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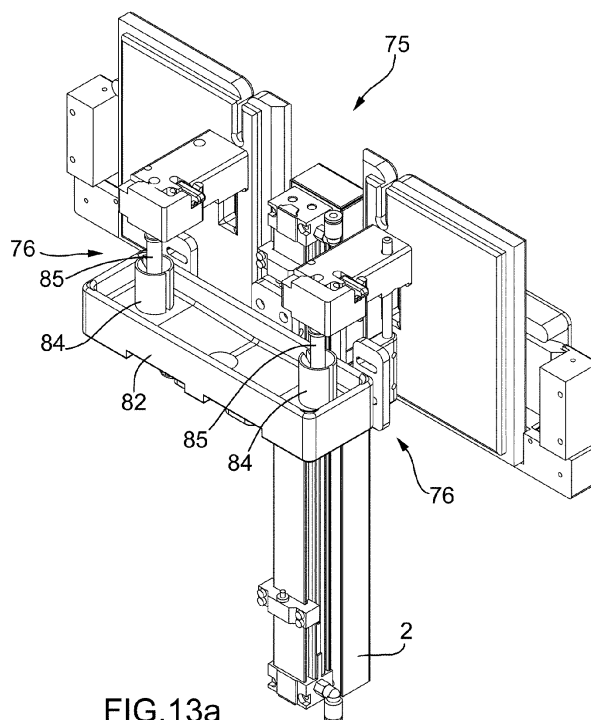
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(54) **Machine for the preparation of pharmaceutical products**

(57) A method for the preparation of pharmaceutical products according to which a diluent is fed into a container (7) containing a lyophilized or powder pharmaceu-

tical by means of a needle (78), which is then extracted from the container (7), inserted into its protective cap (85), and rinsed by feeding the diluent through the needle (78) and into the protective cap (85) itself.



**FIG.13a**

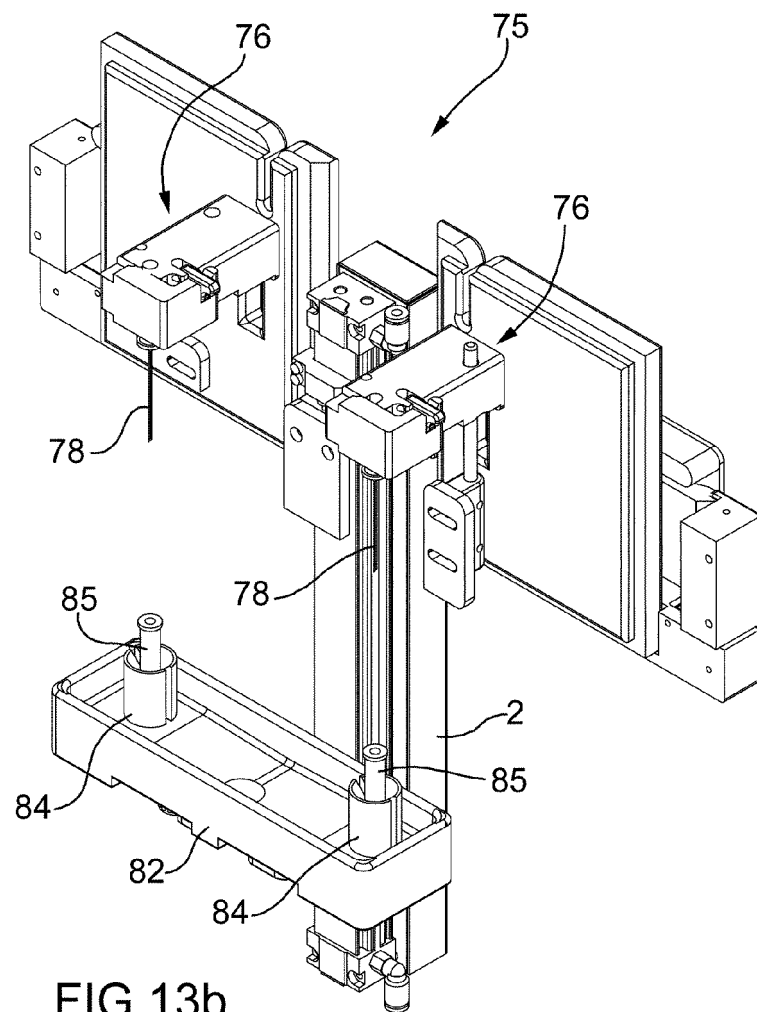


FIG.13b

## Description

**[0001]** The present invention relates to a method for the preparation of pharmaceutical products.

**[0002]** A machine is known in the pharmaceutical product preparation field, comprising a store for storing bottles containing a lyophilized or powder pharmaceutical; a dilution station of the lyophilized or powder pharmaceutical contained in the bottles; and a gripping and transporting device for transferring the bottles between the store and the dilution station.

**[0003]** The pharmaceutical is generally diluted by a diluent fed into the bottle by means of a needle inserted into the bottle itself.

**[0004]** Once the diluent has been fed into the bottle, the needle is firstly extracted from the bottle, then inserted into a diluent collection tank, and finally rinsed with the diluent to eliminate possible residues of the lyophilized or powder pharmaceutical from the needle itself.

**[0005]** The known machines of the above-described type for the preparation of pharmaceutical products have some drawbacks mainly deriving from that the collection tank needs to be rinsed and sterilized each time after the needle is rinsed in order to prevent any transfer of pharmaceutical from one bottle to the other.

**[0006]** It is an object of the present invention to provide a method for the preparation of pharmaceutical products which is free from the above-described drawbacks, and which is simple and cost-effective to be implemented.

**[0007]** According to the present invention, a method for the preparation of pharmaceutical products is provided as claimed in the appended claims.

**[0008]** The present invention will now be described with reference to the accompanying drawings, which show a non-limitative embodiment thereof, in which:

figure 1 is a diagrammatic perspective view, with parts removed for clarity, of a preferred embodiment of the machine according to the present invention;  
figure 2 is a diagrammatic perspective view, with parts removed for clarity, of a first detail of the machine in figure 1;

figure 3 is a diagrammatic perspective view, with parts removed for clarity, of a detail in figure 2;

figure 4 is a diagrammatic perspective view, with parts removed for clarity, of a second detail of the machine in figure 1;

figure 5 is a diagrammatic perspective view, with parts removed for clarity, of a third detail of the machine in figure 1;

figure 6 is a diagrammatic perspective view, with parts removed for clarity, of a detail in figure 5;

figure 7a is a diagrammatic perspective view, with parts removed for clarity, of a fourth detail of the machine in figure 1;

figure 7b is a perspective view of a detail in figure 7a;

figure 8 is a schematic perspective view, with parts enlarged and parts removed for clarity, of a fifth detail

of the machine in figure 1;

figure 9 is a diagrammatic front view, with parts removed for clarity, of the detail in figure 8;

figure 10 is a diagrammatic perspective view, with parts removed for clarity, of a sixth detail of the machine in figure 1;

figure 11 is a diagrammatic perspective view, with parts removed for clarity, of a seventh detail of the machine in figure 1;

figure 12 diagrammatically shows the operating principle of the detail in figure 11;

figure 13 is a diagrammatic perspective view, with parts removed for clarity, of an eighth detail of the system in figure 1 shown in two different operating positions;

figure 14 diagrammatically shows the operating principle of the detail in figure 13; and

figure 15 is a diagrammatic perspective view, with parts removed for clarity, of a ninth detail of the machine in figure 1.

**[0009]** With reference to figure 1, numeral 1 indicates as a whole a machine for the preparation of pharmaceutical products, comprising a box-like containment frame 2 having a substantially parallelepiped shape and defining an inner chamber 3, which is kept under substantially sterile conditions by a pneumatic device of known type, shaped so as to feed a flow of sterile air through chamber 3 and prevent the introduction of air from the external environment into chamber 3.

**[0010]** Chamber 3 accommodates a store 4 therein for storing syringes 5; a store 6 for storing bottles 7; an annular store 8 for storing infusion bags 9; and a robotized device 10 for gripping and transporting syringes 5 and/or bottles 7.

**[0011]** Each syringe 5 (figure 3) has a longitudinal axis 11, and comprises a cylinder 12 provided with an end flange 13 orthogonal to axis 11, a needle (not shown) coupled to cylinder 12, a closing cap 14 mounted to protect the needle (not shown) from possible contaminations, and a piston 15, which is slidably engaged in cylinder 12, and is provided with an end head 16 perpendicular to axis 11.

**[0012]** Each bag 9 is provided with an adapter member 17 of known type, which comprises two shaped jaws 18 movable between a clamping position and a releasing position of an upper edge of bag 9, and has a drawing pin 19 protruding upwards from one of the jaws 18 (figure 5).

**[0013]** As shown in figures 1, 3, and 4, device 10 is mounted within store 8, comprises a plurality of articulated arms 20 hinged to one another, and is provided with a gripping claw 21, which is mounted to the free end of the arms 20, and is defined by two jaws 22 movable between a clamping position and a releasing position of a syringe 5 or a bottle 7.

**[0014]** With reference to figure 2, each store 4, 6 comprises two reciprocally parallel belt conveyors 23, each

of which extends in a substantially vertical direction A, faces the other conveyor 23, and is looped about a pair of pulleys (not shown), which are coaxial with the pulleys (not shown) of the other conveyor 23, and are mounted so as to intermittently rotate about respective horizontal rotation axis 24 parallel to one another and transversal to direction A.

**[0015]** Each store 4, 6 further comprises a plurality of transport cradles 25, which extend between the conveyors 23, are coupled to the conveyors 23 to oscillate, with respect to conveyors 23, about respective horizontal fulcrum axes 26 parallel to one another and to axes 24, and which are uniformly distributed along the conveyors 23 themselves.

