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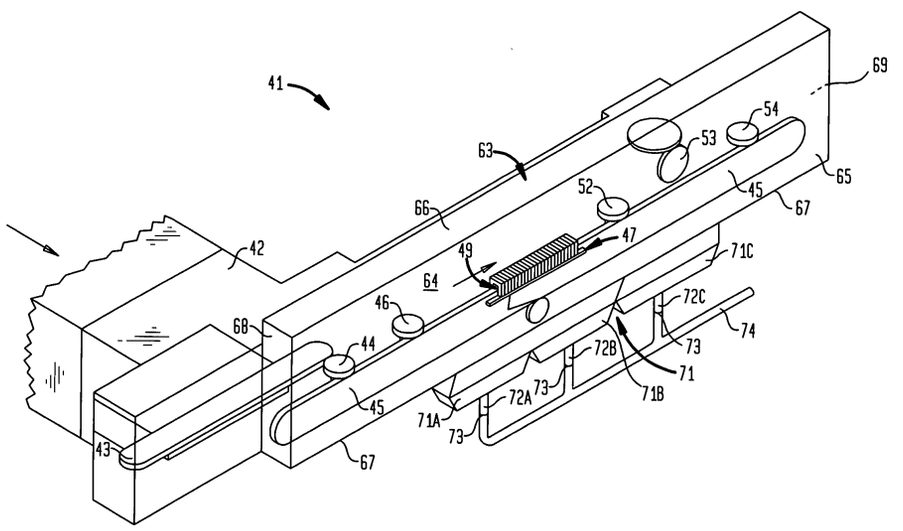
(54) Aseptic vial filling apparatus

(57) An apparatus for filling pharmaceutical containers in a substantially sterile environment may include an upright wall dividing the apparatus into a substantially contamination free sterile zone and a non-sterile zone and an enclosure cooperating with the upright wall to define the sterile zone. The apparatus may also include a transfer apparatus that receives empty containers from a point outside the sterile zone and a transport at least partially disposed within the sterile zone that moves the containers through the sterile zone. The apparatus may include a filling apparatus that fills the containers with pharmaceuticals in the sterile zone as the containers are moved through the sterile zone. The filling apparatus may include at least one dispenser disposed within the sterile zone and a drive disposed in the non-sterile zone. The filling apparatus may extend through a sealed opening in the upright wall generally between the filling apparatus dispenser in the sterile zone and the drive in the non-sterile zone. The apparatus may also include a device movable with the at least one dispenser and configured and positioned to control flow of pharmaceuticals from the at least one dispenser. The at least one dispenser may be movable into and out of filling engagement with the containers.

FIG. 1



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Description

[0001] The invention relates generally to a filling apparatus and, more particularly, to an improved filling apparatus configured to fill containers, for example, vials, with liquid products, for example, pharmaceuticals and the like.

[0002] In the pharmaceutical industry, many preparations, for example, injectable drugs and medicines, are packaged in containers such as vials, which are often small in size. In-line filling machines, or in-line fillers, are often used to package these pharmaceutical preparations to high standards of sterility.

[0003] The in-line fillers may be "isolated" so as to maintain a high level of sterility. Isolated in-line fillers may define a clean and sterile area for packaging the preparations by coupling an enclosure to a horizontal or substantially horizontal table or by coupling an enclosure to a vertical wall. In the case of a table, components of the filling system are mounted to the table such that only the necessary components for packaging the preparation are located in the sterile area. The drive mechanisms and other components that are difficult to maintain to a high degree of sterility are below the table.

[0004] In the case of a vertical wall filler, such as disclosed in U.S. Patent No. 5,673,535, the components of the filling system are mounted to the wall such that only the necessary components for packaging the preparation are located in the sterile area. The drive mechanisms and other components that are difficult to maintain to a high degree of sterility are on an opposite side of the wall from the sterile area.

[0005] Alternatively, in-line fillers could be used without an enclosure that defines a sterile zone. These types of fillers are kept in a "clean room" where the entire room is maintained to the necessary high degree of sterility. Optionally, in a clean room application, the filling system may include an enclosure for enclosing mechanical drives and other components, thereby confining these components to a non-sterile zone.

[0006] Conventional fillers may include a filling system, for example, a pump-activated filling system or a time and pressure filling system. In a time and pressure system, a liquid product may be fed from a stationary pressurized manifold through a plurality of flexible supply lines to a corresponding plurality of dispensers, for example, filling needles, nozzles, or the like. A valve may be associated with each flexible supply line in either type of filling system.

[0007] The quantity of liquid dispensed may be controlled by the valves. In order to dispense a desired quantity, the valves may be opened for a certain period of time dependent upon, among other things, the pressure and temperature of the liquid product. The valves may be configured as pinch valves that pinch the flexible supply line to stop the flow of liquid and lessen the pinch to start the flow. When the valves open, the liquid product may be dispensed from the dispensers into a corresponding plurality of vials.

[0008] The dispensers may be associated with a structure that follows the motion of the vials as they progress along a conveyor system through the filling system. In the case of needle-type filling dispensers, the structure may be referred to as a needle bridge. Because the liquid supply lines are flexible, the dispensers may move while the product supply manifold remains stationary. Since the valves in conventional fillers are also stationary, the dispensers may move relative to their corresponding valves. This relative motion may cause the flexible supply lines to change shape, which in turn causes a change in internal volume. As a result, the accuracy of the filling system may be compromised.

[0009] In addition, the measurement of temperature and pressure of the liquid product is conventionally performed in the product supply manifold. The measurement of temperature remote from the dispensers can introduce filling errors if the fluid flow properties are temperature sensitive.

[0010] According to one aspect of the invention, an improved apparatus is provided for filling pharmaceutical containers in a substantially clean and sterile environment. The apparatus may include an upright wall dividing the apparatus into a substantially contamination free sterile zone and a non-sterile zone and an enclosure cooperating with the upright wall to define the sterile zone or, alternatively, the non-sterile zone. The apparatus may also include a transfer apparatus that receives empty containers from a point outside the sterile zone and a transport at least partially disposed within the sterile zone that moves the containers through the sterile zone. The apparatus may include a filling apparatus that fills the containers with pharmaceuticals in the sterile zone as the containers are moved through the sterile zone. The filling apparatus may include at least one dispenser disposed within the sterile zone and a drive mechanism disposed in the non-sterile zone. The filling apparatus may extend through a sealed opening in the upright wall generally between the filling apparatus dispenser in the sterile zone and the drive mechanism in the non-sterile zone. The apparatus may also include a device movable with the at least one dispenser and configured and positioned to control flow of pharmaceuticals from the at least one dispenser. The at least one dispenser may be movable into and out of filling engagement with the containers.

