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(71) Applicant: **Capsulit S.P.A.**  
**20877 Roncello (MB) (IT)**

(72) Inventor: **RIZZARDI, Marco Maria Carlo**  
**20131 Milano (MI) (IT)**

(74) Representative: **Di Gennaro, Sergio et al**  
**Barzano & Zanardo Milano S.p.A.**  
**Via Borgonuovo 10**  
**20121 Milano (IT)**

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(54) **CLOSURE DEVICE, PARTICULARLY FOR BOTTLES OF LYOPHILIZED PRODUCTS, AND PROCESS FOR CLOSING A BOTTLE OF LYOPHILIZED PRODUCTS**

(57) The present finding relates to a closure device (1), particularly for bottles of lyophilized products, comprising:

- a perforable closure cap (3) adapted for closing the mouth (5) of a bottle (7);
- an inner capsule (9), fittable at least on said closure cap (3), comprising a plurality of elastically deformable tabs (29) protruding radially towards the inside said inner capsule (9) and further comprising an opening (13) adapted for allowing access to said closure cap (3);
- an outer tab (15) fittable on said inner capsule (9) and comprising an upper portion (17), at least partially removable, adapted for closing said closure (13) of said inner capsule (9).

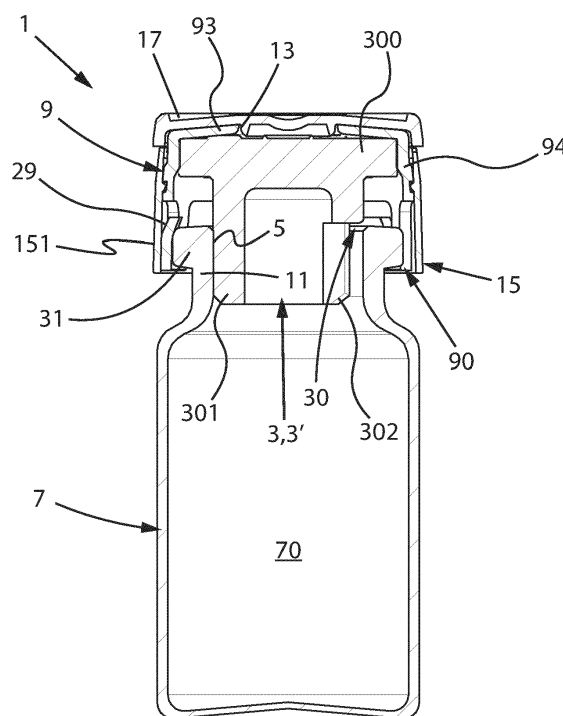
The closure device (1) has a closing configuration wherein said outer tab (15) is fixedly fitted to said inner capsule (9), said inner capsule (9) is fitted to the neck (11) of said bottle (7) and said tabs (29) engage at the bottom with the lip (31) of said bottle (7) so as to retain said closure cap (3) in a closing configuration to seal said mouth (5) of said bottle (7).

The closure device (1) also has a preassembly configuration wherein:

- said inner capsule (9) rests, with said tabs (29), on the mouth (5) of said bottle (7),
- a slit (30) is present between said closure cap (3) and said mouth (5) of said bottle (7) adapted for allowing the passage of air.

According to the finding, at least one air passage channel (90) is obtained in the inner capsule (9), said channel (90) extending, in the axial direction (A) towards said opening (13), beyond said tabs (29); in said preassembly configuration said outer tab (15) is fixedly fitted to said inner capsule (9) to form a preassembled closure

assembly (2). Furthermore, the at least one air passage channel (90) putting the internal volume (70) of said bottle (7) in fluid communication with the external environment through said slit (30).



**Fig. 4**

## Description

**[0001]** The present finding relates to a closure device, particularly for bottles of lyophilized products, and a related process for closing a bottle of lyophilized products.

**[0002]** As known, the bottles or flasks containing lyophilized products are generally closed by a perforable rubber cap, for example by a needle, being retained on the neck of the bottle by means of an aluminium capsule entirely covering the rubber cap. Aluminium capsules generally have a tear-off removable portion which allows the access to the perforable portion of the rubber cap.

**[0003]** The process of lyophilization of a product contained in a bottle generally provides to partially insert the rubber cap in the mouth of the bottle and extract the air inside the bottle through a dedicated system for drawing air. Indeed, for these purposes, the rubber caps for bottles of lyophilized products generally have, in the shank, slits allowing the passage of air when the cap shank is partially inserted in the mouth of the bottle. In a step following the lyophilization step, the aluminium capsule is applied on the rubber cap and tightened on the mouth of the bottle so that the rubber cap is retained to seal the mouth of the bottle.

**[0004]** One of the drawbacks of such process consists in the fact that in the lines for packaging lyophilized products, the lyophilization step requires to handle, separately and in two distinct steps, firstly the rubber cap and then the aluminium capsule, which is put in place by a sealing machine placed sequentially to the lyophilization machine, with subsequent repercussions on the length and complexity of the operations of lyophilizing and closing to seal the bottle. Furthermore, before applying the aluminium capsule, the cap is in an instable position and can easily escape from the mouth of the bottle.

**[0005]** In addition to this, with the current technology, the rubber cap is positioned in such instable position following the step of filling the bottle and there is a risk that, during the line transport of the bottles, and the handling of rubber caps and aluminium capsules, one component or the other falls or is not suitably positioned on the bottle and on the rubber cap, respectively, with subsequent problems in the lyophilization step or in the step of closing and tightening the aluminium capsule. In such case, furthermore, remarkable economic damage also arises, since the product contained in the bottle whose cap, or whose capsule, is accidentally fallen cannot be used anymore and should be disposed.