**[0016]** As shown in figure 3, each cradle 25 of store 4 (hereinafter indicated by numeral 25a) has a substantially V-shaped transversal section, is arranged with a longitudinal axis 27a thereof parallel to axes 24, 26, is provided with a first slot 28 adapted to receive the flange 13 of a syringe 5 to ensure the correct longitudinal positioning of syringe 5 into cradle 25a, and furthermore has a second slot 29 adapted to be engaged by the jaws 22 to allow device 10 to collect the syringe 5 from the cradle 25a itself.

**[0017]** With reference to figure 4, each cradle 25 of store 6 (hereinafter indicated by numeral 25b) has a substantially V-shaped transversal section, is arranged with a longitudinal axis thereof 27b inclined with respect to axis 24, 26, and is provided with a slot 30, which is obtained close to the lower end of cradle 25b, allows to correctly place a bottle 7 with its concavity facing downwards, and allows the jaws 22 to collect the bottle 7 itself.

**[0018]** As each store 4, 6 extends through a loading station obtained through frame 2 to allow the operator to load the syringes 5 or bottles 7 into the respective cradles 25a, 25b, and through a single collecting station, where the syringes 5 or bottles 7 are collected from the respective cradles 25a, 25b by means of device 10, the device 10 is relatively simple and cost-effective. Furthermore, the loading and unloading of syringes 5 and bottles 7 into, and respectively from, the corresponding cradles 25a, 25b does not require machine 1 to be stopped.

**[0019]** As shown in figures 5 and 6, store 8 comprises an star-like wheel 31 having an annular shape, which extends about the device 10, is mounted to rotate intermittently, with respect to frame 2 and under the bias of an actuating device (known and not shown), about a substantially vertical rotation axis 32, and has a plurality of pockets 33, which are obtained along a peripheral edge of wheel 31, are open radially outwards and are each adapted to receive and hold a respective infusion bag 9.

**[0020]** The pockets 33 are fed by wheel 31 about axis 32 and along a circular path P extending through a loading and unloading station 34 of the bags 8 into, and respectively from, store 8, a weighing station 35 of bags 9, and a dosing station 36 for injecting a predetermined amount of pharmaceutical product into the bags 9 themselves.

**[0021]** Each station 34, 35, 36 is provided with a linear transfer device 37 comprising a rectilinear guide 38 parallel to a horizontal direction 39 transversal to axis 32, a slide 40 slidably coupled to the guide 38 to perform rectilinear movements along guide 38 in direction 39, and a gripping fork 41 slidably coupled to slide 40 to move, with respect to the slide 40 and transversally to direction 39, between a coupling position and a releasing position of the pin 19 of a corresponding adapter member 17.

**[0022]** Device 37 of station 34 cooperates with a guide 42, which is parallel to the corresponding guide 38, is radially aligned with pocket 33 arranged each time in the station 34 to be slidably engaged by the member 17 of a respective bag 9, and extends between store 8 and an opening 43 obtained through frame 2 to allow an operator to load the bags 9 on the guide 42 and to collect the bags 9 from the guide 42 itself.

**[0023]** With reference to figures 7a and 7b, the device 37 of station 35 cooperates with a weighing device 44 comprising a movable supporting member 45, which is coupled in a known manner to a fixed part of the device 44 to vertically move under the weight of the bags 9, is fork-shaped, and defines a guide 46 radially aligned with the pocket 33 arranged each time in station 35 to be slidably engaged by the member 17 of a corresponding bag 9.

**[0024]** The device 37 of station 36 cooperates with a guide (not shown), which is parallel to the corresponding guide 38, is radially aligned with the pocket 33 arranged each time in station 36 to be slidably engaged by the member 17 of a corresponding bag 9, and is adapted to stop the bag 9 itself underneath a syringe 5, which is transferred from device 10 between store 4 and a gripping and actuating assembly 47 of the syringe 5 itself.

**[0025]** As shown in figures 8 and 9, assembly 47 comprises a supporting block 48, which is mounted to rotate about a horizontal rotation axis 49 transversal to axis 32, and supports a gripping device 50 of cylinder 12 and a gripping device 51 of piston 15.

**[0026]** Device 50 comprises two claws 52, which are aligned to each other in a direction 53, the orientation of which depends on the position of the block 48 about axis 49, and each comprise two respective jaws 54, which are slidably coupled to the block 48 in order to move, with respect to the block 48 itself, transversally to direction 53, and are normally kept in a clamping position of the cylinder 12 by respective springs 55 interposed between block 48 and jaws 54, and loaded so as to allow the axial movement of syringe 5 through the claws 52.

**[0027]** Device 50 further comprises an intermediate claw 56, which extends between the claws 52, and comprises, in turn, two jaws 57 slidably coupled to the block 48 in order to move with respect to block 48 and under the bias of an actuating device (known and not shown), transversally to direction 53 between a clamping position and a releasing position of the cylinder 12 of a syringe 5.

**[0028]** With regards to the above description, it is worth noting that the jaws 57 are shaped so as to allow one of

the jaws 57 to be inserted into the other jaw 57 and also to clamp syringes 5 of relatively small diameter.

**[0029]** Device 51 comprises two jaws 58, which are slidably coupled to the block 48 in order to move with respect to block 48 and under the bias of an actuating device (known and not shown), transversally to direction 53 between a clamping position and a releasing position of the head 16 of a syringe 5, and are further slidably coupled to block 48 in order to perform rectilinear movements in direction 53 itself with respect to block 48 and under the bias of an actuating device (known and not shown). Each jaw 58 has a plurality of grooves 59 (two grooves 59, in this case) reciprocally overlapping in direction 53 to allow device 51 to receive and hold the heads 16 of syringes 5 of different size.

**[0030]** The operation of assembly 47 will now be described starting from when jaws 57 and jaws 58 are arranged in their releasing positions, and syringe 5 is inserted by means of the device 10 into the jaws 54 against the bias of the springs 55.

**[0031]** Once syringe 5 has been inserted into claws 52, the jaws 58 are firstly closed over head 16 and then lowered in direction 53 so as to move the syringe 5 through the claws 52, arrange the flange 13 in contact with the upper claw 52 and, possibly, push piston 15 fully into cylinder 12.

**[0032]** The above-described operating sequence allows to correctly place syringe 5 in direction 53 while ensuring a correct, constant positioning of all syringe 5 regardless of the size thereof, of the initial position of pistons 15 along the corresponding cylinders 12, and of the initial axial, angular positions of syringes 5 within the claws 52.

**[0033]** Finally, the jaws 57 are moved to their clamping position of syringe 5 within assembly 47, and the jaws 58 are moved to their clamping position of head 16 to control the movement of piston 15 during the steps of aspirating and injecting the pharmaceutical.

**[0034]** With reference to figure 10, machine 1 further comprises a mixer device 60 for mixing together a lyophilized or powder pharmaceutical and a diluent contained in a bottle 7.

**[0035]** Device 60 comprises a rotating plate 61, which is mounted to alternatively rotate about a substantially horizontal rotation axis 62, and is provided with a pair of jaws 63 coupled in a known manner to plate 61 in order to move, with respect to plate 61, transversally to axis 62, between a clamping position and a releasing position of a bottle 7. Each jaw 63 is shaped so as to have, in this case, a pair of seats 64, which cooperate with the corresponding seats 64 of the other jaw 63 to allow the jaws 63 to hold bottles 7 of different size.

**[0036]** As shown in figures 11 and 12, path P further extends through a collecting station 65 of a predetermined amount of liquid from bags 9. The liquid of bag 9 is necessarily collected when the overall weight of pharmaceutical and diluent contained in bag 9 once the pharmaceutical has been injected needs to be equal to a de-

termined value lower than the weight of the sole diluent first contained in bag 9.

**[0037]** Station 65 has an aspiration assembly 66 comprising a gripping device 67 adapted to receive and hold an extraction needle 68, which is connected to a hydraulic aspiration circuit 69, is transferred by device 10 into device 67 once it has been separated from a protective cap thereof (known and not shown), and is moved by device 67 in direction A between a raised resting position, in which needle 68 is arranged outside bag 9, and a lowered operating position, in which needle 68 protrudes within bag 9 over the diluent contained in the bag 9 itself.

**[0038]** Circuit 69 comprises an extraction pump 70, in this case a peristaltic pump, having an inlet hydraulically connected to needle 68 by means of a first pipe 71, and an outlet hydraulically connected to a collection reservoir 72 of the diluent collected from bags 9 by means of a second pipe 73.

**[0039]** As bags 9 contain a given amount of air therein, pipe 71 is provided with a flow sensor 74, a capacitance sensor in this case, which allows to discriminate between the passage of air and of liquid along pipe 71, and thus correctly calculate the volume of liquid aspirated from the bags 9 by means of pump 70. In other words, the volume of liquid aspirated from the bags 9 is calculated only starting from when sensor 74 detects the passage of liquid along pipe 71.

**[0040]** With reference to figures 13 and 14, machine 1 further comprises a feeding device 75 to feed a diluent into a bottle 7 containing a lyophilized or powder pharmaceutical.

**[0041]** Here, device 75 comprises two feeding assemblies 76, each of which comprises, in turn, a feeding reservoir 77 (e.g. a bag 9) for the diluent; a feeding needle 78 coupled to frame 2 and hydraulically connected to reservoir 77 by means of a pipe 79; and a pumping device defined, in this case, by a syringe 80, which is connected to an intermediate point of pipe 79, and is actuated in a known manner to aspirate a predetermined amount of diluent from reservoir 77 and to feed the diluent itself into bottle 7.