[0011] According to another aspect of the invention, an apparatus for filling containers in a substantially sterile environment may comprise a frame, an upright wall carried by the frame and dividing the apparatus into a substantially contamination free sterile zone and a non-sterile zone at least partially disposed in side-by-side relation, and an enclosure cooperating with the upright wall to define the sterile zone. The apparatus may also include a transfer apparatus that receives empty containers from a point outside the sterile zone, a transport at least partially disposed within the sterile zone that

moves the containers through the sterile zone, and a filling station that fills containers with pharmaceuticals as they are moved through the sterile zone by the transport. The filling station may be disposed in the sterile zone. The apparatus may also include a drive mechanism in operable communication with the filling station and disposed within the non-sterile zone and connecting apparatus between the drive mechanism and the filling station. The connecting apparatus may extend through a sealed opening in the upright wall. The apparatus may include at least one dispenser associated with the filling station and a device configured and positioned to control flow of pharmaceuticals from the at least one dispenser. The device may be movable with the at least one dispenser, and the at least one dispenser being movable into and out of filling engagement with the containers.

[0012] According to yet another aspect of the invention, an apparatus for filling containers in a substantially sterile environment may comprising frame means, upright wall means carried by the frame means and dividing the apparatus into a substantially contamination free sterile zone and a non-sterile zone at least partially disposed in side-by-side relation, and enclosure means carried by the frame means and cooperating with the upright wall means to define the sterile zone. The apparatus may include transport means at least partially disposed within the sterile zone for transporting containers through the sterile zone, container transfer means for transferring empty containers from a point outside the sterile zone to the transport means in the sterile zone, and means for filling containers with pharmaceuticals as they are moved through the sterile zone by the transport means. The means for filling containers may be disposed in the sterile zone. The apparatus may also include drive means disposed within the non-sterile zone for operating the means for filling containers and connection means for operably connecting the drive means with the means for filling containers. The connection means may extend through a sealed opening in the upright wall means. The apparatus may include at least one dispenser associated with the filling means and a device configured and positioned to control flow of pharmaceuticals from the at least one dispenser. The device may be movable with the at least one dispenser, and the at least one dispenser may be movable into and out of filling engagement with the containers.

[0013] According to still another optional aspect of the invention, an apparatus for filling pharmaceutical containers in a substantially sterile environment may include an upright wall dividing the apparatus into a substantially contamination free sterile zone and a non-sterile zone.

[0014] The zones may be at least partially disposed in side-by-side relation. The apparatus may also include an enclosure cooperating with the upright wall to define the sterile zone, a transfer apparatus that receives empty pharmaceutical containers from a point outside the sterile zone, and a plurality of operating apparatus disposed in sequential relation. Each of the operating apparatus may comprise at least a portion disposed within the sterile zone and a drive disposed within the non-sterile zone, wherein a given operation may be performed with respect to the pharmaceutical containers at each of the operating apparatus. Each of the operating apparatus may extend through a sealed opening in the upright wall generally between the portion in the sterile zone and the drive in the non-sterile zone. The apparatus may also include a transport at least partially disposed within the sterile zone that moves the pharmaceutical containers through the plurality of operating apparatus, at least one dispenser structured and arranged to direct flow of pharmaceuticals into the pharmaceutical containers, and a device configured and positioned to control flow of pharmaceuticals from the at least one dispenser. The device may be movable with the at least one dispenser, and the at least one dispenser may be movable into and out of filling engagement with the containers.

[0015] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed.

[0016] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate exemplary embodiments of the invention and, together with the description, serve to explain the principles of the invention. In the drawings,

FIG. 1 is a schematic representation of a conventional container filling apparatus modified in accordance with some aspects of the present invention;

FIG. 2 is a top plan view of the modified container filling apparatus of FIG. 1;

FIG. 3 is a transverse section view of the modified container filling apparatus taken along line III-III of FIG. 2;

FIG. 4 is a cross-sectional view of a filling apparatus in accordance with an embodiment of the present invention;

FIG. 5 is a cross-sectional view of a portion of the filling apparatus shown in FIG. 4;

FIG. 6 is a partial perspective view of a known exemplary vertical container conveyor that could be used with the container filling apparatus in accordance with the invention;

FIG. 7 is a partial perspective view of a known exemplary horizontal container conveyor that could be used with the container filling apparatus in accordance with the invention; and

FIG. 8 is a cross-sectional view of the exemplary horizontal container conveyor taken along line VIII-VIII of FIG. 7.

[0017] Reference will now be made in detail to embodiments of the invention, examples of which are illustrated in the accompanying drawings. In accordance

with the present invention, a filling apparatus is provided. The filling apparatus may be used, for example, to fill containers, for example, vials, with fluid.

[0018] Referring to FIGS. 1-3, a vial filling apparatus embodying the invention is represented generally by the numeral 41 and is disclosed generally in U.S. Patent No. 5,673,535, except for the modifications and improvements discussed in detail herein. The apparatus 41 is intended for use in the sequential filling of continuously fed vials for injectable drugs, but the invention contemplates the filling of any type of container in a clean and sterile environment.

[0019] With particular reference to FIG. 2, apparatus 41 includes a sterilized infeed enclosure 42 through which vials 14 pass on a conveyor 48. Infeed enclosure 42 represents the inlet to a sterile zone, discussed below, and it is essential that the vials 14 entering at this point be in a sterilized condition. To that end, enclosure 42 is connected to a conventional vial washer/sterilizing tunnel 50 that receives unsterilized vials, performs a multiple step procedure that sterilizes the vials, generally including depyrogenization, and delivers sterilized vials to the conveyor 48 of sterilized infeed enclosure 42. At this point, the sterilized vials are transferred to an oscillating belt infeed station 43 that moves the vials to a transfer star wheel 44, which sequentially loads the vials 14 onto a principal container conveyor 45 or 45'. Although a vertical conveyor 45 is depicted in FIGS. 1-3, an improved horizontal conveyor 45', as shown and described with respect to FIGS. 7 and 8, may be used.

[0020] Conveyor 45, 45' sequentially moves the vials 14 to a pre-fill check weigh station 46 that randomly removes a vial to establish a reference pre-fill weight. The vials are then carried by conveyor 45, 45' through a filling station 47 which comprises a filling device 414, including a plurality of nozzles 49, described in further detail below.

[0021] After filling, the vials 14 are moved by conveyor 45, 45' past a post-fill check weigh station 52, which removes each of the randomly selected empty vials previously weighed at pre-fill check weigh station 46. This comparative weighing ensures that the specific amount of pharmaceutical preparation has been metered and dispensed into each vial. The weigh stations may include contact or non-contact weighing devices.

[0022] Conveyor 45, 45' then moves the vials through a stoppering station 53 at which each of the filled vials is closed and sealed with a stopper. Vials 14 then move into an eject and outfeed station 54, where the vials are removed from conveyor 45, 45' and carried by means not shown to a packing station.

[0023] With reference to FIG. 3, apparatus 41 comprises an elongated frame, certain components of which are shown in this transverse sectional view. These include vertical leg members 55, a cross rail member 56, a mounting plate 57 and a vertical frame support member 58 that extends between the cross rail member 56 and plate 57, at an intermediate point between the vertical leg members 55. It is will be understood that the various components 55-58 repeat over the length of the apparatus frame.