**[0006]** Another typical drawback of aluminium capsules consists in that the steps of mounting the capsule on the rubber cap and on the neck of the bottle cannot be performed in conditions of sterilization and absence of undesired particles, since the operations of folding and cutting aluminium sheets for making capsules and mounting them on the mouth of the bottle involve producing aluminium powders which remain on the capsule and are incompatible with the conditions of sterilization and absence of undesired particles required for the type

of products contained in the bottle itself. Thus, such aluminium capsules make keeping the minimum level of particle contamination allowed in controlled-atmosphere environments, such as a cleanroom, difficult.

**[0007]** Still, another drawback of the aluminium capsules consists in that the operator removing the removable portion risks to hurt himself/herself with the sharp edges of the aluminium sheet.

**[0008]** On the other hand, even the use of capsules made of plastic-type materials is not free of drawbacks.

**[0009]** Indeed, plastic has not possibilities of processing and deformation mechanical performance typical of aluminium. Accordingly, the closure capsules of bottles of lyophilized products made of plastic are capsules having different and several components reciprocally assembled to each other in various operations. Indeed, multi-component capsules comprising, at least, an outer tab fittable on an inner capsule, also referred to as "cage", fittable in turn on the rubber cap, are generally known. Indeed, in plastic multi-component capsules the outer tab, once fitted on the cage, allows tabs in the cage itself to engage at the bottom to the lip of the bottle and thus closing the mouth thereof.

**[0010]** However, it is apparent that handling even three different components (i.e., outer tab, cage and rubber cap) involves a clear increasing in time and costs for producing the capsule itself, and also has drawbacks during the operations of packaging the bottles of lyophilized products, in particular (i) during the transport of the components themselves in the packaging lines, since due to the vibrations they can be lost, (ii) during their reciprocal positioning on the mouth of the bottles, (iii) during the step of extracting air from the internal volume of the bottles to operate the lyophilization of the product, and (iv) during the step of tightening all the components on the mouth of the bottle, particularly in the case in which the various components are not suitably positioned with respect to each other. The occurrence of a problem even in only one of the four above-listed steps causes the undesired interruption of the packaging line and causes remarkable economic damage consequent of the fact that the product contained in non-correctly capped bottles cannot be used anymore and should be disposed.

**[0011]** An object of the present finding is to make a closure device, particularly for bottles containing lyophilized products, which is easier to be made and assembled on the bottles, and thus economically competitive if compared to the known art, and in particular to plastic multi-component capsules.

**[0012]** Another object of the present finding is to make a closure device which simplifies the assembling and closing operations on the bottles, as well as the lyophilization operation itself and which minimizes the risks of interruption of the operation of the packaging line.

**[0013]** Another object of the present finding is to make a closure device which does not cause powder formation while mounting on the bottles.

**[0014]** Another object of the present finding is to make

a closure device which is capable of providing the widest guarantees about reliability and safety in use.

**[0015]** These objects, according to the present finding, are achieved by making a closure device, particularly for bottles of lyophilized products, as set forth in claim 1.

**[0016]** Other features are provided in the dependent claims.

**[0017]** Further features and advantages will be more apparent from the description of a preferred, but non-exclusive, embodiment of a closure device, particularly for bottles of lyophilized products, illustrated for illustrative and non-limiting purposes with the aid of the attached drawings where:

figure 1 is a front elevation view of a bottle provided with a closure device according to an embodiment of the finding;

figure 2 is a top plan view of the bottle of figure 1;

figure 3 is a sectional view of the bottle depicted in figure 2, carried out according to the axis A-A, with the closure device in closing configuration on the bottle;

figure 4 is a view corresponding to that of figure 3, but with the closure device resting on the mouth of the bottle, in a preassembly configuration;

figure 4a shows an enlarged portion of figure 4;

figure 4b shows an enlargement of the portion denoted by B in figure 4a;

figure 4c shows an enlargement of the portion denoted by C in figure 4a;

figure 5 is an exploded perspective view of a bottle provided with a closure device, according to the finding;

figure 6 is a perspective view of the closure device, according to the finding;

figure 7 is a perspective view corresponding to that of figure 6 of the closure device, according to the finding, but illustrated without the closure cap;

figure 8 is a sectional view of the bottle depicted in figure 2, carried out according to the axis A-A, but with a variant of the closure device, in closing configuration on the bottle;

figure 9 is a view corresponding to that of figure 8, with the variant of the closure device resting on the mouth of the bottle, in a preassembly configuration;

figure 9a shows an enlarged portion of figure 9;

figures 10a, 11a and 12a are sectional views of a bottle provided with three different variants of the closure device;

figures 10b, 11b and 12b are perspective views of the closure device, without the closure cap, according to the three different variants of figures 10a, 11a and 12a, respectively;

figures 10c, 11c and 12c show enlarged portions of the three different variants of the closure device, respectively, illustrated in figures 10a, 11a and 12a.

**[0018]** With particular reference to the cited figures,

the closure device, particularly for bottles of lyophilized products, globally denoted by reference number 1, comprises:

- 5 - a closure cap 3, perforable, adapted for closing the mouth 5 of a bottle 7;
- an inner capsule 9, fittable at least on the closure cap 3, comprising an upper portion 93 in which an opening 13 adapted for allowing access to said closure cap 3 is present, and a side wall 94 comprising a plurality of elastically deformable tabs 29 protruding radially towards the inside of the inner capsule 9;
- 10 - an outer tab 15 fittable on the inner capsule 9 and comprising an upper portion 17, at least partially removable, adapted for closing the opening 13 of the inner capsule 9.

