedly connected to one end of the cannula (302; 312; 323; 333, 335).



## Description

### Needle hub and Needle

5 The present patent application generally relates to medical devices of delivering at least two drug agents from separate reservoirs. Such drug agents may comprise a first and a second medicament. The medical device includes a dose setting mechanism for delivering the drug automatically or manually by the user. Especially the invention relates to a needle hub used in the medical device as well as to a specific needle  
10 construction.

The drug agents may be contained in two or more multiple dose reservoirs, containers or packages, each containing independent (single drug compound) or pre-mixed (co-formulated multiple drug compounds) drug agents.

15 Certain disease states require treatment using one or more different medicaments. Some drug compounds need to be delivered in a specific relationship with each other in order to deliver the optimum therapeutic dose. The present patent application is of particular benefit where combination therapy is desirable, but not possible in a single  
20 formulation for reasons such as, but not limited to, stability, compromised therapeutic performance and toxicology.

For example, in some cases it might be beneficial to treat a diabetic with a long acting insulin (also may be referred to as the first or primary medicament) along with a  
25 glucagon-like peptide-1 such as GLP-1 or GLP-1 analog (also may be referred to as the second drug or secondary medicament).

Accordingly, there exists a need to provide devices for the delivery of two or more medicaments in a single injection or delivery step that is simple for the user to perform  
30 without complicated physical manipulations of the drug delivery device. The proposed drug delivery device provides separate storage containers or cartridge retainers for two or more active drug agents. These active drug agents are then only combined and/or

delivered to the patient during a single delivery procedure. These active agents may be administered together in a combined dose or alternatively, these active agents may be combined in a sequential manner, one after the other.

- 5 The drug delivery device also allows for the opportunity of varying the quantity of the medicaments. For example, one fluid quantity can be varied by changing the properties of the injection device (e.g., setting a user variable dose or changing the device's "fixed" dose). The second medicament quantity can be changed by manufacturing a variety of secondary drug containing packages with each variant containing a different volume  
10 and/or concentration of the second active agent.

The drug delivery device may have a single dispense interface. This interface may be configured for fluid communication with the primary reservoir and with a secondary reservoir of medicament containing at least one drug agent. The drug dispense  
15 interface can be a type of outlet that allows the two or more medicaments to exit the system and be delivered to the patient.

The combination of compounds as discrete units or as a mixed unit can be delivered to the body via a double-ended needle assembly. This would provide a combination drug  
20 injection system that, from a user's perspective, would be achieved in a manner that closely matches the currently available injection devices that use standard needle assemblies. One possible delivery procedure may involve the following steps:

1. Attach a dispense interface to a distal end of the electro-mechanical injection  
25 device. The dispense interface comprises a first and a second proximal needle. The first and second needles pierce a first reservoir containing a primary compound and a second reservoir containing a secondary compound, respectively.
2. Attach a dose dispenser, such as a double-ended needle assembly, to a distal  
30 end of the dispense interface. In this manner, a proximal end of the needle assembly is in fluidic communication with both the primary compound and secondary compound.

3. Dial up/set a desired dose of the primary compound from the injection device, for example, via a graphical user interface (GUI).
4. After the user sets the dose of the primary compound, the micro-processor controlled control unit may determine or compute a dose of the secondary compound and preferably may determine or compute this second dose based on a previously stored therapeutic dose profile. It is this computed combination of medicaments that will then be injected by the user. The therapeutic dose profile may be user selectable.
5. Optionally, after the second dose has been computed, the device may be placed in an armed condition. In such an optional armed condition, this may be achieved by pressing and/or holding an "OK" button on a control panel. This condition may provide for greater than a predefined period of time before the device can be used to dispense the combined dose.
6. Then, the user will insert or apply the distal end of the dose dispenser (e.g., a double ended needle assembly) into the desired injection site. The dose of the combination of the primary compound and the secondary compound (and potentially a third medicament) is administered by activating an injection user interface (e.g., an injection button).

Both medicaments may be delivered via one injection needle or dose dispenser and in one injection step. This offers a convenient benefit to the user in terms of reduced user steps compared to administering two separate injections.

The needle hubs known so far need a construction of the dispense interface wherein the first and second proximal needles have to be glued to be connected to the body of the needle hub as part of the dispense interface. This glue can be harmful, because ingredients of the glue may influence the chemical composition of the drug component. The needles also can be overmolded during the injection process. Different and difficult requirements have to be fulfilled like the fixedness between both needle and plastic as soon as an injection process under clean room conditions.

It is therefore an object to the present invention to overcome these deficiencies during the production of the needle hub of the dispense interface.

- 5 The above problem can be solved by an apparatus comprising a needle hub comprising at least one channel configured to guide a liquid, especially a liquid drug component, a needle comprising a cannula configured to guide the liquid and a plate fixedly connected to one end of the cannula, wherein the plate is configured to interact with the needle hub for fixing the needle to the needle hub.

10

In this construction the needle with the plate notches into the plastic of the body needle hub or of the dispense interface for centering, thus orienting and ensuring fixation of the needle relative to the needle hub.

- 15 With this construction the needle is mechanically more stable per se and can therefore be mounted onto any body of the dispense interface, preferably made from plastic, without the use of glue and without using the combined injection molding technique.

The plate, which may be of circular or otherwise plane design, can be introduced into  
20 the material of the body of the dispense interface and therefore build up a positive fit. Thus a mechanically stable position of the needle relative to the body is formed.

In the afore described apparatus or needle, the plate can be configured to be mounted in an indentation of a needle hub. This indentation is advantageous in that the position  
25 of the plate of the needle within the construction of the needle hub is prescribed and the needle only has to be positioned within the indentation. Thus the connection between the needle and the needle hub is facilitated.

In a preferred embodiment the body of the needle hub comprises two halves configured  
30 to be fixedly connected to each other. These halves may be connected by gluing or welding together thus establishing the channels, especially in the form of a "Y", in between the halves for guiding the liquid or liquid drug component.

In a preferred embodiment, the needle is mounted by pressing the plate partly into one half of the body of the needle hub, the other half can be pressed and thus fit on the first half. Especially because of the fixation on the metal plate, both plates fit together. If the connection between the two halves shall be stronger, both halves can be welded or glued to each other.

It is further preferred, that at least on half of the needle hub comprises an indentation configured to receive the plate at least partially. Due to the indentation the plate is precisely positioned relative to the halves of the needle hub.

As mentioned before, it is further preferred that the needle hub comprises two channels configured to guide two liquids, especially liquid drugs, to a common outlet port. This shape can be called "Y-shape".

These as well as other advantages of various aspects of the present invention will become apparent to those of ordinary skill in the art by reading the following detailed description, with appropriate reference to the accompanying drawings, in which:

Fig. 1 illustrates a perspective view of the delivery device illustrated in Fig. 1a and 1b with an end cap of the device removed;

Fig. 2 illustrates a perspective view of the delivery device distal end showing the cartridge;

Fig. 3 illustrates a perspective view of the cartridge holder illustrated in Fig. 1 with one cartridge retainer in an open position;

Fig. 4 illustrates a dispense interface and a dose dispenser that may be removably mounted on a distal end of the delivery device illustrated in Fig. 1;

Fig. 5 illustrates the dispense interface and the dose dispenser illustrated in Fig. 4 mounted on a distal end of the delivery device illustrated in Fig. 1;

5 Fig. 6 illustrates one arrangement of the dose dispenser that may be mounted on a distal end of the delivery device;

Fig. 7 illustrates a perspective view of the dispense interface illustrated in Fig. 4;

10 Fig. 8 illustrates another perspective view of the dispense interface illustrated in Fig. 4;

Fig. 9 illustrates a cross-sectional view of the dispense interface illustrated in Fig. 4;

Fig. 10 illustrates an exploded view of the dispense interface illustrated in Fig. 4;

15 Fig. 11 illustrates a cross-sectional view of the dispense interface and dose dispenser mounted onto a drug delivery device, such as the device illustrated in Fig. 1;

20 Fig. 12 illustrates a cross-sectional view of an embodiment of an inventive needle with a plate;

Fig. 13 illustrates a cross-sectional view of an embodiment of an inventive needle with a plate;

25 Fig. 14 illustrates a perspective view of the embodiment of the needle according to Fig. 13;

Fig. 15 illustrates a cross-sectional view of a further embodiment of the present invention;

30 Fig. 16 illustrates a cross-sectional view of another embodiment of the present invention;

Fig. 17 illustrates a perspective view of the embodiment according to Fig. 13; and

Fig. 18 illustrates a cross-sectional view of the dispense interface and dose dispenser mounted onto a drug delivery device, such as the device illustrated in Fig. 1, but with the needle assembly according to an embodiment of the present invention.