[0024] A vertically disposed mounting plate 59 is secured to the several frame support members 58, extending longitudinally over the length of the apparatus 41 (see also FIG. 2). A portion of vertical mounting plate 59 extends above the mounting plate 57. A thin stainless steel sheet 61 corresponding in size to vertical mounting plate 59 is mounted thereto in spaced relation. The stainless steel sheet 61 defines the elongated barrier or back plate of a stainless steel cabinet bearing general reference numeral 63, which in turn defines an internal sterile zone 64. The area outside cabinet 63 (i.e., that portion on the left side of barrier plate 61 as viewed in FIG. 3) constitutes a non-sterile zone bearing the general reference numeral 70.

[0025] With continued reference to FIGS. 1 and 3, sterile cabinet 63 further comprises a front plate 65 that is shown as corresponding generally in size to the back plate 61 in the schematic representation of FIG. 1. However, and as shown in FIG. 2, the front plate 65 includes several outward steps to accommodate various of the components described above. Referring again to FIG. 1, a cabinet top 66 and cabinet bottom 67 interconnect the back plate 61 and front plate 65, and the cabinet ends are enclosed by end plates 68, 69.

[0026] As shown in FIG. 2, the primary inlet to sterile zone 64 is the sterile tunnel 42 as discussed above. The stoppering station 53 also includes a stopper inlet or docking port 53a through which sterilized stoppers are admitted in a sterile manner as is known in the art. The sole outlet from sterile zone 64 is the eject and outfeed station 54, which may, for example, comprise a plurality of conventional star wheels, the first of which is disposed within sterile zone 64 and the second of which is disposed outside the sterile zone 64. Vials 14 are transferred between these first and second star wheels through a small opening in cabinet 63. Sterile zone 64 may be maintained at a pressure higher than that of the ambient surroundings to cause an outflow of air through the vial outlet between the star wheels, thus resisting contaminant entry. The means for maintaining such pressure, which is not shown, is conventional and typically includes a supply of air that is filtered to remove contaminants.

[0027] In an embodiment, cabinet 63 includes a plurality of conventional glove ports 80 or other conventional means for permitting sealed access to the sterile zone 64. Preferably, glove ports 80 are disposed at spaced points to permit operators of the apparatus 41 to have access at all points along the line of vial movement.

[0028] With reference to FIG. 1, a drain portion 71 of the cabinet 63 projects downwardly below the filling station 47. The respective bottom portions 67 adjacent the drain portion 71 are inclined downwardly toward the drain portion 71. The bottom of drain portion 71 defines a plurality collecting drain pans 7 IA-C which respective-

ly lead to drains 72A-C. Each of the drains 72A-C is connected through a sealed coupling 73 to a common drain pipe 74. The purpose of these drain components is discussed in further detail below.

[0029] Referring now to FIGS. 4 and 5, the filling apparatus may include the filling station 47, a product supply manifold 411, at least one supply line 412, and a filler configured to fill containers, for example, a vial filling device 414. The product supply manifold may be positioned in the sterile zone 64 or in the non-sterile zone 70. Each supply line 412 may be disposed between the product supply manifold 411 and the vial filling device 414. Each supply line 412 may be configured as a conduit, at least a portion 413 of which may be elastically deformable. The vial filling device 414 may include at least one dispenser 49. It should be appreciated that one supply line 412 may be provided for and associated with each dispenser 49. The dispensers 49 may be configured, for example, as filling needles, nozzles, or the like. Optionally, the dispensers 49 may be provided with mechanical, electrical, or electro-mechanical out-of-position sensors 417.

[0030] The filling apparatus may further comprise at least one valve 418. The valve 418 may comprise, for example, a pinch valve provided for and associated with each supply line 412 and dispenser 49. Accordingly, there may be a one-to-one-to-one correspondence between the number of supply lines 412, dispensers 49, and valves 418. A portion 420 of the supply line 412 between the valve 418 and the dispenser 49 may be rigid, or at least semi-rigid.

[0031] The vial filling device 414 may further include a structure 426, for example, a walking beam, with which the dispensers 49 and valves 418 are associated. The structure 426 may be configured to follow the motion of the vials 14 as they progress along the conveyor 45, 45' through the vial filling device 414 during the filling process.

[0032] The dispensers 49 and valves 418 may be associated with the structure 426 such that there is substantially no relative motion between the dispensers 49 and valves 418 as the structure 426 moves. In the case of needle-type filling dispensers, the structure 426 may be a needle bridge walking beam.

[0033] The filling apparatus may include a drive 151 (FIG. 2), for example, a drive pulley, operatively connected to the vial filling device 414 via a mechanism 434 that passes from the non-aseptic zone 70 to the aseptic zone 64 via a sealed opening 436. The mechanism 434 may carry the structure 426, including a housing 438. Referring to FIG. 5, the housing 438 may contain valve actuators 440. The housing 438 may provide a seal between a surrounding aseptic zone 64 and an interior, non-sterile or non-aseptic zone 433. The mechanism 434 may also be hollow to provide a non-sterile or non-aseptic zone 435, including an enclosed path 442 communicating with the non-aseptic zone 70 for filler operation and/or drive utilities 150, for example, the drive 151, a power supply, motion and actuation control, and the like, that support the actuation and operation of the valves 418. The valve actuators 440 may be separated from the valves 418 by a flexible diaphragm 444, which provides a seal between aseptic and non-aseptic zones 64, 433.

[0034] Additionally, a temperature sensor 446 may be positioned at or proximate to the dispenser 49. Thus, the temperature of the liquid product may be measured proximate the dispenser 49 rather than in a more distally-located product supply manifold 411. As a result, filling errors associated with temperature-sensitive fluid flow properties of a product may be reduced.

[0035] With reference to FIGS. 2, 3, and 6, the vertical container conveyor 45 may include a conveyor belt 87 having a row of sprocket holes 88 disposed along each edge. Conveyor belt 87 may be endlessly driven by a pair of opposed sprocket wheels 89, 90 (only sprocket wheel 89 is shown in FIG. 6). The sprocket wheels 89, 90 may rotate about a horizontal axis as shown by reference numeral 91 in FIG. 3. For purposes of simplicity in FIG. 3, the horizontal shafts upon which drive sprocket wheels 89 rotate are not shown. Such shafts extend through appropriate seals in the stainless steel sheet 61 and mounting plate 59 and are driven as discussed below. With such a configuration, the width of conveyor 4- may be significantly reduced. Further, since the drive for conveyor 45 may be located outside sterile cabinet 63 as discussed below, cabinet 63 and sterile zone\ 64 may be significantly reduced in size from the standpoint of width.

[0036] Referring now to FIG. 7, in a preferred embodiment, an improved horizontal container conveyor 45' for transporting the vials may be configured with drive sprocket wheels or the like 89' that rotate about vertical axes. For example, as shown in FIGS. 7 and 8, the horizontal conveyor 45' may include one or more conveyor belts 87' configured to move upper container holders 800 and lower container holders 802 through a conveyor path. The lower container holders 802 may support the containers 14, and the upper container holders 800 may separate the containers 14 from one another and hold them substantially still relative to one another. The distance between adjacent upper container holders 800 may be adjustable so as to accommodate different sized container 14. With such a conveyor 45', the containers may be carried to the side of a conveyor belt rather than above the belt 87 as discussed above. Therefore, although such an alternative configuration of the conveyor 45' may increase the width of the cabinet 63 and sterile zone 64, the conveyor belt 87' may be less susceptible to contamination in the alternative configuration than in the configuration that carries the containers above the belt-87.