**[0042]** The connection between pipe 79 and syringe 80 divides pipe 79 into two segments 79a, 79b, which are arranged in sequence and in the order between reservoir 77 and needle 78, and which are provided with respective check valves 81a, 81b, valve 81a of which avoids the flow back of diluent into segment 79a when diluent is fed to needle 78, and valve 81b avoids the flow back of the diluent from segment 79b when the diluent is aspirated from reservoir 77.

**[0043]** Device 75 further comprises a collection tank 82, which extends underneath the needles 78, is coupled in a known manner to frame 2 in order to move with respect to the frame 2, in direction A between a lowered resting position (figure 13b) and a raised operating position (figure 13a), and is hydraulically connected to a collection manifold 83 of the diluent. Moreover, the tank 82 has a pair of tubes 84, each of which protrudes upwards

from a bottom wall of tank 82, and is substantially coaxial to the corresponding needle 78.

**[0044]** In use, tank 82 is moved to its lowered position to allow the robotized device 10 to feed, to each assembly 76, a corresponding needle 78 closed by a protective cap 85 fixed to the needle 78 itself.

**[0045]** Once needle 78 has been coupled to frame 2, device 10 is lowered and/or turned to separate the cap 85 from the needle 78 and to release the cap 85 itself within the corresponding tube 84, with its concavity facing upwards.

**[0046]** At this point, the tank 82 is kept in its lowered position to allow two bottles 7 to be inserted underneath the needles 78 and the diluent to be fed into the bottles 7 themselves.

**[0047]** When the needles are extracted from the corresponding bottles 7, they may have residues of the lyophilized or powder pharmaceutical contained in the bottles 7 themselves, and at the end of each injection operating cycle of the feeding device 75, the tank 82 is moved to its raised operating position so as to fit the caps 85 on the corresponding needles 78, and the syringes 80 are actuated to allow needles 78 to be washed with the diluent contained in the reservoirs 77.

**[0048]** Firstly, the diluent fed through the needles 78 flows into the corresponding caps 85 and then into tank 82 and manifold 83. With this regard, it is worth noting that:

the amount of diluent used to wash the needles 78 also allows the caps 85 to be washed; like needles 78, caps 85 are initially sterile and therefore may be used to wash the corresponding needles 78 at the end of each programmed injection operating cycle in a working session of machine 1; and the conclusion of the working session of machine 1 requires only the replacement of the needles 78 and the corresponding respective caps 85, and does not require the sterilization of tank 82.

**[0049]** As shown in figure 15, machine 1 is further provided with a collection device 86 of the processing waste (e.g. syringes 5, bottle 7, needles 78, and caps 85) accommodated within frame 2 underneath store 8, and comprising, in this case, two collection containers 87, one of which (hereinafter indicated by numeral 87a) communicates with chamber 3 by means of a pair of chutes 88, while the other (hereinafter indicated by numeral 87b) communicates with chamber 3 by means of one chute only 89.

**[0050]** In use, the various processing waste is selectively fed by device 10 to the various chutes 88, 89 and, therefore, to the various containers 87a, 87b, thus allowing to separate the processing waste.

**[0051]** The operation of machine 1 is easily inferred from the above description and no further explanations are required.

## Claims

1. A method for the preparation of pharmaceutical products comprising the steps of:

feeding a container (7) containing a lyophilized or powdered pharmaceutical to a dilution station (75);  
feeding a needle (78) closed by a protective cap (85) fixed to the needle (78) itself to the dilution station (75);  
locking the needle (78) closed by its protective cap (85) in the dilution station (75);  
separating the protective cap (85) from the needle (78);  
inserting the needle (78) into the container (7);  
feeding a diluent into the container (7) by means of the needle (78); and  
extracting the needle (78) from the container (7); and **characterized in that** it further comprises the steps of:

inserting the needle (78) into its protective cap (85) once it has been extracted from the container (7); and  
feeding the diluent through the needle (78) and into the protective cap (85) to rinse the needle (78) itself.

2. A method according to claim 1, wherein:

the needle (78) closed by its protective cap (85) is fed to the dilution station (75) by means of a robotized gripping and transporting device (10); and  
the protective cap (85) is separated from the needle (78) by means of the robotized device (10) itself.

3. A method according to claim 1 or 2 and further comprising the steps of:

releasing the needle (78) from the dilution station (75); and  
removing the assembly defined by the needle (78) and its protective cap (85) from the dilution station (75).

4. A method according to claim 3, wherein the assembly defined by the needle (78) and its protective cap (85) is removed from the dilution station (75) by means of a robotized gripping and transporting device (10).

5. Method according to any one of the preceding claims, and further comprising the step of:

inserting the protective cap (85), once it has

been separated from the needle (78), into a collection tank (82) of the diluent fed through the needle (78) itself.

6. A method according to claim 5 and further comprising the step of: 5

discharging the diluent from the collection tank (82) into a collection manifold (83). 10

7. A method according to claim 6 and further comprising the steps of:

lowering the collection tank (82) to disengage the needle (78) from the protective cap (85); and 15  
lifting the collection tank (82) to engage the needle (78) in the protective cap (85).

8. A method according to any one of the preceding claims, and further comprising the steps of: 20

aspirating the diluent from a containment reservoir (77) by means of a syringe (80); and 25  
feeding the diluent to the needle (78) by means of the syringe (80) itself.

9. A method according to any one of the preceding claims, and further comprising the step of:

rinsing the needle (70) with an amount of diluent 30  
sufficient to also rinse the protective cap (85).

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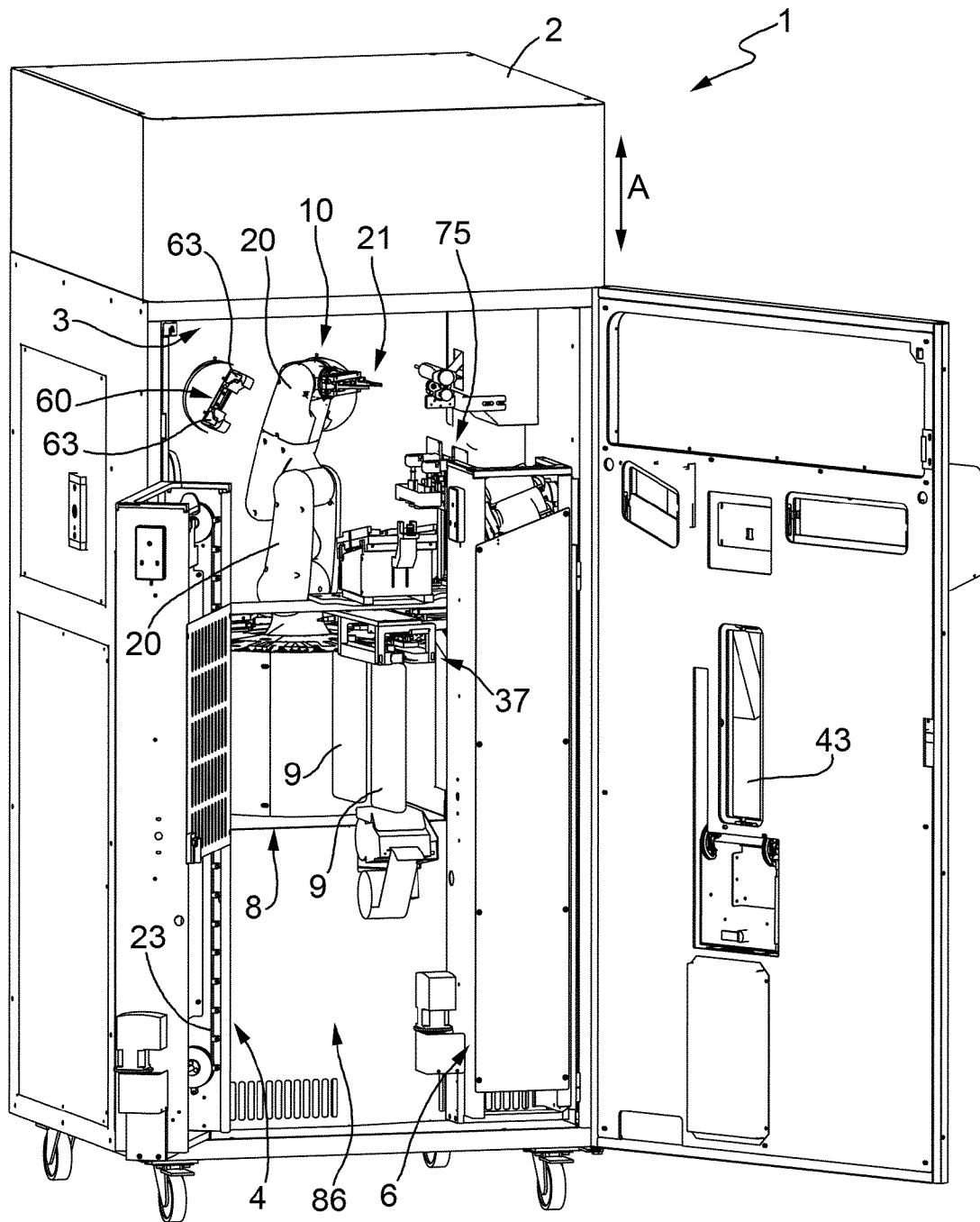