**[0019]** The closure device 1 has a closing configuration wherein the outer tab 15 is fixedly fitted to the inner capsule 9 and wherein the inner capsule 9 is in turn fitted to the neck 11 of the bottle 7 with the tabs 29 engaging at the bottom with the lip 31 of the bottle 7, so as to retain the closure cap 3 in a closing configuration to seal the mouth 5 of the bottle 7, as shown, for example, in figures 3 and 8.

**[0020]** The closure device 1 also has a preassembly configuration, exemplarily shown in figures 4, 4a and 9, 9a, wherein:

- 30 - the inner capsule 9 rests, with the tabs 29, on the mouth 5 of the bottle 7;
- a slit 30 is present between the closure cap 3 and the mouth 5 of the bottle adapted for allowing the passage of the air.

**[0021]** According to the finding, at least one air passage channel 90 is obtained in the inner capsule 9, said channel 90 extending, in the axial direction A, towards the opening 13, beyond the tabs 29. In the above-mentioned preassembly configuration, the outer tab 15 is fixedly fitted to the inner capsule 9 to form a preassembled closure assembly 2 wherein the upper portion 17 of the outer tab 15 is in abutment against the upper portion 93 of the inner capsule 9. Furthermore, in the preassembly configuration the at least one air passage channel 90 puts the internal volume 70 of the bottle 7 in fluid communication with the external environment, through the slit 30.

**[0022]** Therefore, advantageously, the outer tab 15 is fixedly fitted to the inner capsule 9, with the respective upper portions 17 and 93 in abutment against each other, also in the preassembly configuration, as well as in the closing configuration. In other words, the preassembled closure assembly 2 formed by the inner capsule 9 and the outer tab 15 fixedly fitted thereto has the same configuration both in preassembly and closure step.

**[0023]** The present finding also relates to a process for closing a bottle of lyophilized products, by means of a

closure device 1 as described above, comprising the steps of:

- (a) providing a closure cap 3, and an outer tab 15 fixedly fitted to an inner capsule 9, to define a pre-assembled closure assembly 2 wherein the upper portion 17 of the outer tab 15 is in abutment against the upper portion 93 of the inner capsule 9, where such preassembled closure assembly 2 is adapted to house the above-mentioned closure cap 3;
- (b) placing the preassembled closure assembly 2 and the closure cap 3 on the mouth 5 of a bottle 7 containing a product to be lyophilized;
- (c) extracting the air contained in the bottle 7 to lyophilize said product to be lyophilized, due to the presence of the at least one air passage channel 90 and the slit 30 between the closure cap 3 and the mouth 5 of the bottle;
- (d) tightening, inside a lyophilization machine, the preassembled closure assembly 2 and the closure cap 3 on the mouth 5 of the bottle 7.

**[0024]** Therefore, advantageously, in the steps of packaging a bottle 7 containing lyophilized product, and particularly in the steps of lyophilizing and closing the bottle 7, the inner capsule 9 and the outer tab 15, as reciprocally fixedly fitted so as to constitute a preassembled closure assembly 2, are handled as a single component, namely are transported in the packaging line and tightened on the mouth 5 of the bottle 7 in the lyophilization and tightening station, as a single component.

**[0025]** Preferably, the inner capsule 9 is made of a plastic-type material, by injection moulding, for example a polycarbonate-type material.

**[0026]** Preferably, the outer tab 15 is also made of a plastic-type material, by injection moulding, for example a polypropylene-type material.

**[0027]** Preferably, the closure cap 3 is made of an elastomer, such as for example natural rubber or synthetic polymers.

**[0028]** The inner capsule 9 comprises an upper portion 93 which is preferably disk-shaped, where the opening 13 is obtained, and a side wall 94 preferably cylinder-shaped, linked to the upper portion 93.

**[0029]** As illustrated particularly in figure 5, the tabs 29 are formed at through openings 33 in the side wall 94 of the inner capsule 9 and extending inside such through openings 33 in the axial direction A.

**[0030]** Similarly to the inner capsule 9, the outer tab 15 comprises an upper portion 17, at least partially - or totally - removable, preferably disk-shaped, and a side wall 151 preferably cylinder-shaped.

**[0031]** The outer tab 15 can be made according to variants described below.

**[0032]** In the version of closure device 1 illustrated in figures 1 to 9a, and in the third variant, illustrated in figures 12a, 12b and 12c, the outer tab 15 comprises a disk-shaped upper portion 17 and a cylinder-shaped side wall

151 linked to the disk-shaped upper portion 17.

**[0033]** Preferably, the upper portion 17 is linked to the side wall 151 through a weakened circumferential zone adapted for allowing such upper portion 17 to be removed so as to allow the access to the opening 13 in the upper portion 93 of the inner capsule 9. Preferably the weakened circumferential zone is defined by a plurality of breakable bridges 175 circumferentially connecting the upper disk-shaped portion 17 to the cylinder-shaped side wall 151.

**[0034]** As illustrated particularly in figures 4c and 7, the upper portion 17 also has a ring 171 protruding at the bottom towards the opening 13 and configured to be positioned inside such opening 13, substantially coaxially to the opening 13 itself.

**[0035]** The removal of the upper portion 17 of the outer tab 15 is carried out by tearing such upper portion 17 along the weakened circumferential zone, namely breaking the breakable bridges 175, so as to expose the closure cap 3 through the opening 13 in the inner capsule 9.

**[0036]** In the first variant of outer tab 15, illustrated in figures 10a, 10b, 10c, and in the second variant of outer tab 15, illustrated in figures 11a, 11b, 11c, the outer tab 15 always comprises a disk-shaped upper portion 17, which is however associated with a lower portion 152 being capsule shaped itself. Indeed, such capsule shaped portion 152 comprises in turn a disk-shaped upper part 153, and a cylinder-shaped side wall 151, linked to the upper part 153. The upper disk-shaped portion 17 is then associated to the lower portion configured as a capsule 152 through a plurality of retaining tabs 173.