[0037] With reference to FIG. 2, each of the operating stations disposed within the sterile zone 64 may be driven by an actuating means, for example, a drive, that is disposed outside the sterile zone 64 (i.e., within the non-

sterile zone 70). These various actuating means, although separate, may be interrelatably driven because the various operations performed within sterile zone 64 must be synchronous. An electric motor 131 serves as the primary drive means for the various actuating means. Separate servomotors are used for other actuating means as described below, which are operated in synchronous relation to primary drive motor 131.

[0038] The motor 131 includes a drive pulley 133 at at least one end. Drive pulley 133 is connected through a drive belt 136 to a driven pulley 137, which in turn is mounted to a common drive shaft bearing the general reference numeral 138. Drive shaft 138 comprises a plurality of interconnected drive shaft segments 138A-E.

[0039] Drive shaft segment 138A is connected through a right angle gear drive 139 to a pulley/timing belt configuration. A drive connection 142 extends through a sealed opening 139 of the wall of cabinet 63, connecting the pulley/timing belt 141 to the oscillating belt infeed station 43.

[0040] Drive shaft segment 138A is connected to shaft segment 138B through a right angle drive 144. A right angle drive 145 is connected between drive shaft segments 138B-C, the purpose of which is to drive the star wheel 44 through a pulley/belt configuration 146 and a drive connection 147. Drive connection 147 extends through mounting plate 59 of cabinet 63 through a seal of the same type as seal 143.

[0041] Drive shaft segment 138C is connected through a pulley/belt configuration 148 to a right gear drive 149 having a drive pulley 151 (see also FIG. 3). Drive pulley 151 is connected to drive the walking beam 426 through at least one actuator 86, each of which extends through the mounting plate 59 through a seal similar to seal 143.

[0042] The pre-fill check weigh station 46 and post-fill check weigh station 52 may be separately driven by servomotors (not shown for purposes of clarity), which are operated in synchronous relation to the primary drive motor 131. Pre-fill check weigh apparatus 46 includes a drive connection 152, and post-fill check weigh apparatus 52 includes a drive connection 153.

[0043] Shaft drive segment 138D is connected through a pulley/belt configuration 154 to a right angle gear drive 155 which in turn drives a pulley/belt configuration 156. This, in turn, is connected to a drive connection 157 that actuates a portion of the stoppering station 53. Other components of the stoppering station are driven by a separate variable speed motor.

[0044] Shaft drive segment 1 38D is also connected through a gear drive 158 that drives a pulley/belt configuration 159. A drive connection 161 interconnects the configuration 159 through a seal, similar to seal 143, to the eject and outfeed station 54.

[0045] Shaft drive segment 138E is connected to a right angle gear drive 162 which in turn drives a pulley/belt configuration 163. A drive connection 164 extends through a seal and mounting plate 59 and connects configuration 163 with drive sprocket wheel 89. Sprocket wheel 90 is a driven wheel and does not include a direct drive.

[0046] With particular reference to. FIGS. 1 and 3, the sterile zone 64 within the sterile cabinet 63 can be periodically cleaned and sterilized by techniques utilizing steam and/or a disinfecting liquid wash with all of the internal components in place. As a result, clean zone 64 may be effectively sterilized and decontaminated on a periodic basis in a manner which is far easier than decontaminating an entire room or much larger zone. This also results in a significant decrease in the cost of operating and maintaining the apparatus 41.

[0047] In operation, a liquid product may be fed from a product supply manifold 411 located in the aseptic zone 64 through one or more supply lines 412 to corresponding dispensers 49. The valves 418 may control the quantity of liquid dispensed from the dispensers 49.

[0048] In order to dispense a desired quantity, the valves 418 may be opened for a certain period of time dependent upon, for example, the pressure and temperature of the liquid product proximate the dispensers 49. As shown in FIG. 5, the valves 418 may be configured as pinch valves that pinch an elastically-deformable portion 413 of the supply lines 412 to stop the flow of liquid and lessen the pinching force to start the flow. When the valves 418 open, the liquid product may be dispensed from the dispensers 49 into a corresponding plurality of vials.

[0049] The conveyor 45 or 45' transports vials 14 past the vial filling device 414. The structure 426 may follow the motion of the vials 14 as they progress along the conveyor system 422 past the vial filling device 414. Because the portion 413 of the supply lines 412 is flexible, the dispensers 49 may move to engage the vials 14, such as by a combined translation and reciprocal movement, while the product supply manifold 411 remains stationary. Since the valves 418 and dispensers 49 may move with the structure 426, the internal configuration or flow geometry of the portion 420 of the supply lines 412 between the dispensers 49 and the valves 418 remains substantially unchanged during movement of the structure 426 during the filling process. As a result, the accuracy of the filling apparatus may not be compromised.

[0050] It will be apparent to those skilled in the art that various modifications and variations can be made to the filling apparatus without departing from the scope or spirit of the invention. Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only.

Claims

1. An apparatus for filling containers in a substantially

sterile environment, the apparatus comprising:

an upright wall dividing the apparatus into a substantially contamination free sterile zone and a non-sterile zone, said zones at least partially disposed in side-by-side relation;
an enclosure cooperating with said upright wall to define one of said sterile zone and said non-sterile zone;
a transfer apparatus that receives empty containers from a point outside said sterile zone;
a transport at least partially disposed within said sterile zone that moves the containers through said sterile zone;
a filling apparatus that fills the containers with pharmaceuticals in said sterile zone as the containers are moved through said sterile zone, said filling apparatus comprising at least one dispenser disposed within said sterile zone and comprising a drive disposed in said non-sterile zone, said filling apparatus extending through a sealed opening in said upright wall generally between said filling apparatus dispenser in said sterile zone and said drive in said non-sterile zone; and
a device configured and positioned to control flow of pharmaceuticals from said at least one dispenser, said device being movable with said at least one dispenser, and said at least one dispenser being reciprocally movable at least one of vertically and horizontally into and out of filling engagement with said containers.

2. The apparatus for filling containers according to claim 1, further comprising a transport that moves the containers through said sterile zone.

3. The apparatus for filling containers according to claim 1 or 2, further comprising a frame that supports said upright wall and said enclosure.

4. The apparatus for filling containers according to any preceding claim, further comprising connecting apparatus between said drive and said filling apparatus dispenser, said connecting apparatus extending through said sealed opening in said upright wall.

5. The apparatus for filling containers according to any preceding claim, further comprising a plurality of operating apparatus, including said filling apparatus, disposed in sequential relation, each of said operating apparatus comprising at least a portion disposed within said sterile zone and a drive disposed within said non-sterile zone, a given operation being performed with respect to the containers at each of said operating apparatus; and each of said operating apparatus extending through said sealed opening in said upright wall generally between said portion in said sterile zone and said drive in said non-sterile zone.