FIG.1

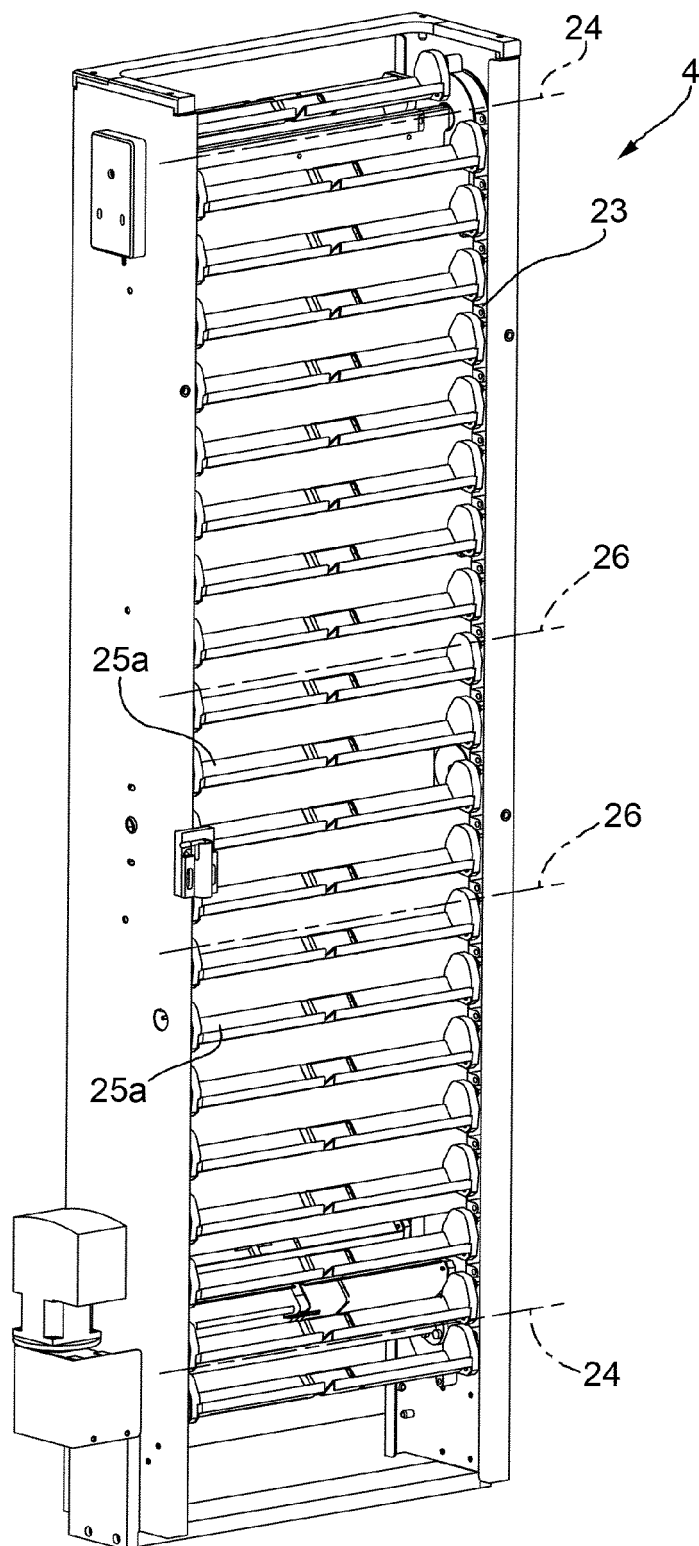
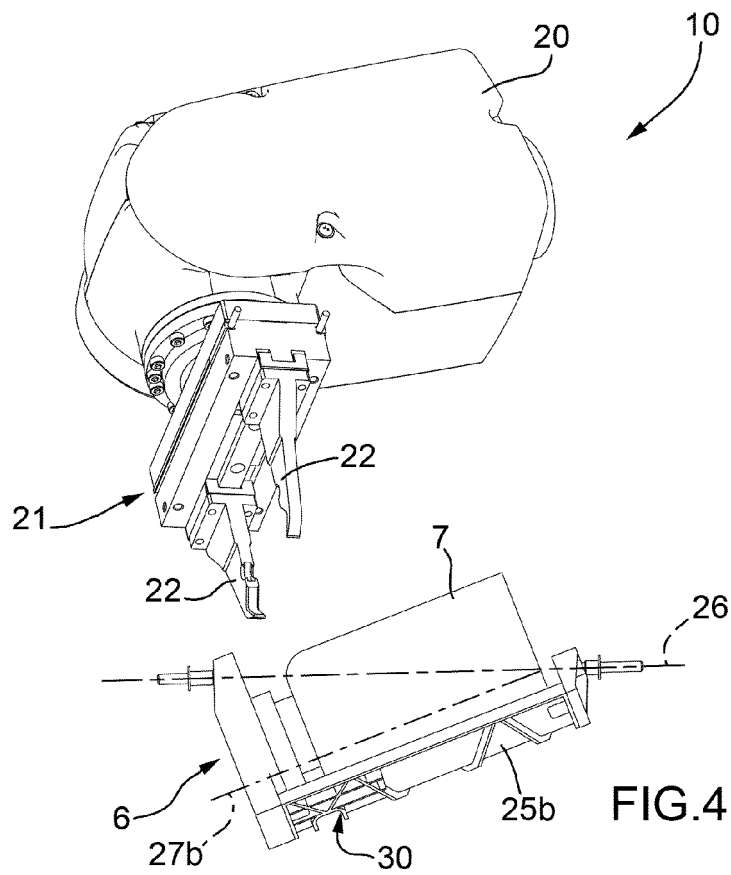
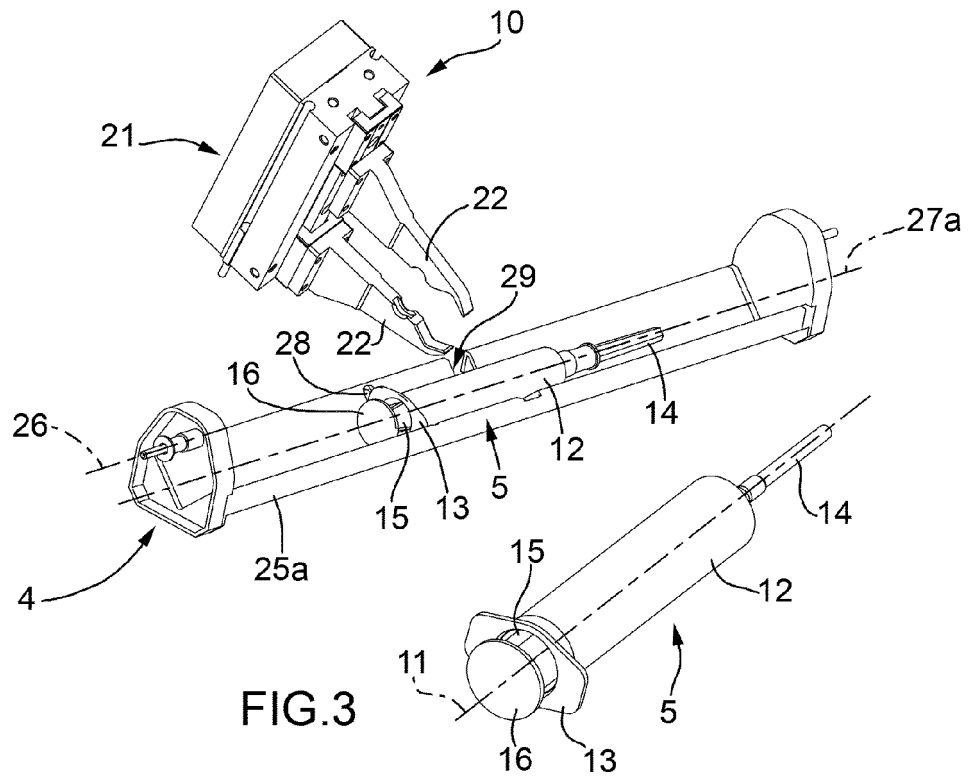