**[0037]** Indeed, the portion configured as a capsule 152 has, in the upper part 153, an opening 154, whose edges are retained by retaining tabs 173 protruding at the bottom from the upper disk-shaped portion 17.

**[0038]** According to the first variant, illustrated in figures 10a, 10b, 10c, the edges of the opening 154 have a reinforcing relief 155 adapted to promote the retaining thereof by the retaining tabs 173, while according to the second variant of outer tab 15, illustrated in figures 11a, 11b, 11c, the edge of the opening 154 has no reinforcing reliefs.

**[0039]** In the case of the first and second variants, the removal of the upper disk-shaped portion 17 of the outer tab 15 is carried out by pulling out the retaining tabs 173 from the edge of the opening 154, thus leaving the opening 13 in the inner capsule 9 exposed.

**[0040]** In the third variant of outer tab 15, illustrated in figures 12a, 12b, 12c, the outer tab 15 comprises a disk-shaped upper portion 17 linked, through a weakened circumferential zone, to a cylinder-shaped side wall 151, as described above with reference to the embodiment of figures 1 to 9a. Preferably the weakened circumferential zone is defined by a plurality of breakable bridges 175 connecting the upper disk-shaped portion 17 to the side wall 151.

**[0041]** The upper disk-shaped portion 17 is associated to the upper portion 93 of the inner capsule 9 through a

plurality of retaining tabs 173 adapted to retain the edges of the opening 13 obtained in such upper portion 93, as described with reference to the first and second variants of the closure device 1.

**[0042]** In this case, the removal of the upper disk-shaped portion 17 is carried out by both breaking the above-mentioned breakable bridges 175 and pulling out the retaining tabs 173 from the edge of the opening 13, thus leaving such opening 13 in the inner capsule 9 exposed.

**[0043]** Preferably the at least one air passage channel 90 has a length L, in the axial direction, greater than the thickness S, in the axial direction, of the lip 31 of the bottle 7. Furthermore, in the preassembly configuration, the at least one air passage channel 90 faces the lip 31 so that the axial ends 91, 92 thereof are span across the thickness S of the lip 31, respectively.

**[0044]** In this way, the upper axial end 91 of the channel 90 is at higher height than the height of the tabs 29 of the inner capsule 9, which rest, in the preassembly configuration, on the upper edge of the mouth 5 of the bottle, and the lower axial end 92 of the channel 90 is at lower height than the height of the lower portion of the lip 31. Accordingly, even in the case in which, in the preassembly configuration, the side wall 94 of the inner capsule 9 protrudes at the bottom with respect to the lip 31 of the bottle 7 itself, the at least one channel 90 has a length L sufficient to allow the passage of air between the internal volume 70 of the bottle 7 and the external environment, through the slit 30.

**[0045]** Preferably the at least one air passage channel 90 is defined by a recess obtained in the side wall 94 of the inner capsule 9.

**[0046]** Preferably, the at least one air passage channel 90 is defined by a through opening 95 obtained in the side wall 94 of the inner capsule 9.

**[0047]** Preferably, since both in the preassembly configuration and in the closing configuration, the outer tab 15 is fixedly fitted to the inner capsule 9, with the respective upper portions 17 and 93 abutting against each other, the at least one air passage channel 90 is defined by the through opening 95 obtained in the side wall 94 of the inner capsule 9 and by the surface of the side wall 151 of the outer tab 15 facing such through opening 95. This is particularly shown in figures 6 and 7.

**[0048]** Preferably a plurality of air passage channels 90 are obtained in the inner capsule 9. Still more preferably, such air passage channels 90 are inter-spaced with the tabs 29.

**[0049]** As illustrated in the attached figures, the air passage channels 90 are angularly distributed around the central axis A, preferably equally spaced from each other. Similarly, the tabs 29 are also angularly distributed around the central axis A, preferably equally spaced from each other.

**[0050]** Preferably there are at least two channels 90 in the closure device 1. Even more preferably, the channels 90 are in number of four.

**[0051]** Each channel 90 has (i) a length, intended as the distance, in the axial direction A, between the ends 91 and 92, (i) a width, intended as the average length of arc of circumference, and (ii) a transverse thickness. Preferably, the overall width of all the channels 90, or of the single channel 90 if there is only one, is comprised between 10% and 50% of the average circumference value of the side wall 94 of the inner capsule 9, preferably comprised between 20% and 30%.

**[0052]** For example, if four channels 90 are provided, each channel has a length comprised between 2.5% and 12.5% of the average circumference value of the side wall 94 of the inner capsule 9, preferably comprised between 5% and 7.5%.

**[0053]** Preferably, the transverse thickness of the channel 90 is at least higher than 70% of the transverse thickness of the side wall 94 of the inner capsule 9. Even more preferably, the transverse thickness of the channel 90 is equal to 100% of the transverse thickness of the side wall 94 of the inner capsule 9, namely, as said above, the channel 90 is constituted by a through opening 95 obtained in the side wall 94 of the inner capsule 9.

**[0054]** Preferably, the outer tab 15 comprises a side wall 151 comprising at least one rib 35 protruding radially towards the inside of the outer tab 15 configured to engage in a corresponding seat 37 obtained on the outer surface of the side wall 94 of the inner capsule 9. The at least one rib 35 engaging in the corresponding seat 37 when the outer tab 15 is fixedly fitted to the inner capsule 9.

**[0055]** The rib 35 and the corresponding seat 37 are formed in a position respectively of the outer tab 15 and the inner capsule 9, such that, when the rib 35 is placed in the corresponding seat 37, the upper portion 17 of the outer tab 15 is in abutment against the upper portion 93 of the outer tab 9.