The drug delivery device illustrated in Fig. 1 comprises a main body 14 that extends from a proximal end 16 to a distal end 15. At the distal end 15, a removable end cap or cover 18 is provided. This end cap 18 and the distal end 15 of the main body 14 work together to provide a snap fit or form fit connection so that once the cover 18 is slid onto the distal end 15 of the main body 14, this frictional fit between the cap and the main body outer surface 20 prevents the cover from inadvertently falling off the main body.

The main body 14 contains a micro-processor control unit, an electro-mechanical drive train, and at least two medicament reservoirs. When the end cap or cover 18 is removed from the device 10 (as illustrated in Fig. 1), a dispense interface 200 is mounted to the distal end 15 of the main body 14, and a dose dispenser (e.g., a needle assembly) is attached to the interface. The drug delivery device 10 can be used to administer a computed dose of a second medicament (secondary drug compound) and a variable dose of a first medicament (primary drug compound) through a single needle assembly, such as a double ended needle assembly.

A control panel region 60 is provided near the proximal end of the main body 14. Preferably, this control panel region 60 comprises a digital display 80 along with a plurality of human interface elements that can be manipulated by a user to set and inject a combined dose. In this arrangement, the control panel region comprises a first dose setting button 62, a second dose setting button 64 and a third button 66 designated with the symbol "OK." In addition, along the most proximal end of the main body, an injection button 74 is also provided (not visible in the perspective view of Fig. 1).

The cartridge holder 40 can be removably attached to the main body 14 and may contain at least two cartridge retainers 50 and 52. Each retainer is configured so as to

contain one medicament reservoir, such as a glass cartridge. Preferably, each cartridge contains a different medicament.

In addition, at the distal end of the cartridge holder 40, the drug delivery device  
5 illustrated in Fig. 1 includes a dispense interface 200. As will be described in relation to Fig. 4, in one arrangement, this dispense interface 200 includes a main outer body 212 that is removably attached to a distal end 42 of the cartridge housing 40. As can be seen in Fig. 1, a distal end 214 of the dispense interface 200 preferably comprises a  
10 dispenser, such as a conventional pen type injection needle assembly, to be removably mounted to the drug delivery device 10.

Once the device is turned on, the digital display 80 shown in Fig. 1 illuminates and provides the user certain device information, preferably information relating to the  
15 medicaments contained within the cartridge holder 40. For example, the user is provided with certain information relating to both the primary medicament (Drug A) and the secondary medicament (Drug B).

As shown in Fig. 3, the first and a second cartridge retainers 50, 52 comprise hinged  
20 cartridge retainers. These hinged retainers allow user access to the cartridges. Fig. 3 illustrates a perspective view of the cartridge holder 40 illustrated in Fig. 1 with the first hinged cartridge retainer 50 in an open position. Fig. 3 illustrates how a user might access the first cartridge 90 by opening up the first retainer 50 and thereby having access to the first cartridge 90.

25 As mentioned above when discussing Fig. 1, a dispense interface 200 is coupled to the distal end of the cartridge holder 40. Fig. 4 illustrates a flat view of the dispense interface 200 unconnected to the distal end of the cartridge holder 40. A dose dispenser or needle assembly that may be used with the interface 200 is also illustrated and is  
30 provided in a protective outer cap 420.

In Fig. 5, the dispense interface 200 illustrated in Fig. 4 is shown coupled to the cartridge holder 40. The axial attachment means between the dispense interface 200 and the cartridge holder 40 can be any known axial attachment means to those skilled in the art, including snap locks, snap fits, snap rings, keyed slots, and combinations of such connections. The connection or attachment between the dispense interface and the cartridge holder may also contain additional features (not shown), such as connectors, stops, splines, ribs, grooves, pips, clips and the like design features, that ensure that specific hubs are attachable only to matching drug delivery devices. Such additional features would prevent the insertion of a non-appropriate secondary cartridge to a non-matching injection device.

Fig. 5 also illustrates the needle assembly 400 and protective cover 420 coupled to the distal end of the dispense interface 200 that may be screwed onto the needle hub of the interface 200. Fig. 6 illustrates a cross sectional view of the double ended needle assembly 402 mounted on the dispense interface 200 in Fig. 5.

The needle assembly 400 illustrated in Fig. 6 comprises a double ended needle 406 and a hub 401. The double ended needle or cannula 406 is fixedly mounted in a needle hub 401. This needle hub 401 comprises a circular disk shaped element which has along its periphery a circumferential depending sleeve 403. Along an inner wall of this hub member 401, a thread 404 is provided. This thread 404 allows the needle hub 401 to be screwed onto the dispense interface 200 which, in one preferred arrangement, is provided with a corresponding outer thread along a distal hub. At a center portion of the hub element 401 there is provided a protrusion 402. This protrusion 402 projects from the hub in an opposite direction of the sleeve member. A double ended needle 406 is mounted centrally through the protrusion 402 and the needle hub 401. This double ended needle 406 is mounted such that a first or distal piercing end 405 of the double ended needle forms an injecting part for piercing an injection site (e.g., the skin of a user).

Similarly, a second or proximal piercing end 406 of the needle assembly 400 protrudes from an opposite side of the circular disc so that it is concentrically surrounded by the

sleeve 403. In one needle assembly arrangement, the second or proximal piercing end 406 may be shorter than the sleeve 403 so that this sleeve to some extent protects the pointed end of the back sleeve. The needle cover cap 420 illustrated in Fig. 4 and 5 provides a form fit around the outer surface 403 of the hub 401.

- 5 Referring now to Fig. 4 to 11, one preferred arrangement of this interface 200 will now be discussed. In this one preferred arrangement, this interface 200 comprises:
- a. a main outer body 210,
  - b. an first inner body 220,
  - c. a second inner body 230,
  - 10 d. a first piercing needle 240,
  - e. a second piercing needle 250,
  - f. a valve seal 260, and
  - g. a septum 270.
- 15 The main outer body 210 comprises a main body proximal end 212 and a main body distal end 214. At the proximal end 212 of the outer body 210, a connecting member is configured so as to allow the dispense interface 200 to be attached to the distal end of the cartridge holder 40. Preferably, the connecting member is configured so as to allow the dispense interface 200 to be removably connected the cartridge holder 40. In one
- 20 preferred interface arrangement, the proximal end of the interface 200 is configured with an upwardly extending wall 218 having at least one recess. For example, as may be seen from Fig. 8, the upwardly extending wall 218 comprises at least a first recess 217 and a second recess 219.
- 25 Preferably, the first and the second recesses 217, 219 are positioned within this main outer body wall so as to cooperate with an outwardly protruding member located near the distal end of the cartridge housing 40 of the drug delivery device 10. For example, this outwardly protruding member 48 of the cartridge housing may be seen in Fig. 4 and 5. A second similar protruding member is provided on the opposite side of the cartridge
- 30 housing. As such, when the interface 200 is axially slid over the distal end of the cartridge housing 40, the outwardly protruding members will cooperate with the first and second recess 217, 219 to form an interference fit, form fit, or snap lock. Alternatively,

and as those of skill in the art will recognize, any other similar connection mechanism that allows for the dispense interface and the cartridge housing 40 to be axially coupled could be used as well.

- 5 The main outer body 210 and the distal end of the cartridge holder 40 act to form an axially engaging snap lock or snap fit arrangement that could be axially slid onto the distal end of the cartridge housing. In one alternative arrangement, the dispense interface 200 may be provided with a coding feature so as to prevent inadvertent dispense interface cross use. That is, the inner body of the hub could be geometrically  
10 configured so as to prevent an inadvertent cross use of one or more dispense interfaces.

A mounting hub is provided at a distal end of the main outer body 210 of the dispense interface 200. Such a mounting hub can be configured to be releasably connected to a needle assembly. As just one example, this connecting means 216 may comprise an  
15 outer thread that engages an inner thread provided along an inner wall surface of a needle hub of a needle assembly, such as the needle assembly 400 illustrated in Fig. 6. Alternative releasable connectors may also be provided such as a snap lock, a snap lock released through threads, a bayonet lock, a form fit, or other similar connection arrangements.