FIG.2



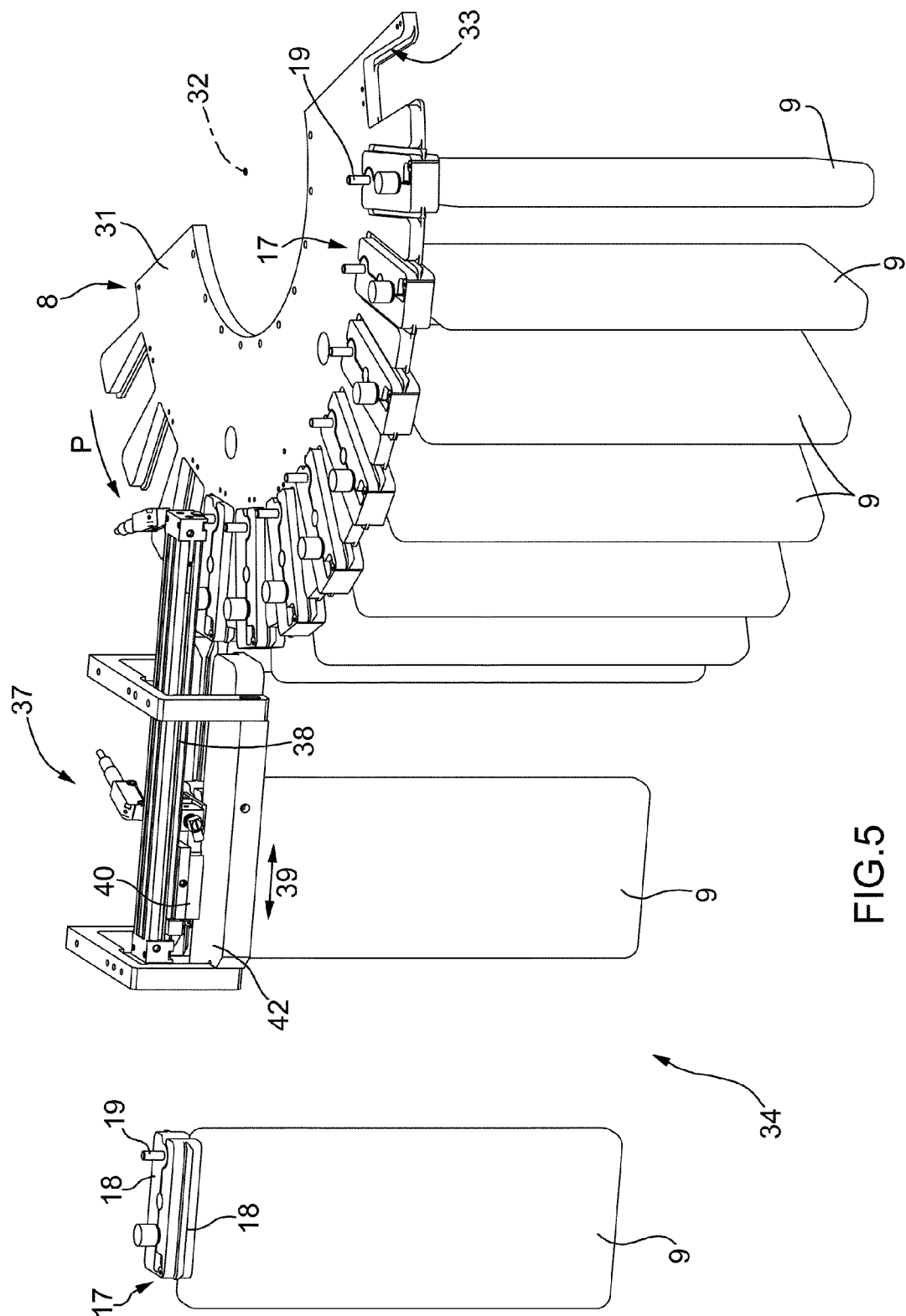


FIG. 5

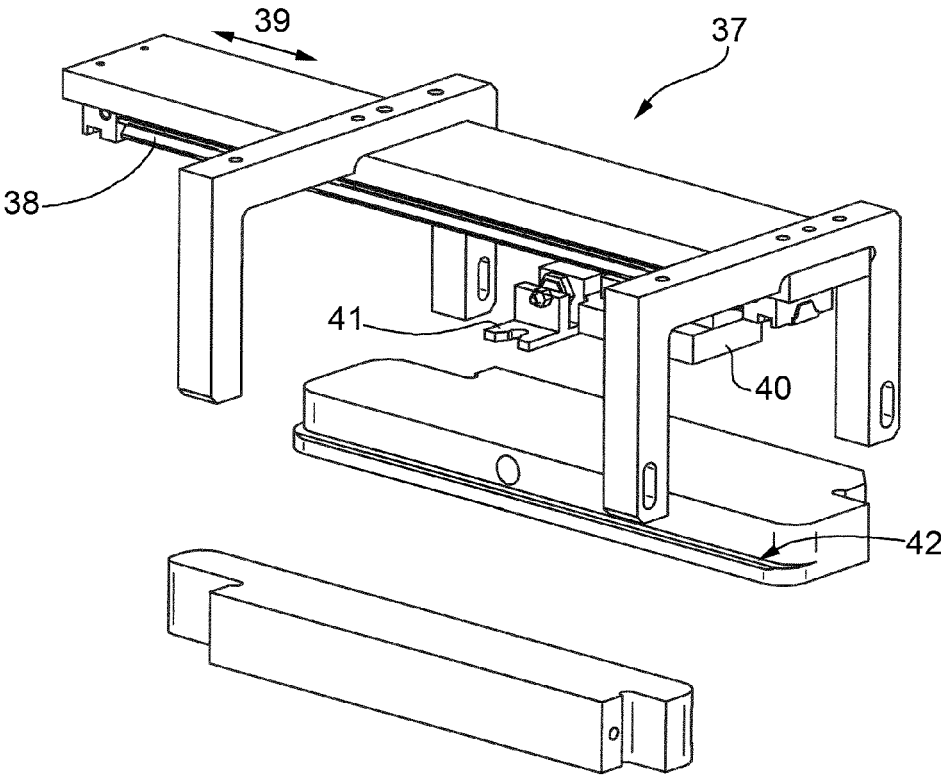
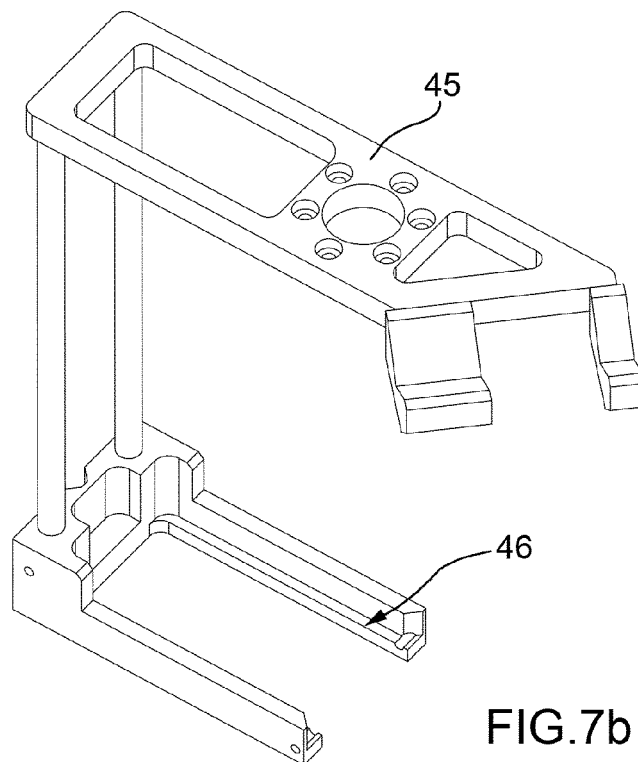
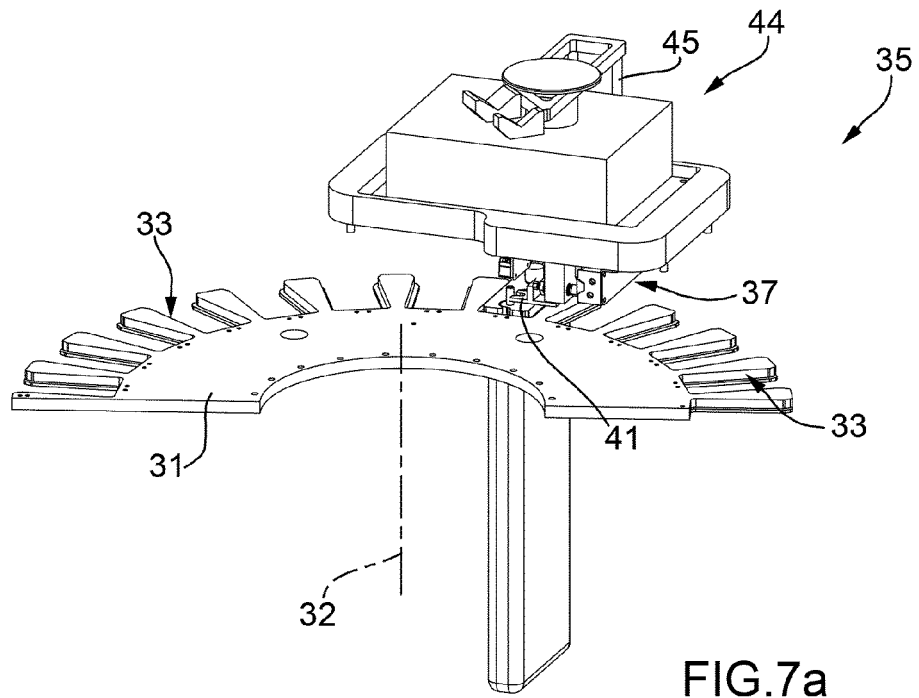