6. The apparatus for filling containers according to claim 5, wherein said plurality of operating apparatus comprises a closure apparatus.

7. An apparatus for filling containers in a substantially sterile environment, the apparatus comprising:

a frame;
an upright wall carried by said frame and dividing the apparatus into a substantially contamination free sterile zone and a non-sterile zone at least partially disposed in side-by-side relation;
an enclosure cooperating with said upright wall to define said sterile zone;
a transfer apparatus that receives empty containers from a point outside said sterile zone;
a transport at least partially disposed within said sterile zone that moves the containers through said sterile zone;
a filling station that fills containers with pharmaceuticals as they are moved through said sterile zone by said transport, said filling station being disposed in said sterile zone;
a drive in operable communication with said filling station, said drive being disposed within said non-sterile zone;
connecting apparatus between said drive and said filling station, said connecting apparatus extending through a sealed opening in said upright wall;
at least one dispenser associated with the filling station; and
a device configured and positioned to control flow of pharmaceuticals from said at least one dispenser, said device being movable with said at least one dispenser, and said at least one dispenser being movable into and out of filling engagement with said containers.

8. The apparatus for filling containers according to claim 7, wherein said filling station comprises a plurality of dispensers disposed in a substantially linear relation.

9. Apparatus for filling containers in a substantially sterile environment, comprising:

frame means;
upright wall means carried by the frame means and dividing the apparatus into a substantially contamination free sterile zone and a non-sterile zone at least partially disposed in side-by-side relation;
enclosure means carried by the frame means

and cooperating with the upright wall means to define said sterile zone;
transport means at least partially disposed within said sterile zone for transporting containers through said sterile zone;
container transfer means for transferring empty containers from a point outside said sterile zone to said transport means in said sterile zone;
means for filling containers with pharmaceuticals as they are moved through the sterile zone by the transport means, the means for filling containers being disposed in said sterile zone;
drive means disposed within said non-sterile zone for actuating said means for filling containers;
connection means for operably connecting the drive means with the means for filling containers, the connection means extending through a sealed opening in said upright wall means;
at least one dispenser associated with said means for filling; and
a device configured and positioned to control flow of pharmaceuticals from said at least one dispenser, said device being movable with said at least one dispenser, and said at least one dispenser being movable into and out of filling engagement with said containers.

10. An apparatus for filling pharmaceutical containers in a substantially sterile environment, the apparatus comprising:

an upright wall dividing the apparatus into a substantially contamination free sterile zone and a non-sterile zone, said zones being at least partially disposed in side-by-side relation;
an enclosure cooperating with said upright wall to define said sterile zone;
a transfer apparatus that receives empty pharmaceutical containers from a point outside said sterile zone;
a plurality of operating apparatus disposed in sequential relation, each of said operating apparatus comprising at least a portion disposed within said sterile zone and a drive disposed within said non-sterile zone, a given operation being performed with respect to the pharmaceutical containers at each of said operating apparatus, each of said operating apparatus extending through a sealed opening in said upright wall generally between said portion in said sterile zone and said drive in said non-sterile zone;
a transport at least partially disposed within said sterile zone that moves the pharmaceutical containers through said plurality of operating apparatus;
at least one dispenser structured and arranged to direct flow of pharmaceuticals into said pharmaceutical containers; and
a device configured and positioned to control flow of pharmaceuticals from said at least one dispenser, said device being movable with said at least one dispenser, and said at least one dispenser being movable into and out of filling engagement with said containers.

11. The apparatus for filling containers according to claim 10, further comprising a transport that moves the containers through said sterile zone.

12. The apparatus for filling containers according to claim 10 or 11, further comprising a frame that supports said upright wall and said enclosure.

13. The apparatus for filling containers according to any of claims 10 to 12, further comprising a plurality of drives in operable communication with corresponding first portions of said plurality of operating apparatus, said drives being disposed within said non-sterile zone.

14. The apparatus for filling containers according to claim 13, further comprising a plurality of connecting apparatus between each of said plurality of drives and said corresponding first portions of said plurality of operating apparatus, said connecting apparatus extending through said sealed opening in said upright wall.

15. The apparatus for filling containers according to any of claims 10 to 14, wherein said plurality of operating apparatus comprises a filling apparatus and a closure apparatus.

16. The apparatus for filling containers according to any of claims 10 to 15, further comprising sealed access for intervention during operation of the apparatus from outside said sterile zone into said sterile zone.

17. The apparatus for filling containers according to claim 16, wherein said sealed access includes glove ports.

FIG. 1

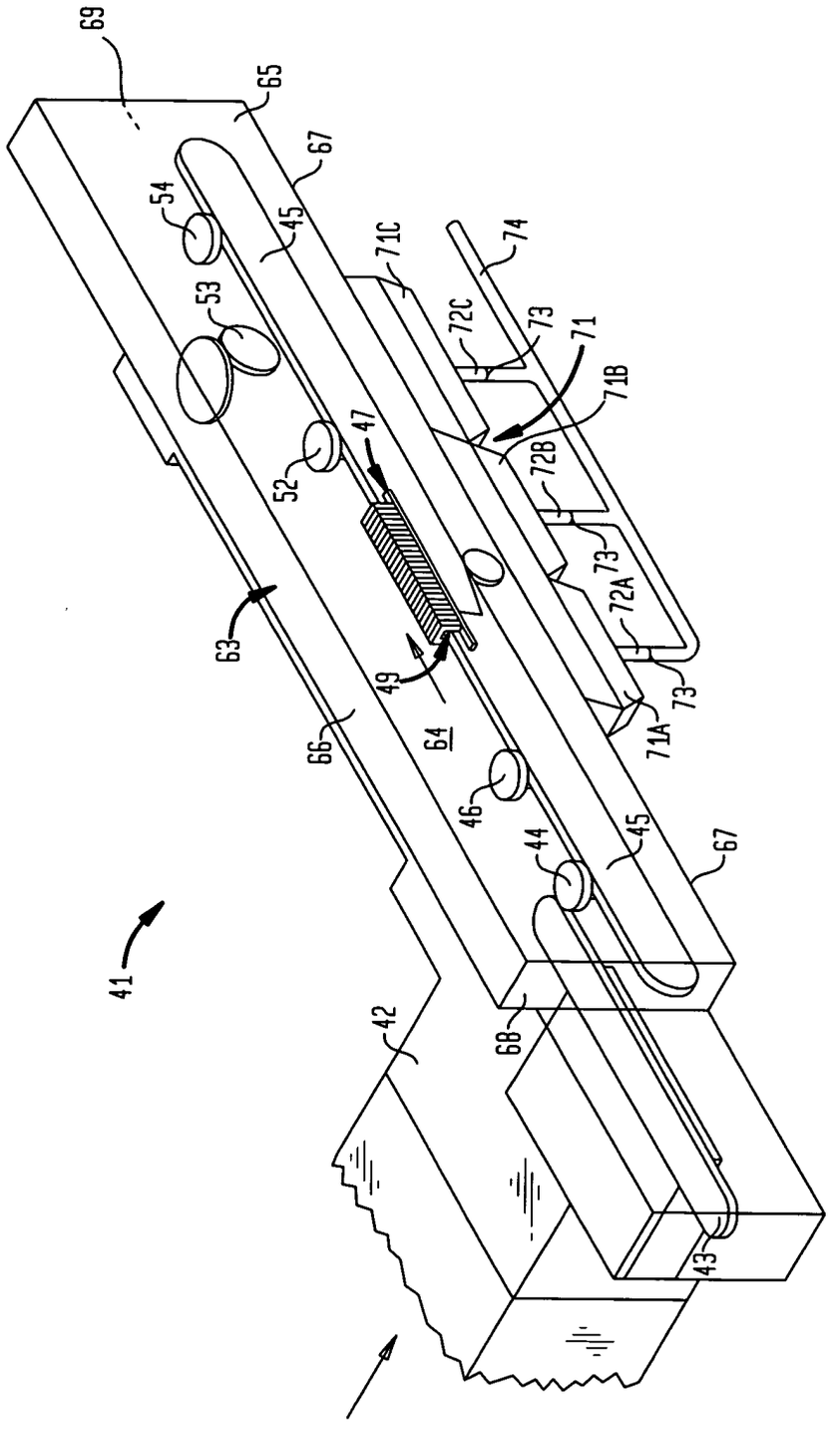
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FIG. 2