20 The dispense interface 200 further comprises a first inner body 220. Certain details of this inner body are illustrated in Fig. 8-11. Preferably, this first inner body 220 is coupled to an inner surface 215 of the extending wall 218 of the main outer body 210. More preferably, this first inner body 220 is coupled by way of a rib and groove form fit  
25 arrangement to an inner surface of the outer body 210. For example, as can be seen from Fig. 9, the extending wall 218 of the main outer body 210 is provided with a first rib 213a and a second rib 213b. This first rib 213a is also illustrated in Fig. 10. These ribs 213a and 213b are positioned along the inner surface 215 of the wall 218 of the outer body 210 and create a form fit or snap lock engagement with cooperating grooves 224a  
30 and 224b of the first inner body 220. In a preferred arrangement, these cooperating grooves 224a and 224b are provided along an outer surface 222 of the first inner body 220.

In addition, as can be seen in Fig. 8-10, a proximal surface 226 near the proximal end of the first inner body 220 may be configured with at least a first proximally positioned piercing needle 240 comprising a proximal piercing end portion 244. Similarly, the first inner body 220 is configured with a second proximally positioned piercing needle 250 comprising a proximally piercing end portion 254. Both the first and second needles 240, 250 are rigidly mounted on the proximal surface 226 of the first inner body 220.

Preferably, this dispense interface 200 further comprises a valve arrangement. Such a valve arrangement could be constructed so as to prevent cross contamination of the first and second medicaments contained in the first and second reservoirs, respectively. A preferred valve arrangement may also be configured so as to prevent back flow and cross contamination of the first and second medicaments.

In one preferred system, dispense interface 200 includes a valve arrangement in the form of a valve seal 260. Such a valve seal 260 may be provided within a cavity 231 defined by the second inner body 230, so as to form a holding chamber 280. Preferably, cavity 231 resides along an upper surface of the second inner body 230. This valve seal comprises an upper surface that defines both a first fluid groove 264 and second fluid groove 266. For example, Fig. 9 illustrates the position of the valve seal 260, seated between the first inner body 220 and the second inner body 230. During an injection step, this seal valve 260 helps to prevent the primary medicament in the first pathway from migrating to the secondary medicament in the second pathway, while also preventing the secondary medicament in the second pathway from migrating to the primary medicament in the first pathway. Preferably, this seal valve 260 comprises a first non-return valve 262 and a second non-return valve 268. As such, the first non-return valve 262 prevents fluid transferring along the first fluid pathway 264, for example a groove in the seal valve 260, from returning back into this pathway 264. Similarly, the second non-return valve 268 prevents fluid transferring along the second fluid pathway 266 from returning back into this pathway 266.

Together, the first and second grooves 264, 266 converge towards the non-return valves 262 and 268 respectively, to then provide for an output fluid path or a holding chamber 280. This holding chamber 280 is defined by an inner chamber defined by a distal end of the second inner body both the first and the second non return valves 262, 5 268 along with a pierceable septum 270. As illustrated, this pierceable septum 270 is positioned between a distal end portion of the second inner body 230 and an inner surface defined by the needle hub of the main outer body 210.

The holding chamber 280 terminates at an outlet port of the interface 200. This outlet 10 port 290 is preferably centrally located in the needle hub of the interface 200 and assists in maintaining the pierceable seal 270 in a stationary position. As such, when a double ended needle assembly is attached to the needle hub of the interface (such as the double ended needle illustrated in Fig. 6), the output fluid path allows both medicaments to be in fluid communication with the attached needle assembly.

15 The hub interface 200 further comprises a second inner body 230. As can be seen from Fig. 9, this second inner body 230 has an upper surface that defines a recess, and the valve seal 260 is positioned within this recess. Therefore, when the interface 200 is assembled as shown in Fig. 9, the second inner body 230 will be positioned between a 20 distal end of the outer body 210 and the first inner body 220. Together, second inner body 230 and the main outer body hold the septum 270 in place. The distal end of the inner body 230 may also form a cavity or holding chamber that can be configured to be fluid communication with both the first groove 264 and the second groove 266 of the valve seal.

25 Axially sliding the main outer body 210 over the distal end of the drug delivery device attaches the dispense interface 200 to the multi-use device. In this manner, a fluid communication may be created between the first needle 240 and the second needle 250 with the primary medicament of the first cartridge and the secondary medicament of 30 the second cartridge, respectively.

Fig. 11 illustrates the dispense interface 200 after it has been mounted onto the distal end 42 of the cartridge holder 40 of the drug delivery device 10 illustrated in Fig. 1. A double ended needle 400 is also mounted to the distal end of this interface. The cartridge holder 40 is illustrated as having a first cartridge containing a first medicament and a second cartridge containing a second medicament.

When the interface 200 is first mounted over the distal end of the cartridge holder 40, the proximal piercing end 244 of the first piercing needle 240 pierces the septum of the first cartridge 90 and thereby resides in fluid communication with the primary medicament 92 of the first cartridge 90. A distal end of the first piercing needle 240 will also be in fluid communication with a first fluid path groove 264 defined by the valve seal 260.

Similarly, the proximal piercing end 254 of the second piercing needle 250 pierces the septum of the second cartridge 100 and thereby resides in fluid communication with the secondary medicament 102 of the second cartridge 100. A distal end of this second piercing needle 250 will also be in fluid communication with a second fluid path groove 266 defined by the valve seal 260.

Fig. 11 illustrates a preferred arrangement of such a dispense interface 200 that is coupled to a distal end 15 of the main body 14 of drug delivery device 10. Preferably, such a dispense interface 200 is removably coupled to the cartridge holder 40 of the drug delivery device 10.

As illustrated in Fig. 11, the dispense interface 200 is coupled to the distal end of a cartridge housing 40. This cartridge holder 40 is illustrated as containing the first cartridge 90 containing the primary medicament 92 and the second cartridge 100 containing the secondary medicament 102. Once coupled to the cartridge housing 40, the dispense interface 200 essentially provides a mechanism for providing a fluid communication path from the first and second cartridges 90, 100 to the common holding chamber 280. This holding chamber 280 is illustrated as being in fluid communication with a dose dispenser. Here, as illustrated, this dose dispenser comprises the double

ended needle assembly 400. As illustrated, the proximal end of the double ended needle assembly is in fluid communication with the chamber 280.

5 In one preferred arrangement, the dispense interface is configured so that it attaches to the main body in only one orientation, that is it is fitted only one way round. As such as illustrated in Fig. 11, once the dispense interface 200 is attached to the cartridge holder 40, the primary needle 240 can only be used for fluid communication with the primary medicament 92 of the first cartridge 90 and the interface 200 would be prevented from being reattached to the holder 40 so that the primary needle 240 could now be used for  
10 fluid communication with the secondary medicament 102 of the second cartridge 100. Such a one way around connecting mechanism may help to reduce potential cross contamination between the two medicaments 92 and 102.

Fig. 12 illustrates a cross-sectional view of a first embodiment of an inventive needle  
15 300 comprising a cannula 312 configured to guide a liquid, especially a liquid drug component, and a plate 314 fixedly connected to one end of the cannula 302. The plate 304 is made separately from the needle 300 and is fixed to the cannula 302 in any possible way by welding, gluing or just by friction. The plate 304 thus established a flange fixed to the cannula 302.

20 Fig. 13 illustrates a cross-sectional view of a second embodiment of an inventive needle 310 comprising a cannula 312 configured to guide a liquid, especially a liquid drug component, and a plate 314 fixedly connected to one end of the cannula 312. Here the plate 314 is preferably made by recasting one of the end parts of a needle. This can be  
25 seen from the rounded parts of the plate 314. Again plate 314 thus established a flange fixed to the cannula 312. Fig. 14 illustrates a perspective view of the needle 310 according to Fig. 13.

Fig. 15 illustrates a cross-sectional view of an embodiment of an apparatus or needle  
30 hub 320 being similar in construction as has been discussed with reference to Fig. 7 to 11. The needle hub 320 comprises two channels configured to guide a liquid, especially a liquid drug component, through a common outlet port. The needle hub 320 is

connected with two needles 322 each including a plate 324. The cross section of Fig. 15 shows a side viewed of the smaller side of needle hub 320 and therefore only one needle 322 is visible.

- 5 It is understood, that the present invention can be carried out with a needle hub using only one needle 320 including the plate 324.

The needle 322 which comprises a cannula 323 configured to guide a liquid, especially a liquid drug component, and a plate 324 fixedly connected to one end of the cannula  
10 323. As can be seen from Fig. 15, the plate 324 is configured to interact with the needle hub 320 for fixing the needle 322 to the needle hub 320.