FIG.6



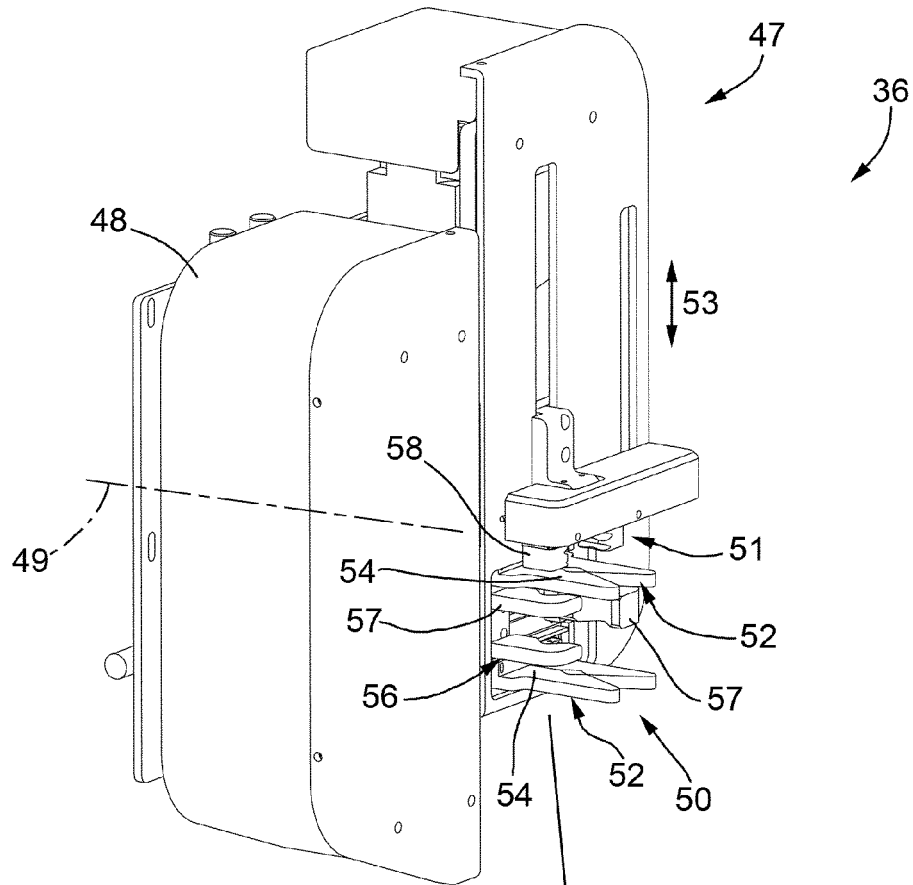
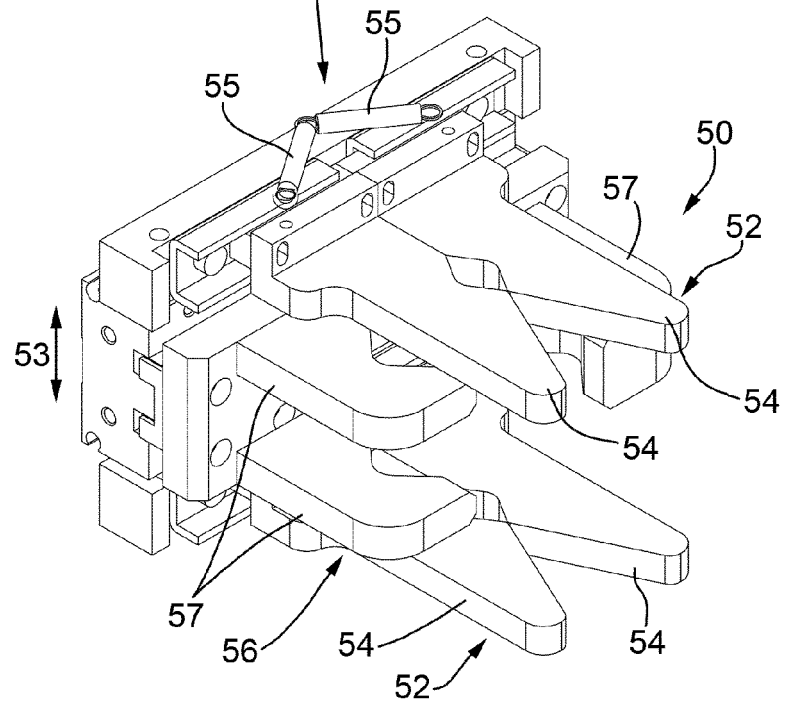
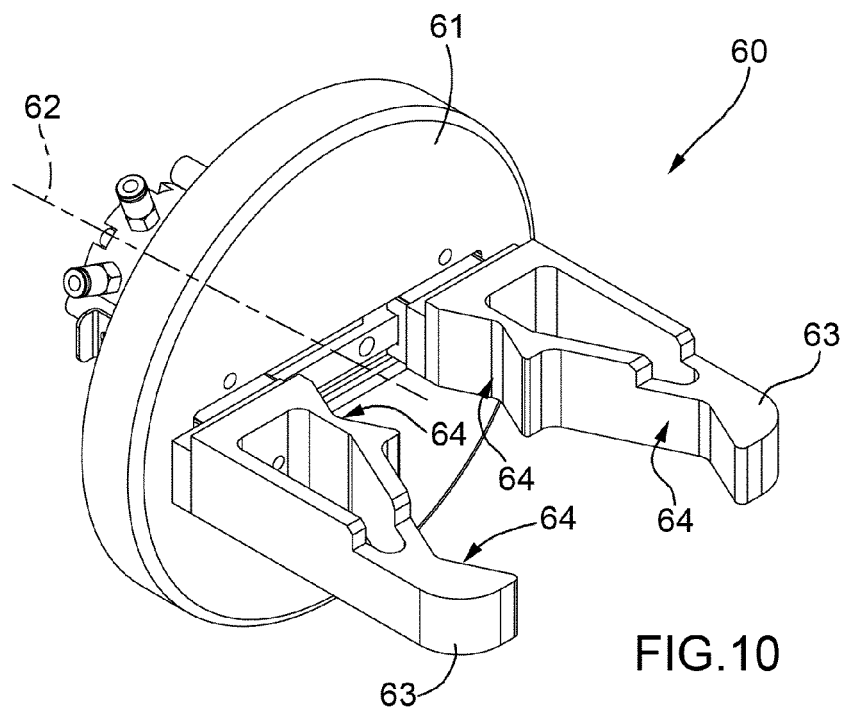
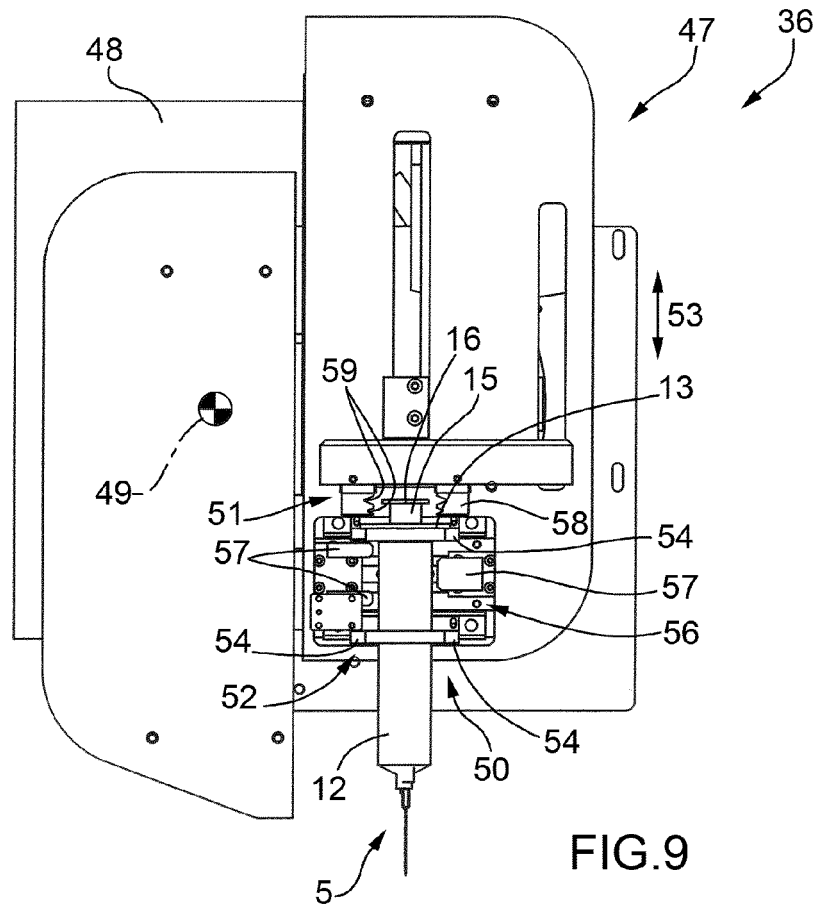