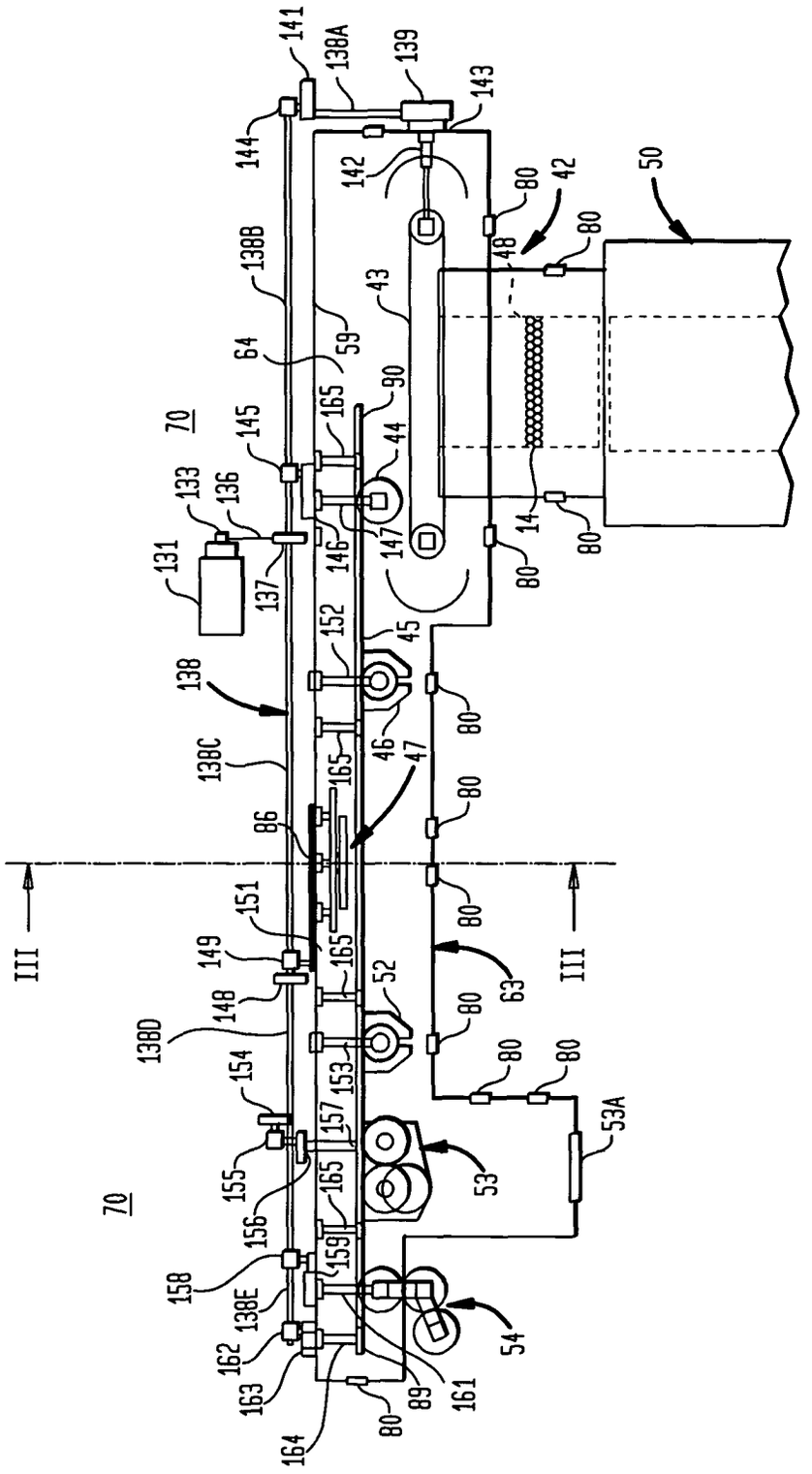
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FIG. 3

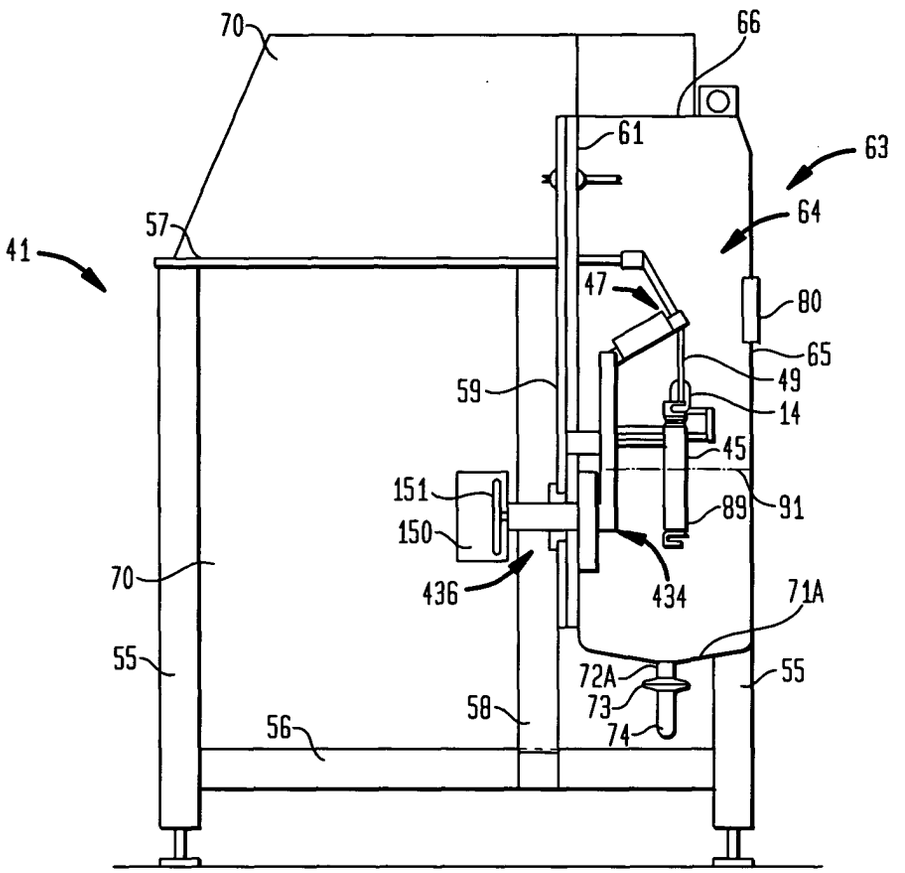
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FIG. 4