The needle 322 is fixed to the body of the needle hub 320 by guiding the cannula 323 of the needle 322 through a corresponding hole within the body of the needle hub 320 and  
15 attaching the upper surface of the plate 324 to the inner surface 325 of the needle hub 320. Thus the plate 324 attaches the inner side of the needle hub 320 with the planar portions.

Fig. 16 shows a cross-sectional view of a further embodiment of the present invention,  
20 wherein the connection between the needle hub 330 and two needles 332 and 334, each showing a plate 336 and 338 respectively. In this embodiment the body of the needle hub 330 comprises indentations 340 and 342 respectively. Since the plates 336 and 338 match into the indentations 340 and 342, the needles 332 and 334 are fixedly connected to the needle hub 330.

25 As can be seen from Fig. 17, the needle hub 330 comprises two halves 330a and 330b configured to be fixedly connected to each other. Further, the two needles 332 and 334 are connected to the needle hub 330, wherein the needles 332 and 334 can be designed according to one of the embodiments according to Fig. 12 to 14.

30 As shown in Fig. 16 at least on half of the needle hub comprises indentations 340 and 342 configured to receive the plate at least partially. In a preferred embodiment, both

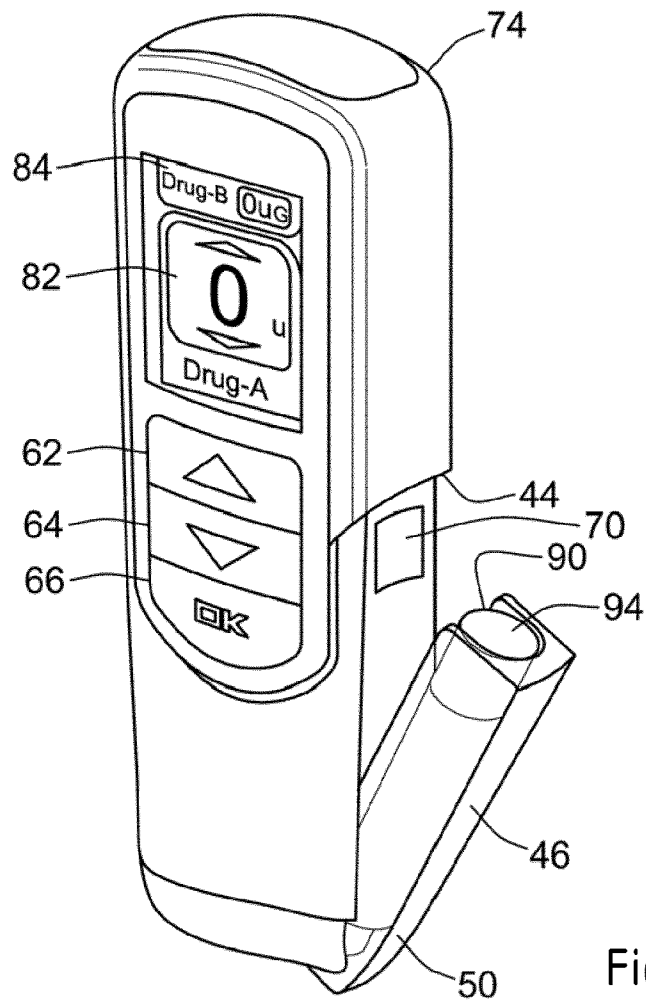
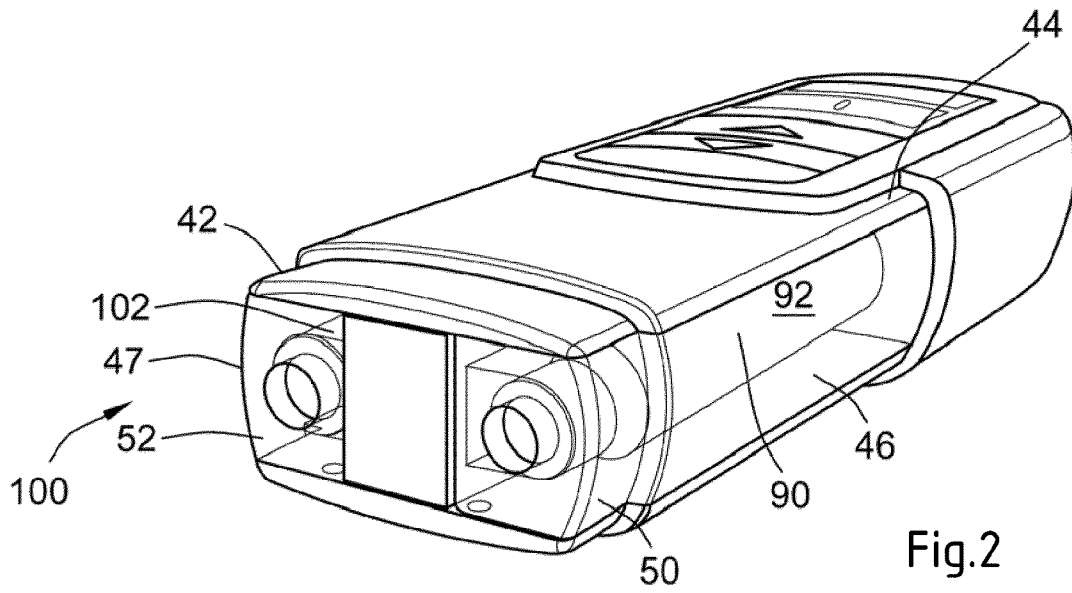
halves 330a and 330b include such an indentation to be symmetrical in construction and to fix and orientate the needle in a symmetrical way.

5 Finally, Fig. 18 illustrates a cross-sectional view of the dispense interface and dose dispenser mounted onto a drug delivery device, such as the device illustrated in Fig. 1, but with the needle hub according to an embodiment of the present invention. Same reference numbers are used which have been introduced before to indicate the same elements. To avoid any repetitions, reference is made to the description of Fig. 11 above as well as to the description of the embodiment according to Fig. 16 and 17.

## Claims

1. An apparatus comprising
  - a needle hub (320; 330) comprising at least one channel configured to guide a liquid, especially a liquid drug component,
  - and a needle comprising a cannula (302; 312; 323; 333, 335) configured to guide a liquid, especially a liquid drug component, and a plate (304, 314; 324; 336, 338) fixedly connected to one end of the cannula (302; 312; 323; 333, 335).
  - wherein the plate (304, 314; 324; 336, 338) fixed to the cannula (302; 312; 323; 333, 335) is configured to interact with the needle hub (320; 330) for fixing the needle (300; 310; 322; 332, 334) to the needle hub (320; 330).
2. Apparatus according to claim 1, wherein the plate (304, 314; 324; 336, 338) is configured to be mounted in an indentation of a needle hub (320, 330).
3. The Apparatus according to claim 1 or 2, wherein the needle hub (330) comprises two halves (330a, 330b) configured to be fixedly connected to each other.
4. The Apparatus according to claim 3, wherein at least on half (330a, 330b) of the needle hub (330) comprises an indentation (340, 342) configured to receive the plate (304, 314; 324; 336, 338) at least partially.
5. The Apparatus according to any of claims 1 to 4, wherein the plate (304, 314; 324; 336, 338) is configured to orientate the needle (300; 310; 322; 332, 334) relative to the needle hub (320; 330).