FIG.8





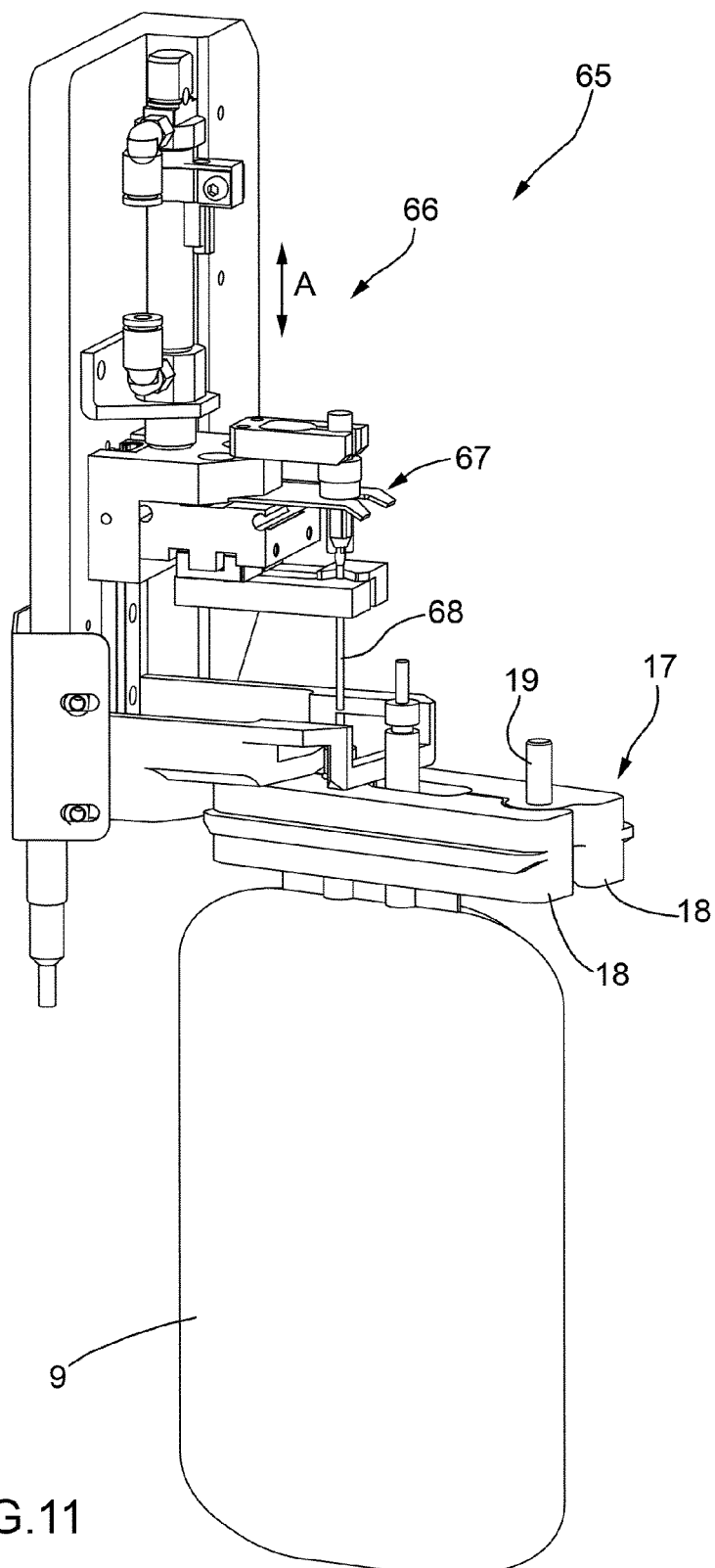


FIG.11

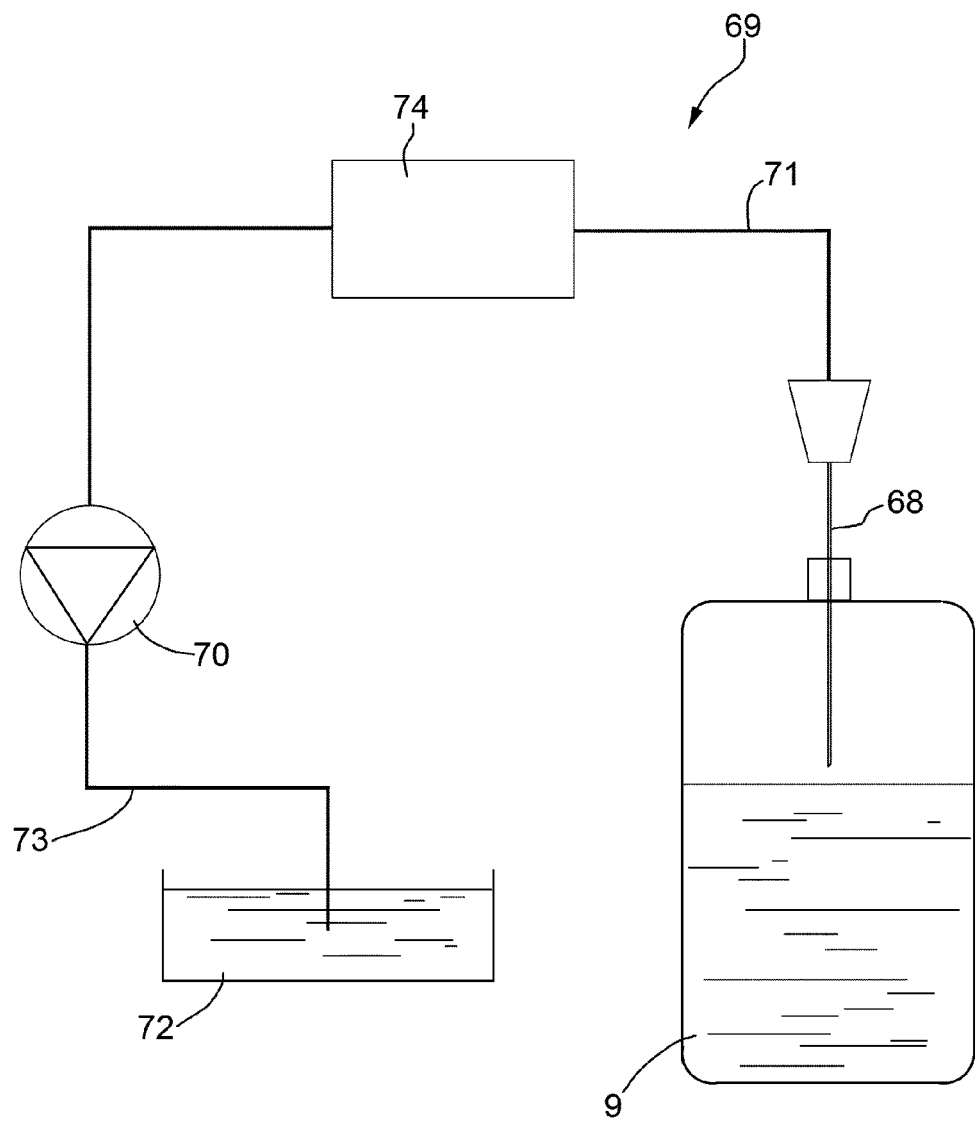


FIG.12

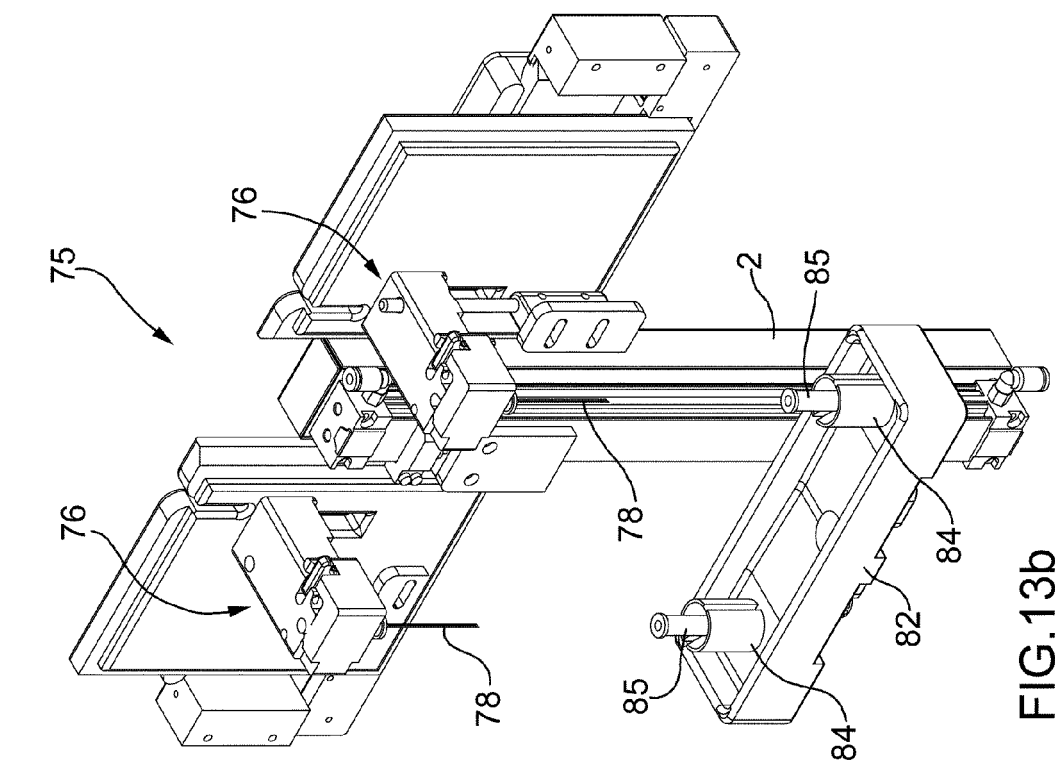


FIG. 13b

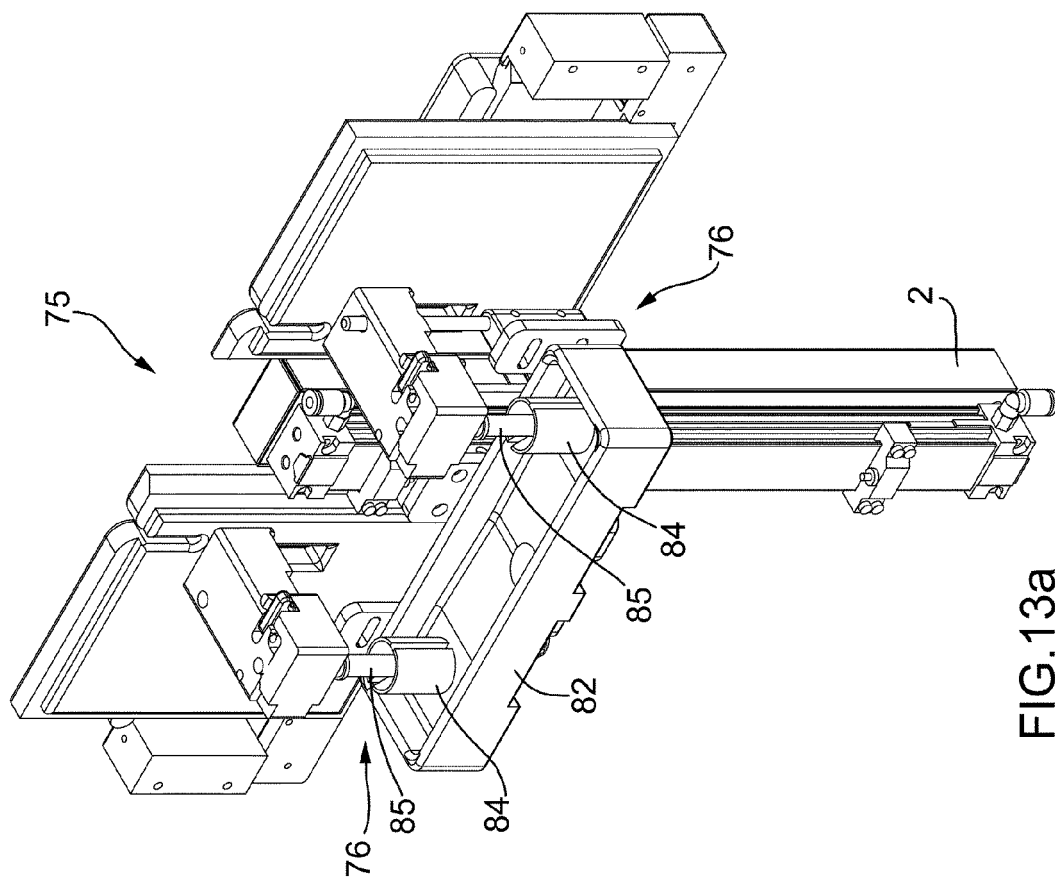


FIG. 13a

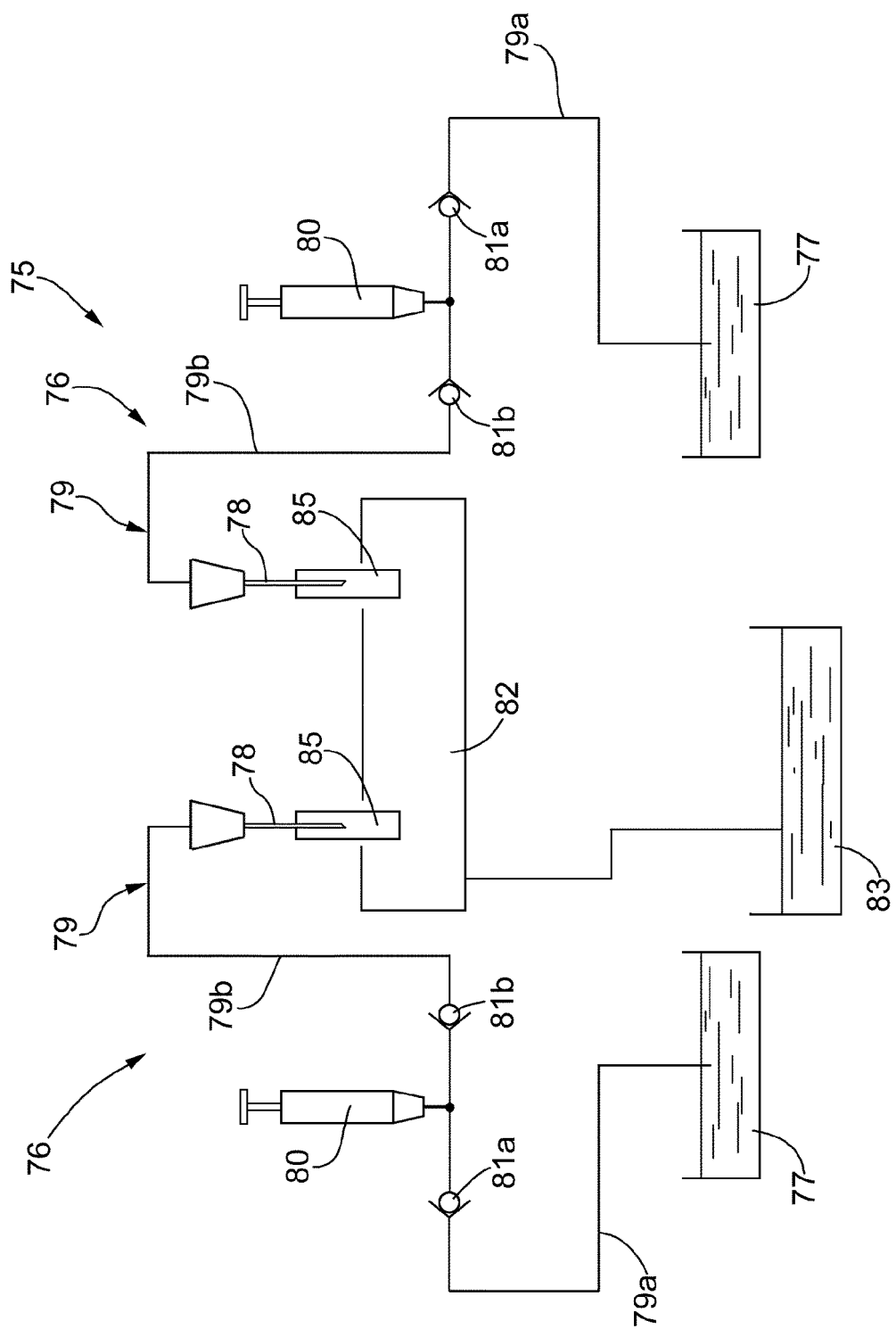


FIG.14

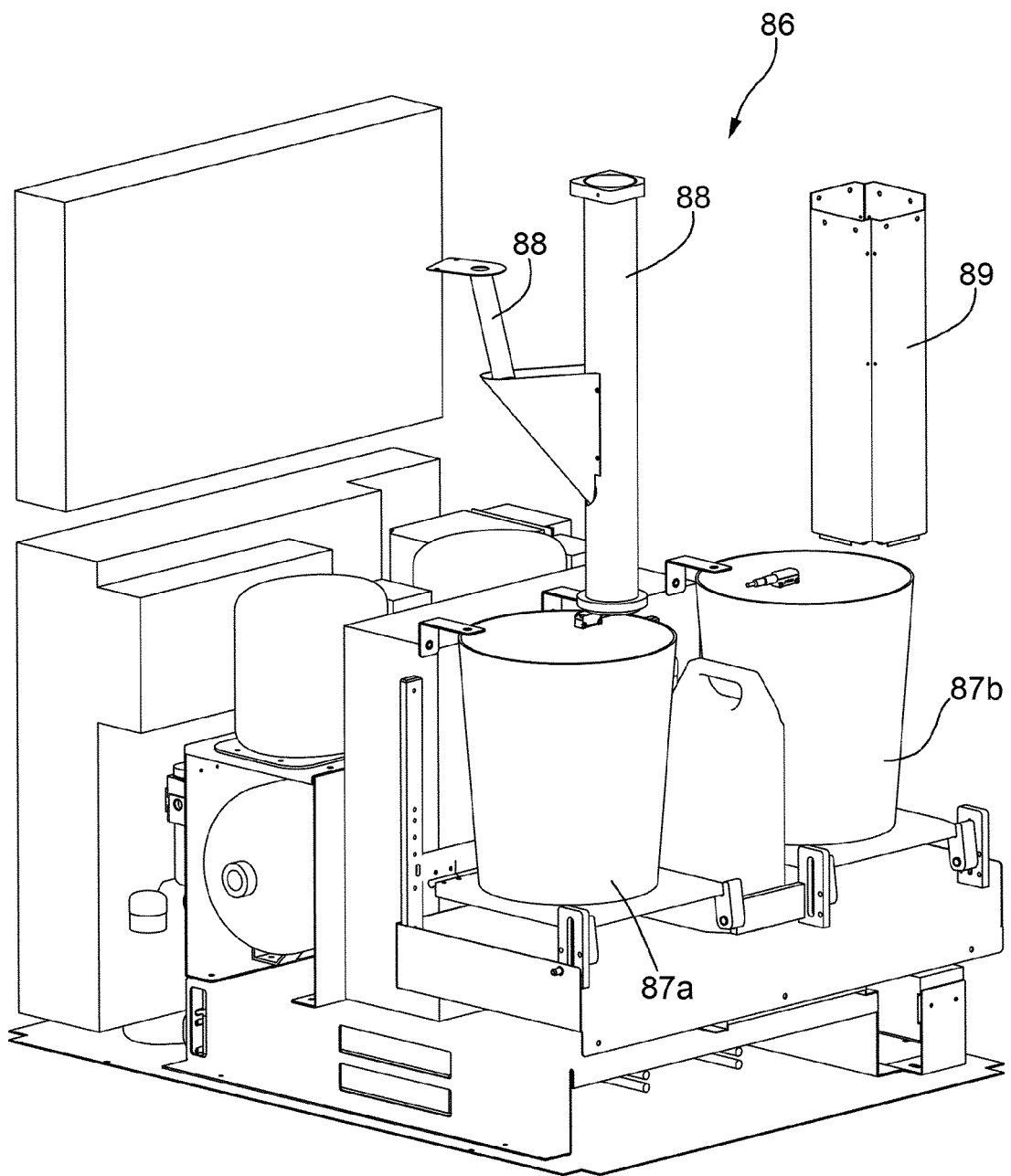


FIG.15



## EUROPEAN SEARCH REPORT

Application Number  
EP 12 16 1133

| DOCUMENTS CONSIDERED TO BE RELEVANT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                      |                                  |                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-----------------------------------------|
| Category                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Citation of document with indication, where appropriate, of relevant passages                                                                        | Relevant to claim                | CLASSIFICATION OF THE APPLICATION (IPC) |
| A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | US 6 616 771 B2 (OSBORNE JOEL A [US] ET AL) 9 September 2003 (2003-09-09)<br>* figures 3,4,6,7 *                                                     | 1                                | INV.<br>A61J1/20<br>B65B3/00            |
| A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | US 2005/045242 A1 (OSBORNE JOEL A [US]) 3 March 2005 (2005-03-03)<br>* figures 9,14,15,16,17,18 *<br>* paragraphs [0077] - [0079], [0111], [0112] *  | 1                                |                                         |
| A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | EP 2 054 145 B1 (HEALTH ROBOTICS S R L [IT]) 20 October 2010 (2010-10-20)<br>* paragraphs [0047], [0060] *                                           | 1                                |                                         |
| A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | US 2005/252574 A1 (KHAN ABDUL W [US] ET AL KHAN ABDUL WAHID [US] ET AL) 17 November 2005 (2005-11-17)<br>* paragraphs [0034] - [0036]; figures 3,6 * | 1                                |                                         |
| The present search report has been drawn up for all claims                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                      |                                  | TECHNICAL FIELDS SEARCHED (IPC)         |
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