**[0056]** Preferably, the rib 35 circumferentially extends around all the side wall 151 of the outer tab 15, as the corresponding seat 37 circumferentially extends around all the outer surface of the side wall 94 of the inner capsule 9.

**[0057]** In this way, when the outer tab 15 is fitted on the inner capsule 9, the two components are stably constrained, fixedly, to each other and define the preassembled closure assembly 2 which can be handled as a single body.

**[0058]** Preferably, the inner capsule 9 comprises one or more protrusions 45 protruding radially towards the inside of the inner capsule 9 configured to retain, with interference, the closure cap 3 inside the inner capsule 9.

**[0059]** Preferably, such one or more protrusions 45 are obtained in proximity of the top of the inner capsule 9 and are adapted to retain the closure cap 3 inside the inner capsule 9 such that the upper surface of the closure cap 3 is in abutment against the upper portion 93 of the inner capsule 9.

**[0060]** Preferably, at least three, and even more preferably at least six of said protrusions 45, are provided,

which are angularly distributed around the central axis A, preferably equally spaced from each other.

**[0061]** Alternatively, the one or more protrusions 45 can be defined by a circumferential rib radially protruding towards the inside of the inner capsule 9.

**[0062]** As an alternative to the protrusions 45, the upper disk-shaped portion 300 of the closure cap 3 is oversized at least with respect to the top part of the side wall 94 of the inner capsule 9.

**[0063]** In this way, the closure cap 3, being retained with interference inside the inner capsule 9, can also be handled together with the preassembled closure assembly 2. Essentially, the three components (outer tab 15, inner capsule 9, and closure cap 3) composing the closure device 1 can be handled as a single body, namely can be transported, and positioned on the mouth 5 of the bottle 7, in the packaging lines, as a single body.

**[0064]** Accordingly, at least in the above-described step (a) of the process for closing a bottle of lyophilized products, the closure cap 3 is inserted in the preassembled closure assembly 2 and retained therein, preferably through said one or more protrusions 45 protruding radially towards the inside the inner capsule 9. Thus, the protrusions 45 allow to obtain a more stable positioning of the closure cap 3 on the bottle 7, preventing the accidental escaping thereof.

**[0065]** Preferably the protrusions 45 are defined by a plurality of radial sectors of the outer tab 15 in relief towards the inside of the same.

**[0066]** As illustrated in figures 1 to 7, the closure cap 3 can be a closure cap 3' for lyophilized products comprising an upper disk-shaped portion 300, and a lower hollow shank 301.

**[0067]** As illustrated particularly in figure 3, in the closing configuration of the closure device 1, the upper disk-shaped portion 300 of the closure cap 3' is adapted to close the mouth 5 of the bottle 7.

**[0068]** The lower shank 301 of the cap 3' has a through opening 302.

**[0069]** As illustrated in figure 4 and 4a, the lower shank 301 has a length, in the axial direction A, such that, in the preassembly configuration of the closure device 1, the lower part of the shank 301 of the closure cap 3' penetrates inside the mouth 5 of the bottle 7. In this configuration the through opening 302 in the cap 3' ensures the formation of the slit 30, between the shank 301 and the upper part of the neck 11 of the bottle 7, adapted for allowing the passage of air inside the bottle 7, towards the outside.

**[0070]** In the preassembly configuration the closure cap 3 is just partially inserted with its shank 301 in the neck 11 of the bottle 7 or due to the presence of the above-described protrusions 45, which retain the cap 3' in a predefined position inside the preassembled closure assembly 2, or due to the interference between the walls of the neck 11 of the bottle 7 and the shank 301 itself, or even due to a combination of both the above-mentioned features.

**[0071]** In a variant of the closure device 1, illustrated in figures 8, 9 and 9a, the closure cap 3 can be a closure cap 3" for injectable or perfusion products also comprising an upper disk-shaped portion 300, and a lower hollow shank 301.

**[0072]** As particularly illustrated in figure 8, in the closing configuration of the closure device 1, the upper disk-shaped portion 300 of the closure cap 3" is adapted for closing the mouth 5 of the bottle 7.

**[0073]** As illustrated in figure 9, the lower shank 301 has a length, in the axial direction A, such that, in the preassembly configuration of the closure device 1, the lower part of the shank 301 of the closure cap 3" remains spaced from the mouth 5 of the bottle 7. In this configuration the slit 30 is defined in the space separating the lower portion of the shank 301 of the cap 3" and the upper portion of the mouth 5 of the bottle 7.

**[0074]** In this case, means for retaining the closure cap 3" towards the top of the inner capsule 9 are provided, such as for example the above-described protrusions 45, to ensure that, in the assembly configuration, the cap 3" remains raised with respect to the mouth 5 of the bottle 7, so as to allow air to be extracted from the internal volume 70 of the bottle 7, during the lyophilization step.

**[0075]** The operation of the closure device, particularly for bottles of lyophilized products, is apparent and evident from the above-described.

**[0076]** In particular, the closure device 1 consists of two capsules 9 and 15 which can be reciprocally fixedly fitted to each other, during the steps of producing the same, indeed being such two capsules 9, 15 able to reach the line for packaging lyophilized products being already assembled in a single preassembled closure assembly 2. This is possible as in the closure device 1 channels 90 for passing air are provided, which allow to extract air from the internal volume 70 of the bottle, in order to lyophilize the product contained therein, when the preassembled closure assembly 2 is placed, with their tabs 29, on the upper edge of the mouth 5 of the bottle 7.