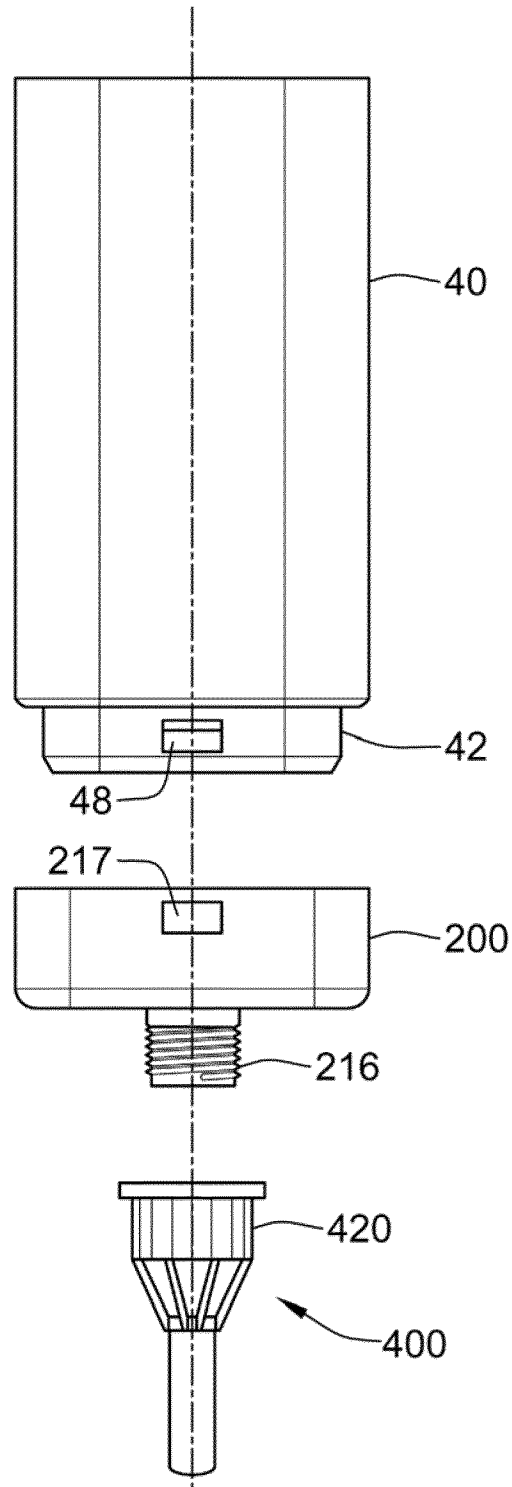


Fig.4

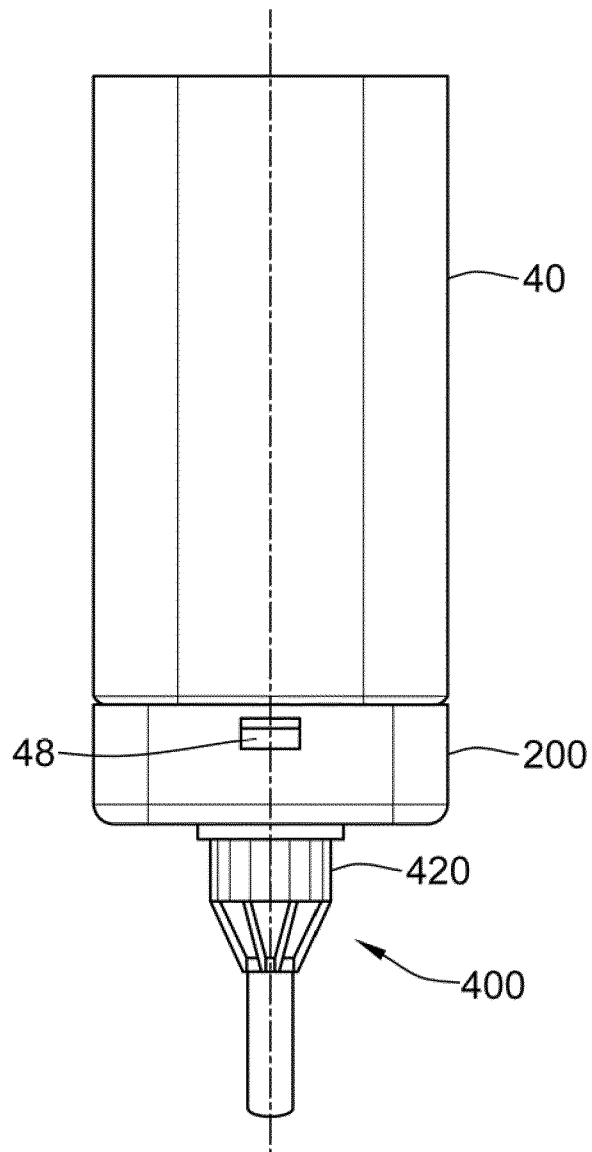


Fig.5

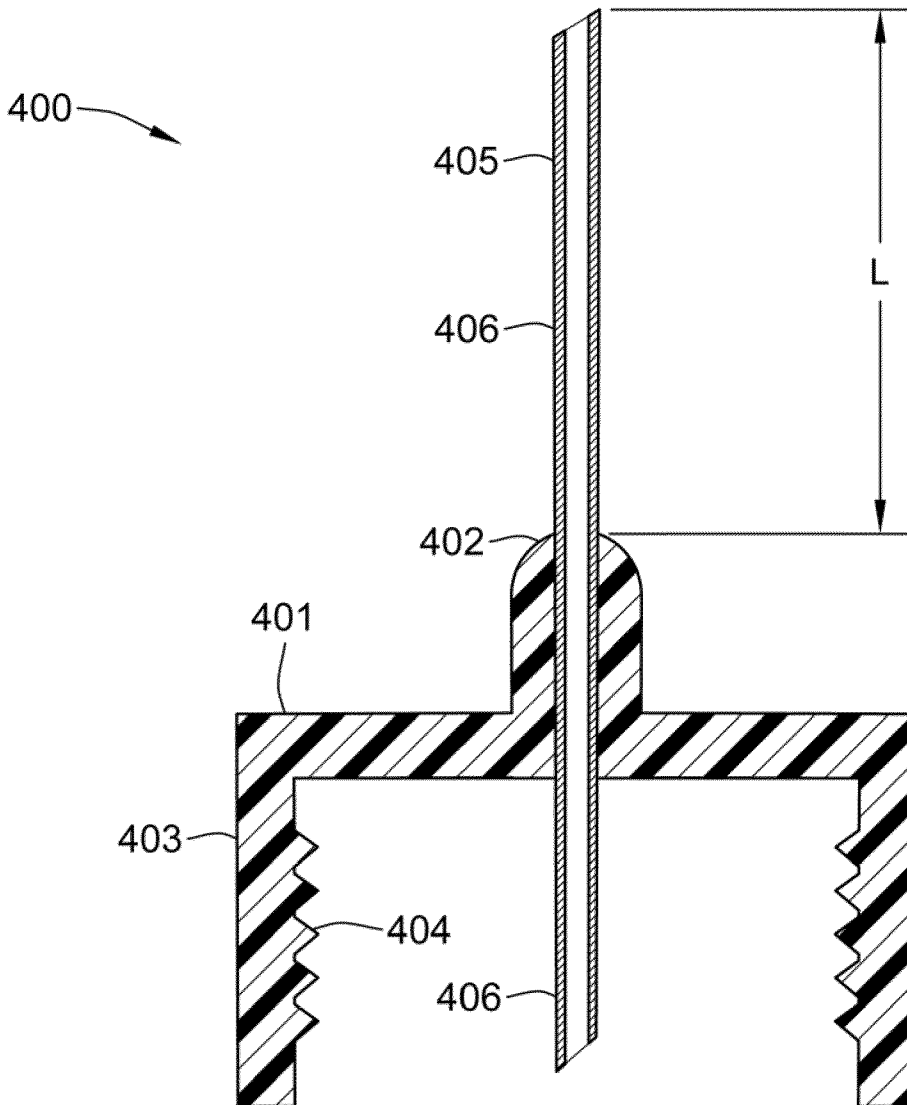


Fig.6

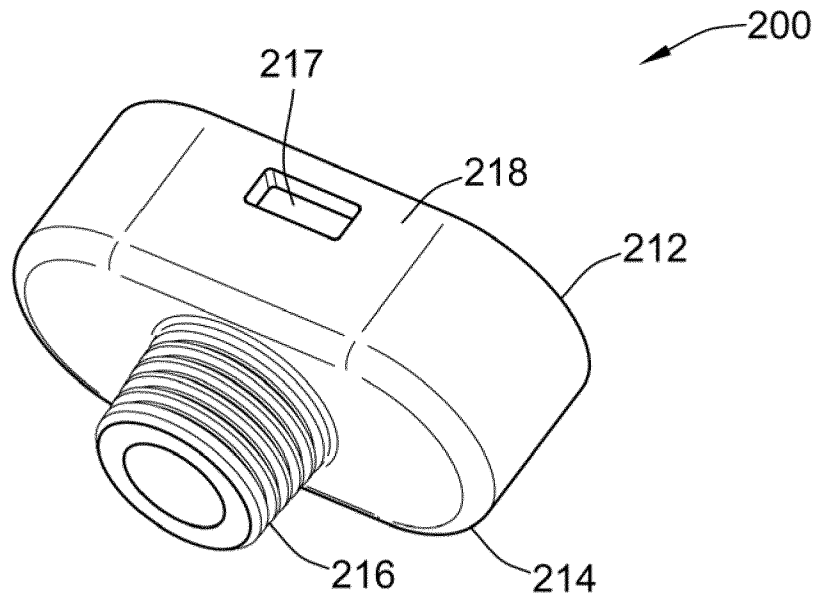


Fig.7

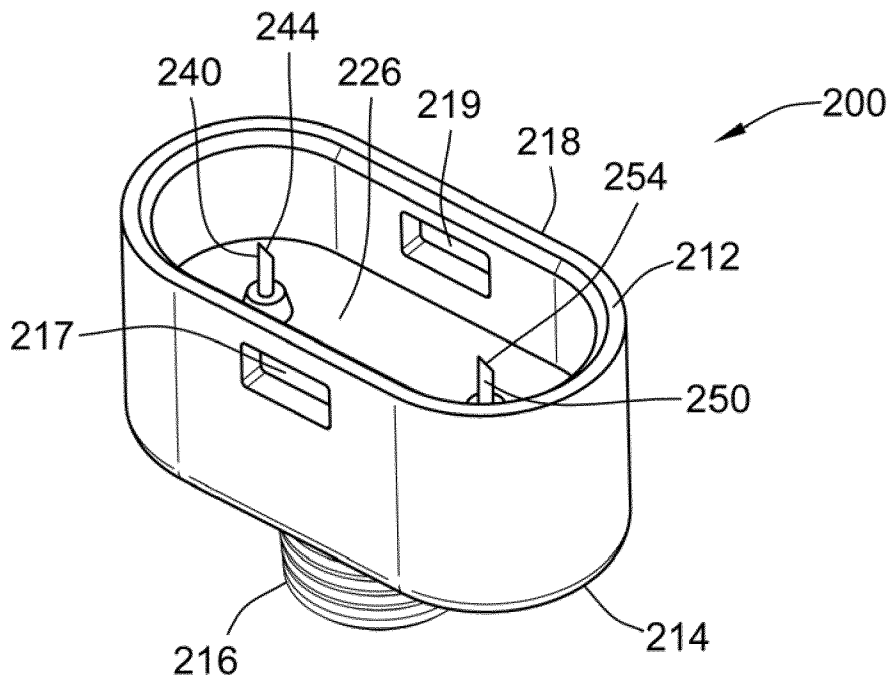


Fig.8

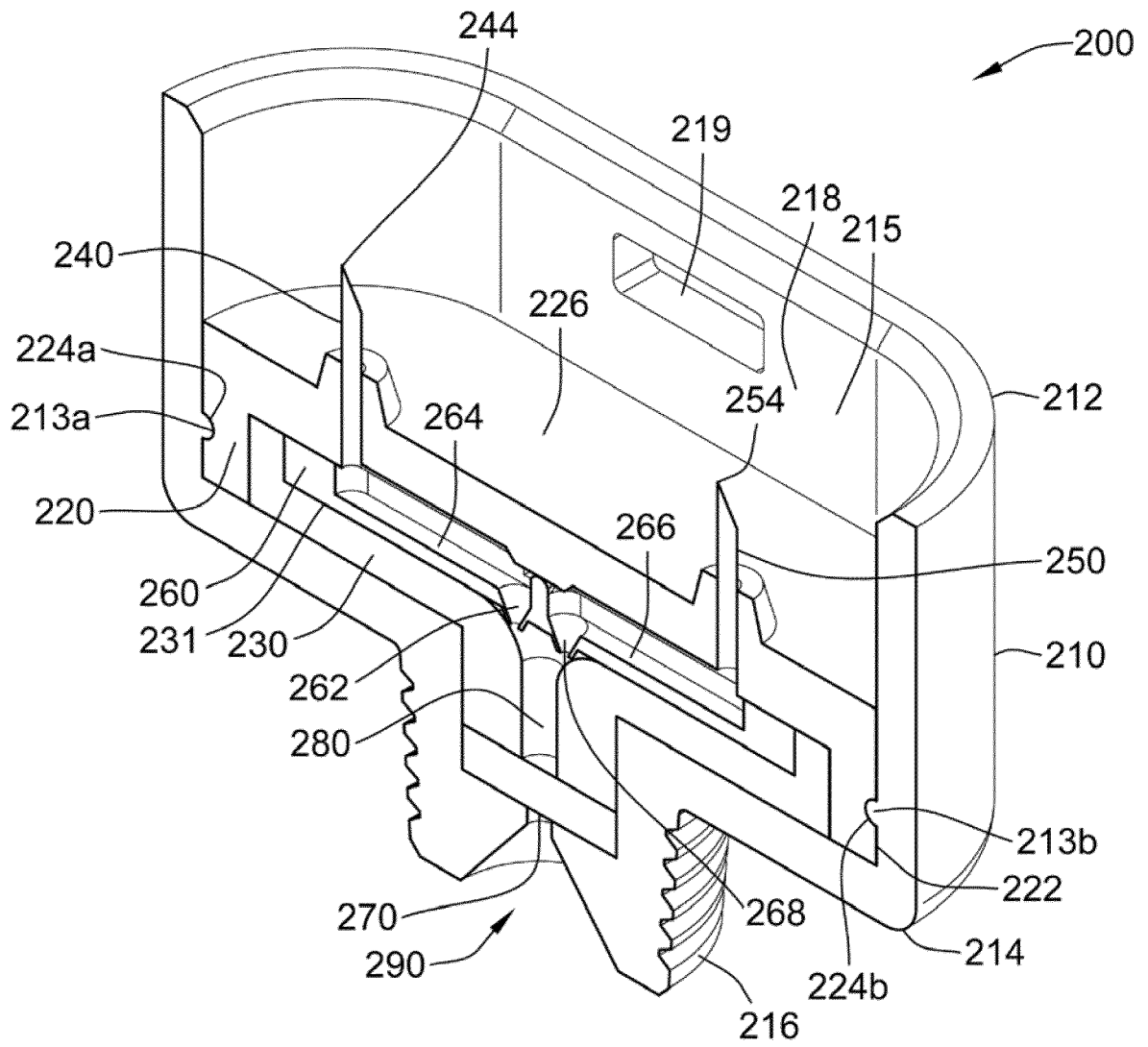


Fig.9

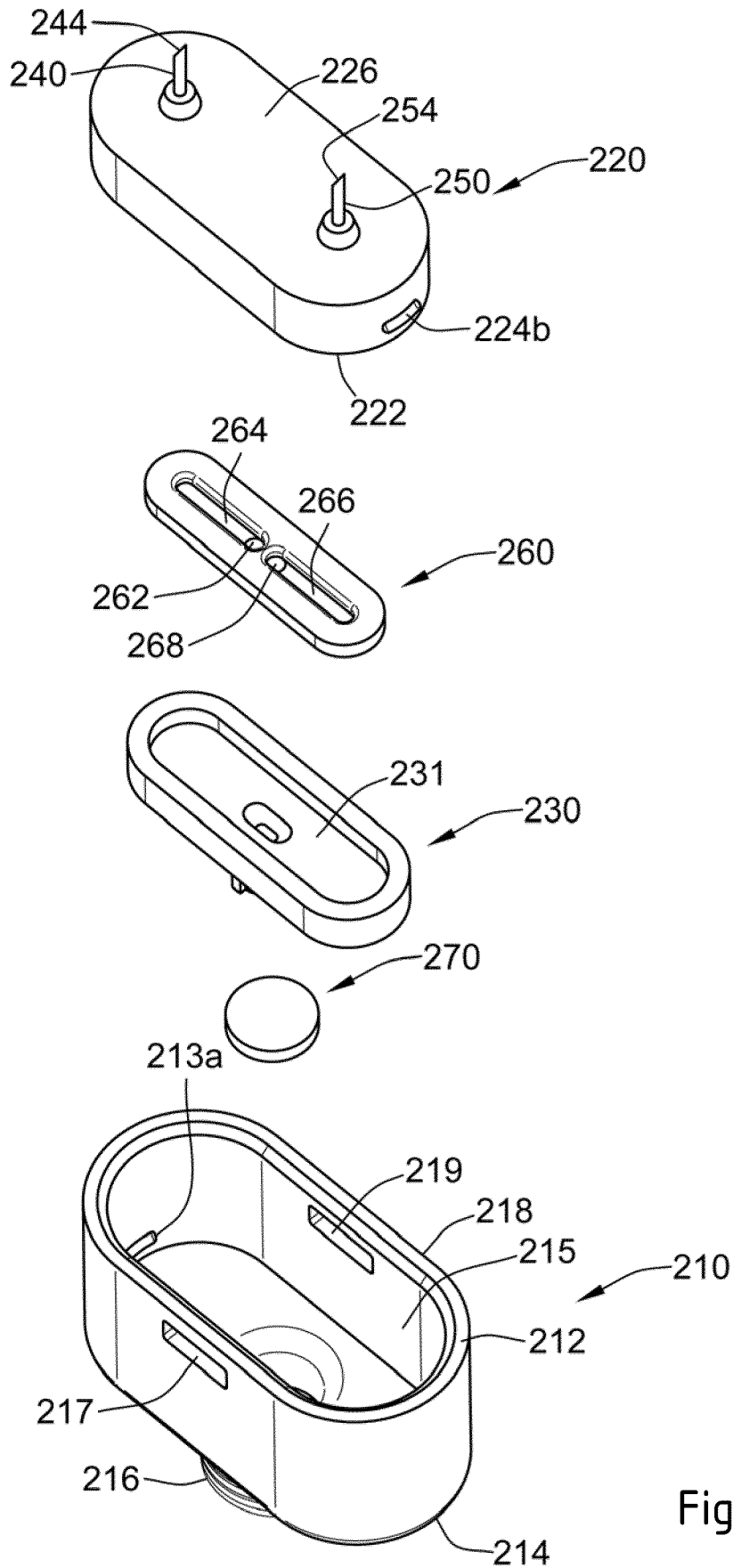


Fig.10

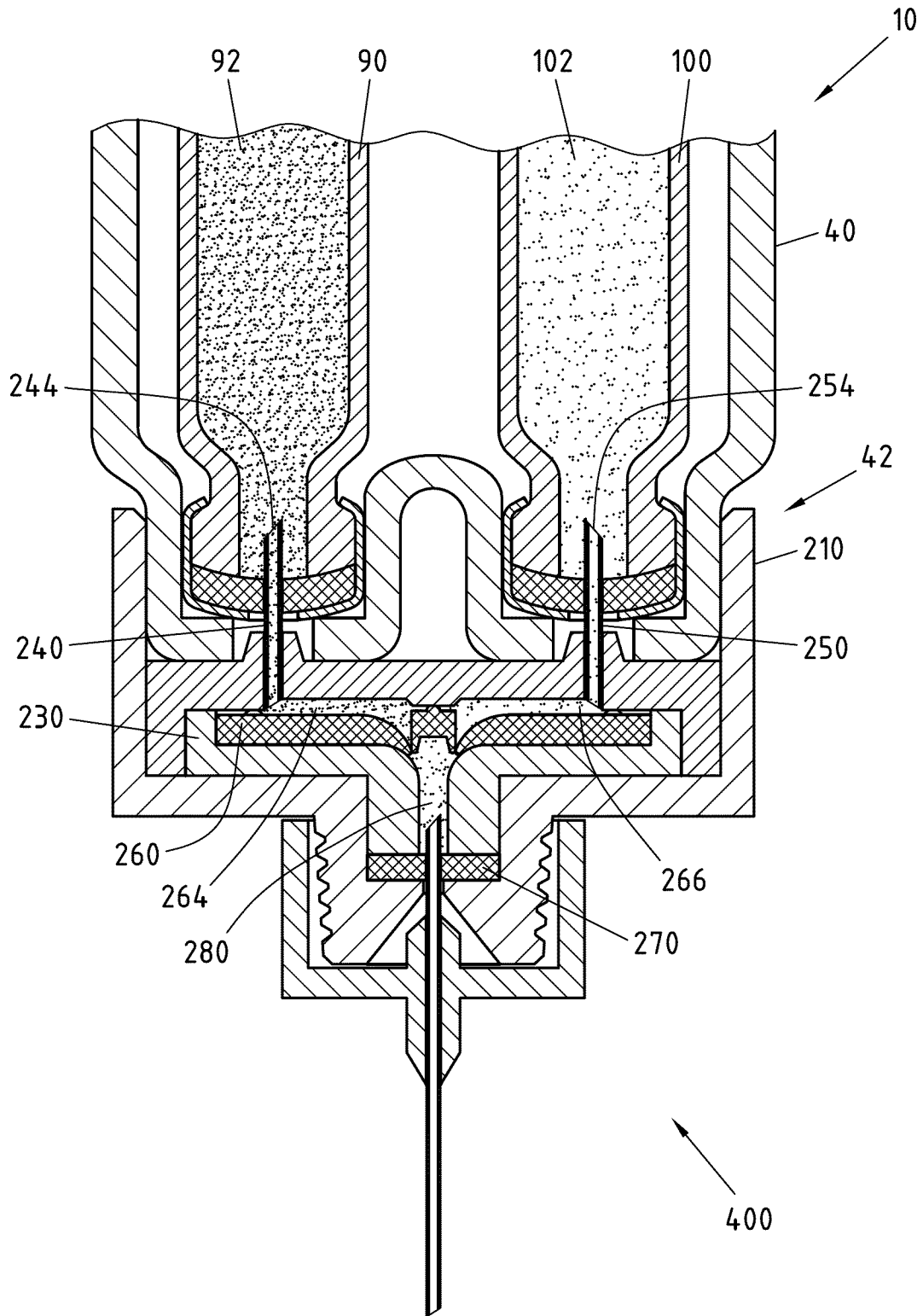


Fig.11

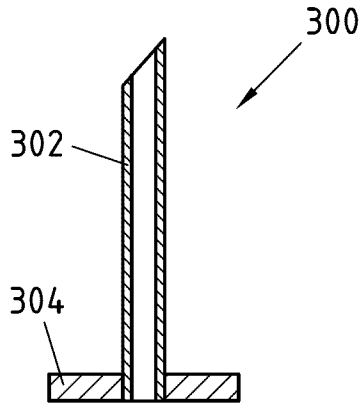


Fig.12

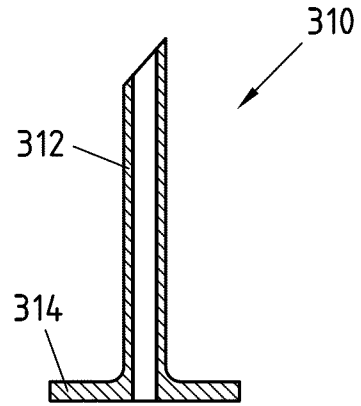


Fig.13

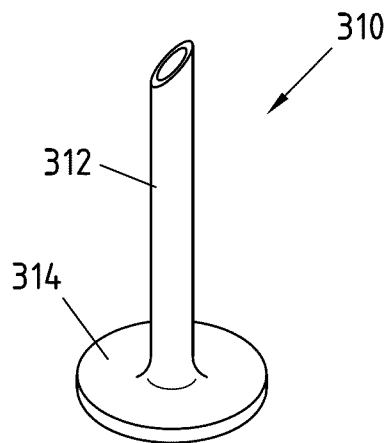


Fig.14

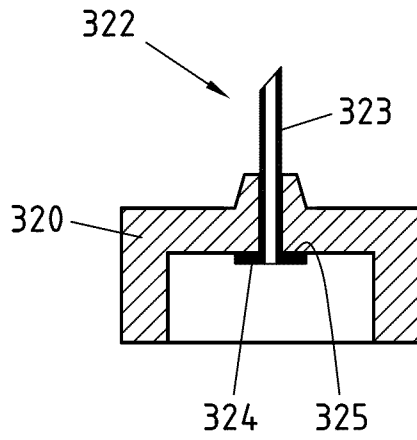


Fig.15

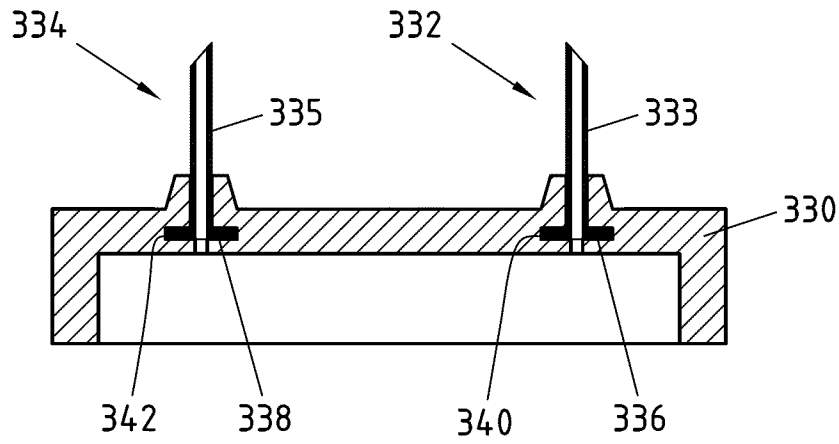


Fig.16

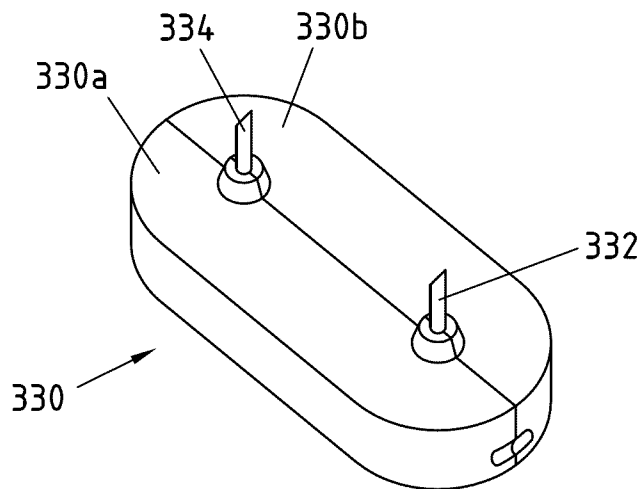


Fig.17

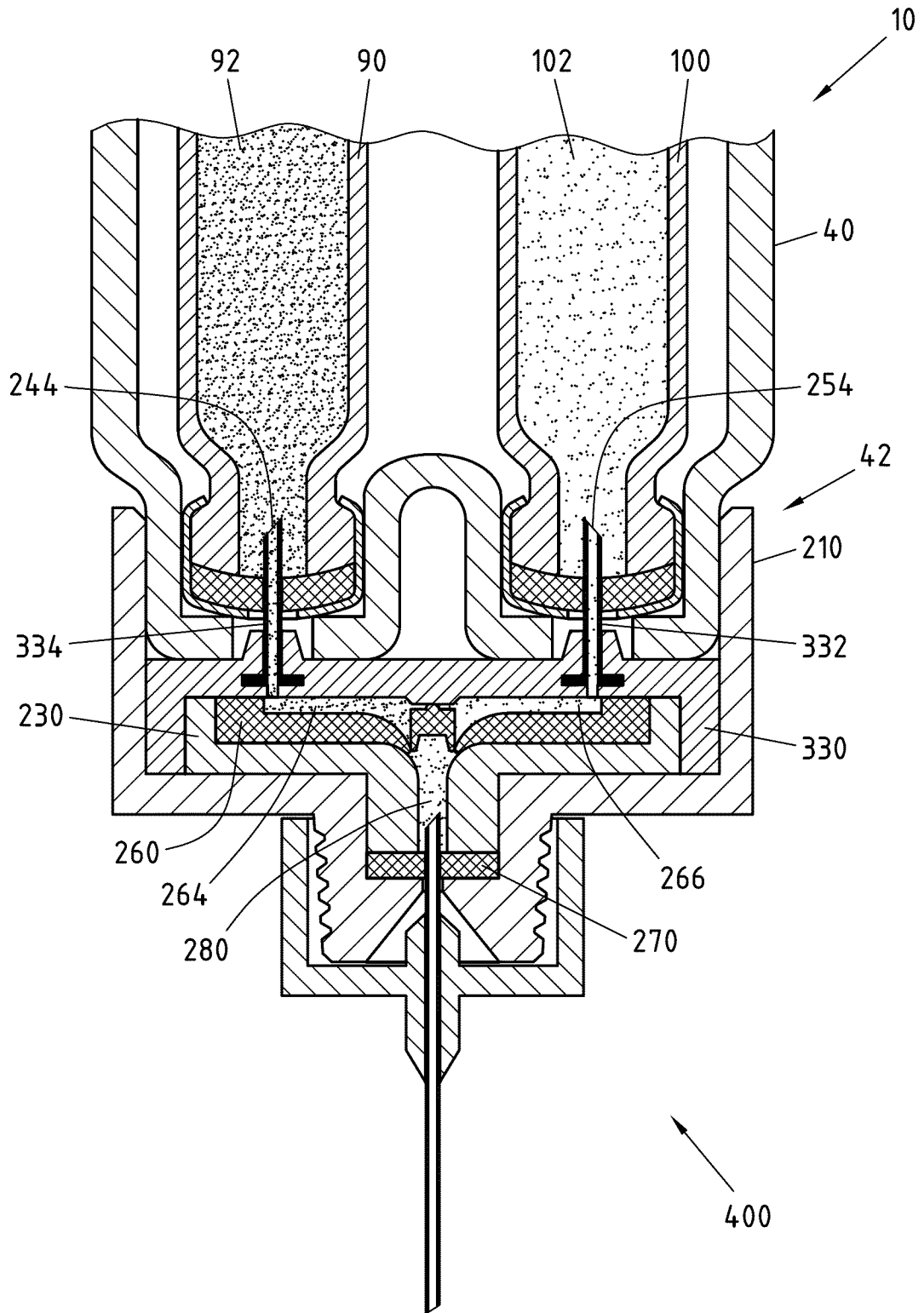


Fig.18

INTERNATIONAL SEARCH REPORT

International application No  
PCT/EP2012/058260

A. CLASSIFICATION OF SUBJECT MATTER  
INV. A61M5/19 A61M5/20  
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 practicable, search terms used)  