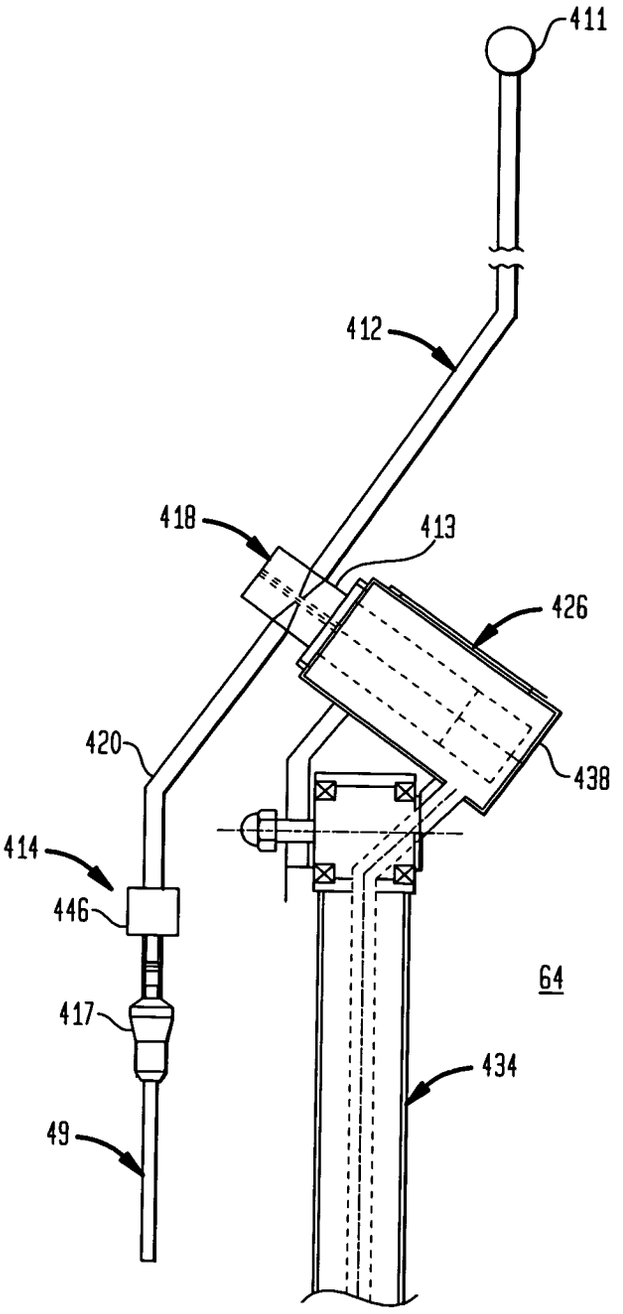


FIG. 5

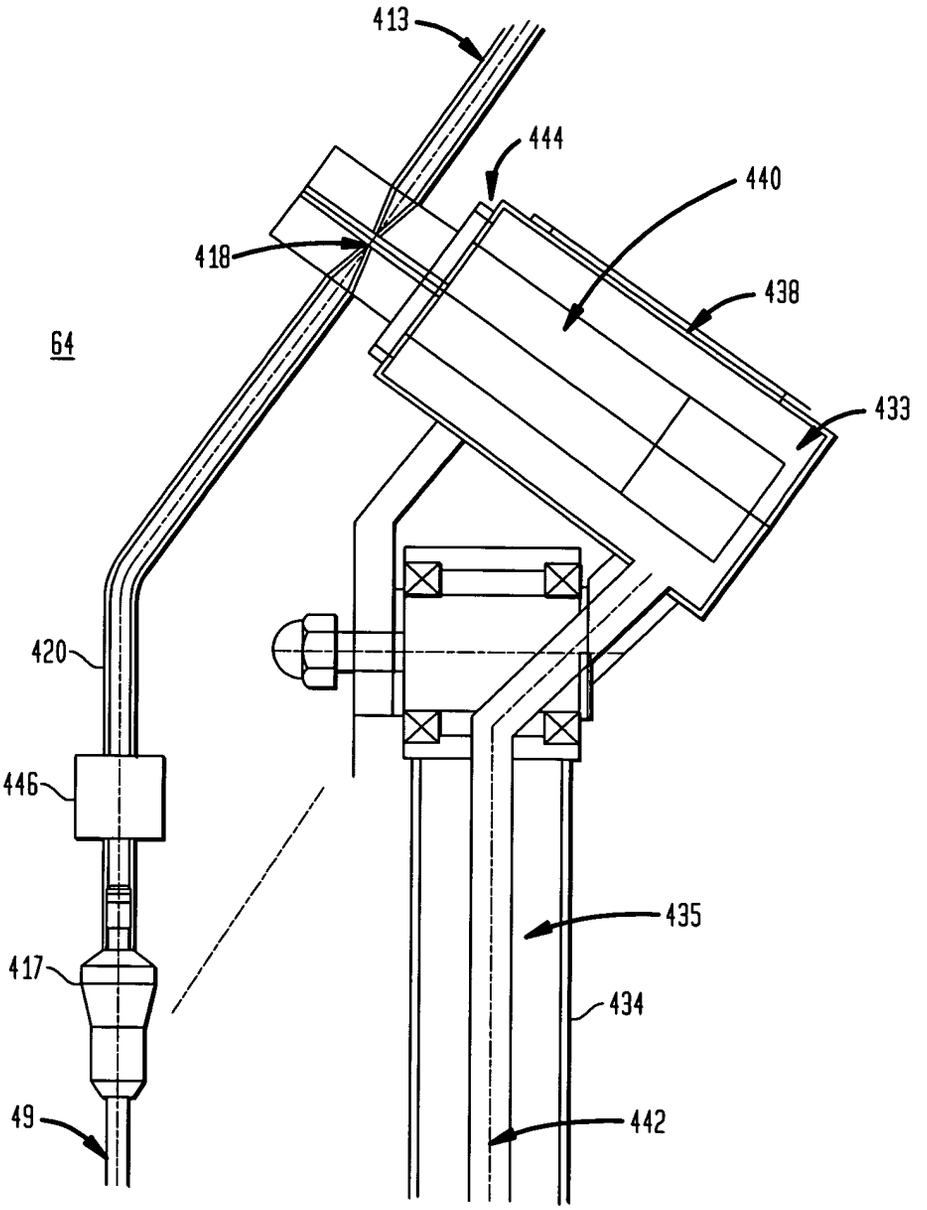


FIG. 6

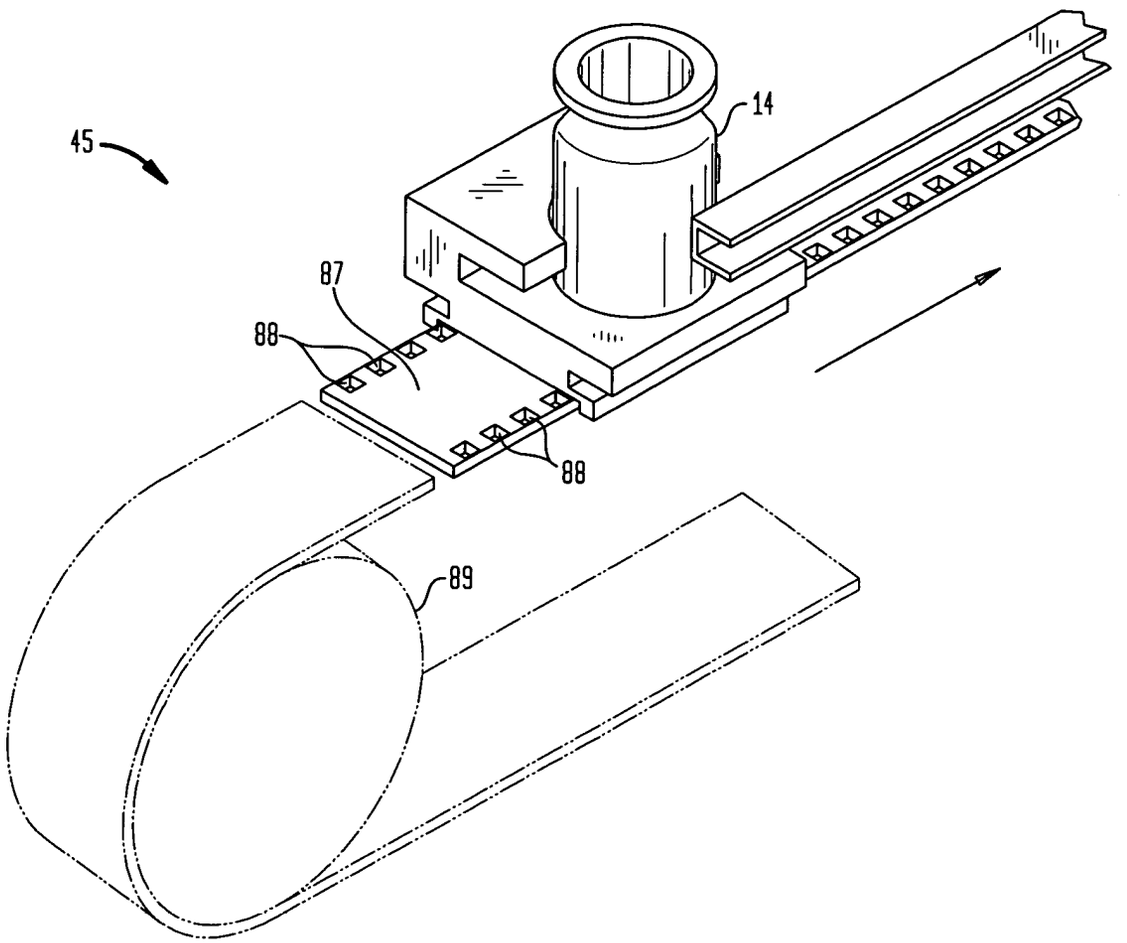


FIG. 7

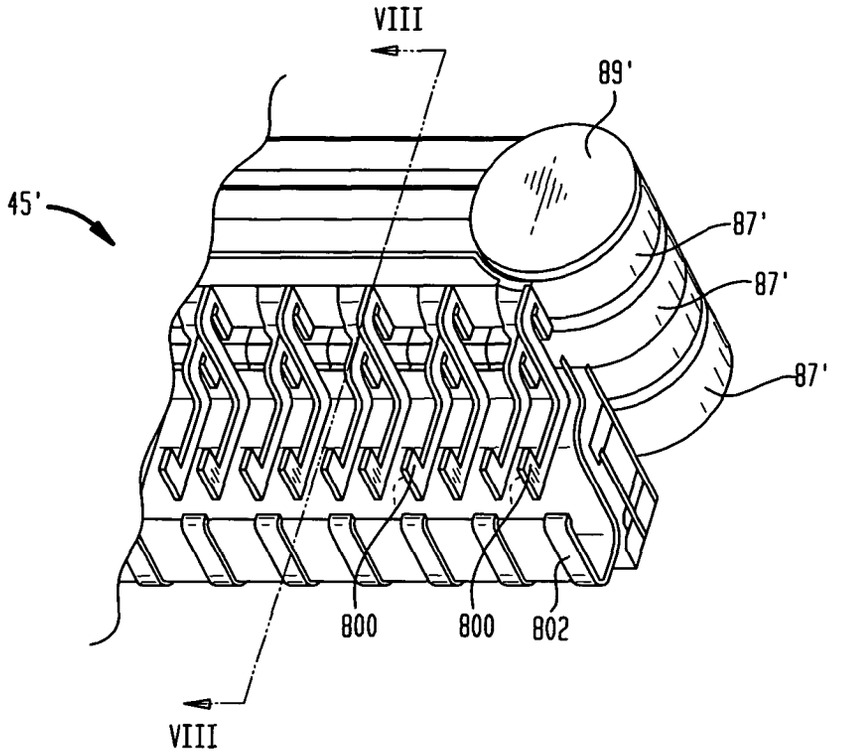
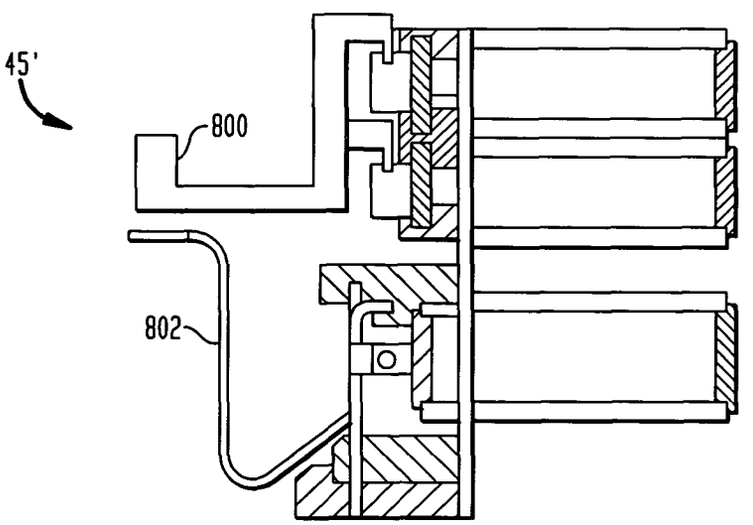


FIG. 8



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Application Number
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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	18 June 2004	Philippon, D

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