**[0077]** Once air is extracted from the bottle 7 and the product contained therein is thus lyophilized, the preassembled closure assembly 2 on the neck 11 of the bottle 7 can be tightened, accordingly retaining to seal the closure cap 3 on the mouth 5 of the bottle 7.

**[0078]** As well as inner capsule 9 and outer tab 15 can be handled as a single body, the closure cap 3 can also be retained, with interference, inside the preassembled closure assembly 2. In this way, all the three components of the closure device 1 can be handled as a single body.

**[0079]** It was practically found that the closure device, particularly for bottles of lyophilized products, according to the present finding, performs the task as well as the prefixed objects, as the assembly of outer tab, inner capsule and closure body can be applied, as a single body, in a single step, to the bottle, and tightened thereon, after lyophilizing the content thereof, by extracting air. The application of the above-mentioned assembly can be further performed in a totally automatized manner.

**[0080]** Another advantage of the invention consists in being entirely made of a plastic-type material and being pressure-appliable on the bottles, without generating powders incompatible with hygiene and sterility requirements of the product contained in the bottle itself, as instead occurs in the case of closure systems made at least partially of aluminium.

**[0081]** A further advantage of the closure device consists in being made in a minimum number of pieces, i.e., outer tab, inner capsule, and closure cap, being easy to be assembled to each other and easy to be transported and handled as a single body.

**[0082]** The fact that the number of distinct components of the closure system is minimized makes both producing the closure system and assembling it on the bottle cheaper and quicker. In particular, the fact that the closure device can be handled as a single body and meanwhile is configured to allow the air to be extracted as required for performing the step of lyophilizing the product in the bottle remarkably simplifies the process of packaging bottles of lyophilized products. Indeed, positioning the closure device resting on the mouth of the bottle, extracting air from the bottle, and pressure-tightening the closure device on the mouth of the bottle is sufficient.

**[0083]** Another advantage of the closure device consists in that it drastically reduces the problems arising from losing one or more components when packaging bottles of lyophilized products, or from incorrectly positioning a component with respect to the other, being the three components of the closure device already pre-assembled to each other.

**[0084]** The closure device, particularly for bottles of lyophilized products, thus conceived is susceptible to a number of modifications and variants, all falling within the scope of the inventive concept.

**[0085]** Furthermore, all the details can be replaced by other technically equivalent elements.

**[0086]** In practice, the used materials, as long as compatible with the specific use, as well as dimensions and contingent forms, can be any depending on the requirements.

## Claims

1. Closure device (1), particularly for bottles of lyophilized products, comprising:

- a perforable closure cap (3), adapted for closing the mouth (5) of a bottle (7);
- an inner capsule (9), fittable at least on said closure cap (3), comprising an upper portion (93) in which an opening (13) adapted for allowing access to said closure cap (3) is present, and a side wall (94) comprising a plurality of elastically deformable tabs (29) protruding radially towards the inside of said inner capsule (9);
- an outer capsule (15) fittable on said inner cap-

sule (9) and comprising an upper portion (17), at least partially removable, adapted for closing said opening (13) of said inner capsule (9);

said closure device (1) having a closing configuration wherein said outer capsule (15) is fixedly fitted to said inner capsule (9), said inner capsule (9) is fitted to the neck (11) of said bottle (7) and said tabs (29) engage at the bottom with the lip (31) of said bottle (7) so as to retain said closure cap (3) in a closing configuration to seal said mouth (5) of said bottle (7);

said closure device (1) having a preassembly configuration wherein:

- said inner capsule (9) rests, with said tabs (29), on the mouth (5) of said bottle (7),
- a slit (30) is present between said closure cap (3) and said mouth (5) of said bottle (7), adapted for allowing the passage of air;

**characterized in that** at least one air passage channel (90) is obtained in said inner capsule (9), said channel (90) extending, in the axial direction (A) towards said opening (13), beyond said tabs (29), in said preassembly configuration, said outer capsule (15) being fixedly fitted on said inner capsule (9) to form a preassembled closure assembly (2) wherein said upper portion (17) of said outer capsule (15) is in abutment against said upper portion (93) of said inner capsule (9), and said at least one air passage channel (90), putting the internal volume (70) of said bottle (7) in fluid communication with the external environment through said slit (30).

2. Closure device (1) according to claim 1, wherein said at least one air passage channel (90) has a length (L), in the axial direction, greater than the thickness (S), in the axial direction, of said lip (31) of said bottle (7), in said preassembly configuration, said at least one air passage channel (90) facing said lip (31) so that the axial ends (91, 92) of said at least one channel (90) respectively span across said thickness (S) of said lip (31).

3. Closure device (1) according to claim 1 or 2, wherein said at least one air passage channel (90) is defined by a recess made in said side wall (94) of said inner capsule (9).

4. Closure device (1) according to one or more of the preceding claims, wherein said at least one air passage channel (90) is defined by a through opening (95) obtained in said side wall (94) of said inner cap-

sule (9).