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 94/22507 A2 (LILLY CO ELI [US]) 13 October 1994 (1994-10-13) abstract page 12, lines 11-23 figure 15	1-5
X	WO 94/11039 A1 (HABLEY MEDICAL TECHNOLOGY CORP [US]; HABER TERRY M [US]; FOSTER CLARK) 26 May 1994 (1994-05-26) abstract figure 3	1-5
X	EP 0 615 762 A1 (LILLY CO ELI [US]) 21 September 1994 (1994-09-21) abstract figure 1	1-5
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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
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"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  26 June 2012	Date of mailing of the international search report  04/07/2012
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  Türkavci, Levent

# INTERNATIONAL SEARCH REPORT

International application No  
PCT/EP2012/058260

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 271 527 A (HABER TERRY M [US] ET AL) 21 December 1993 (1993-12-21) abstract claims figure 2  -----	1-5

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2012/058260

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9422507	A2	13-10-1994	AT 156370 T 15-08-1997
			AU 675534 B2 06-02-1997
			AU 6623694 A 24-10-1994
			BR 9406504 A 09-01-1996
			CA 2159464 A1 13-10-1994
			DE 69404831 D1 11-09-1997
			DK 692988 T3 02-03-1998
			EP 0692988 A1 24-01-1996
			ES 2105699 T3 16-10-1997
			FI 954658 A 29-09-1995
			JP 2826196 B2 18-11-1998
			JP H08503874 A 30-04-1996
			NO 953850 A 28-09-1995
			NZ 265470 A 24-03-1997
			US 5505704 A 09-04-1996
			WO 9422507 A2 13-10-1994
ZA 9401881 A 18-09-1995			
WO 9411039	A1	26-05-1994	EP 0670741 A1 13-09-1995
			US 5378233 A 03-01-1995
			WO 9411039 A1 26-05-1994
EP 0615762	A1	21-09-1994	AT 183932 T 15-09-1999
			AU 695904 B2 27-08-1998
			AU 5775894 A 22-09-1994
			BR 9401147 A 11-10-1994
			CA 2118569 A1 16-09-1994
			CN 1099301 A 01-03-1995
			CO 4180559 A1 07-06-1995
			CZ 9400512 A3 18-01-1995
			DE 69420297 D1 07-10-1999
			DE 69420297 T2 27-01-2000
			DK 0615762 T3 13-12-1999
			EP 0615762 A1 21-09-1994
			ES 2134901 T3 16-10-1999
			FI 941197 A 16-09-1994
			GR 3031599 T3 31-01-2000
			HU 215366 B 28-12-1998
			IL 108882 A 30-10-1998
			JP 3214973 B2 02-10-2001
			JP 6296691 A 25-10-1994
			NO 940830 A 16-09-1994
			NZ 260038 A 24-11-1997
			PH 30622 A 06-08-1997
			PL 174801 B1 30-09-1998
RU 2132704 C1 10-07-1999			
US 5383865 A 24-01-1995			
ZA 9401579 A 07-09-1995			
US 5271527	A	21-12-1993	AT 188130 T 15-01-2000
			CA 2138528 A1 17-02-1994
			DE 69327464 D1 03-02-2000
			DE 69327464 T2 13-07-2000
			EP 0652783 A1 17-05-1995
			ES 2139666 T3 16-02-2000
			JP H07509636 A 26-10-1995
			US 5271527 A 21-12-1993
			WO 9403222 A2 17-02-1994

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2012/058260

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
-----			