5. Closure device (1) according to one or more of the preceding claims, wherein a plurality of said air passage channels (90) are obtained in said inner capsule (9), said air passage channels (90) being preferably inter-spaced with said tabs (29). 5
6. Closure device (1) according to one or more of the preceding claims, wherein said outer capsule (15) comprises a side wall (151) comprising at least one rib (35) protruding radially towards the inside of said outer capsule (15) configured to engage in a corresponding seat (37) obtained on the outer surface of the side wall (94) of said inner capsule (9), said at least one rib (35) engaging in said corresponding seat (37) when said outer capsule (15) is fixedly fitted on said inner capsule (9). 10 15
7. Closure device (1) according to one or more of the preceding claims, wherein said inner capsule (9) comprises one or more protrusions (45) protruding radially towards the inside of said inner capsule (9) configured to retain, with interference, the closure cap (3) inside said inner capsule (9). 20 25
8. Closure device (1) according to claim 7 wherein said one or more protrusions (45) are formed in proximity of the top of said inner capsule (9) and are adapted for retaining said closure cap (3) inside said inner capsule (9) so that the upper surface of said closure cap (3) abuts against said upper portion (93) of said inner capsule (9). 30
9. Process for closing a bottle of lyophilized products, by means of a closure device (1) according to one or more of the preceding claims, comprising the steps of: 35
  - (a) providing a closure cap (3), and an outer capsule (15) fixedly fitted to an inner capsule (9), said outer capsule (15) fitted to said inner capsule (9) defining a preassembled closure assembly (2) wherein said upper portion (17) of said outer capsule (15) abuts against said upper portion (93) of said inner capsule (9), said preassembled closure assembly (2) being adapted to house said closure cap (3); 40 45
  - (b) placing said preassembled closure assembly (2) and said closure cap (3) on the mouth (5) of a bottle (7) containing a product to be lyophilized; 50
  - (c) extracting the air contained in said bottle (7) to lyophilize said product to be lyophilized;
  - (d) tightening said preassembled closure assembly (2) and said closure cap (3) on the mouth (5) of said bottle (7). 55

10. Process for closing a bottle of lyophilized products, according to the preceding claim, wherein, at least in said step (a), said closure cap (3) is inserted in said preassembled closure assembly (2) and held there by means of one or more protrusions (45) protruding radially towards the inside of said inner capsule (9).



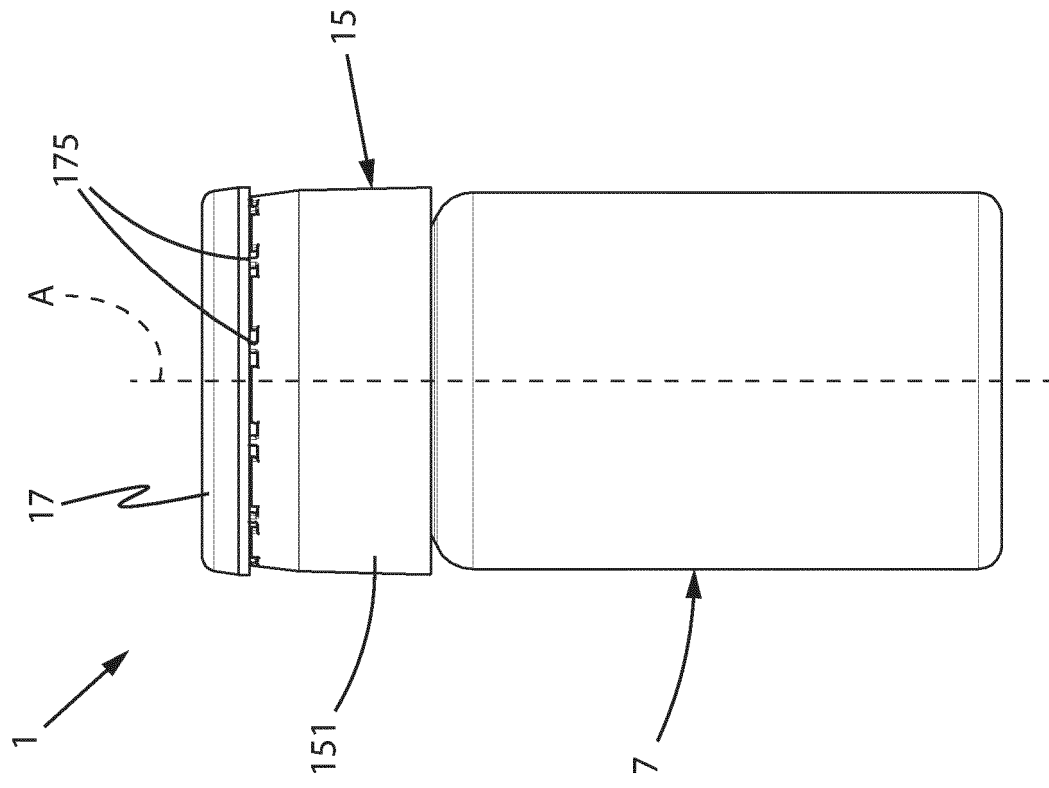


Fig. 1

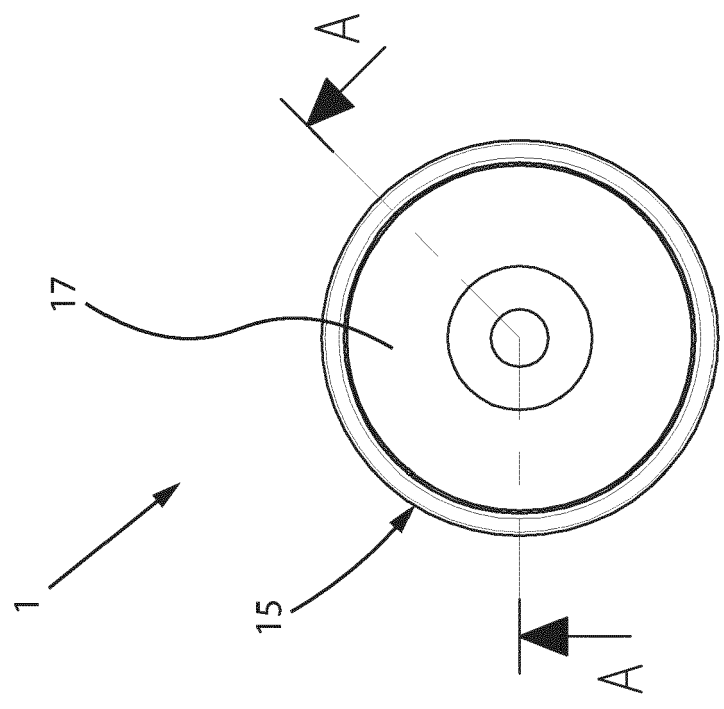


Fig. 2

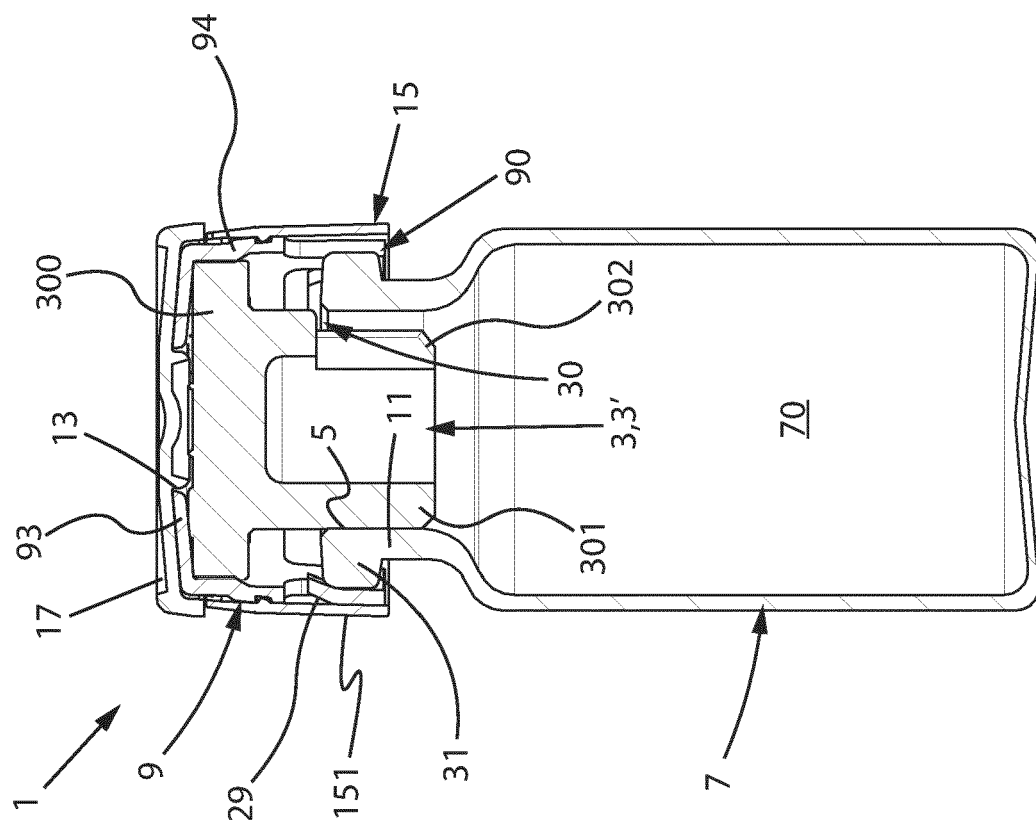
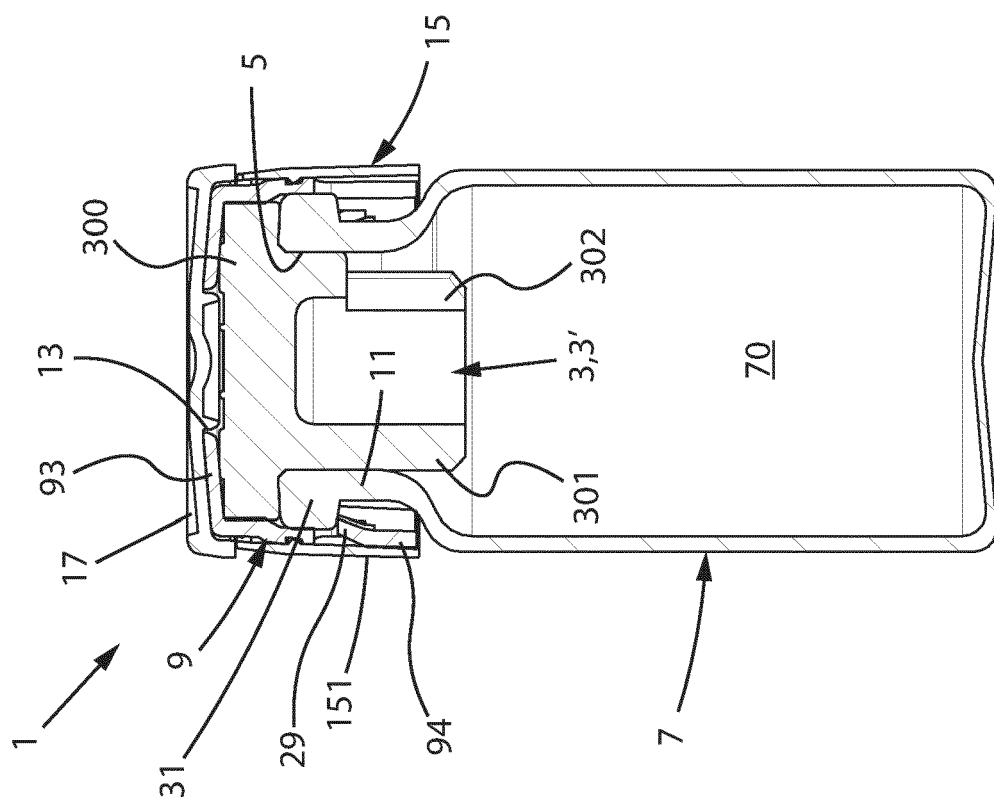
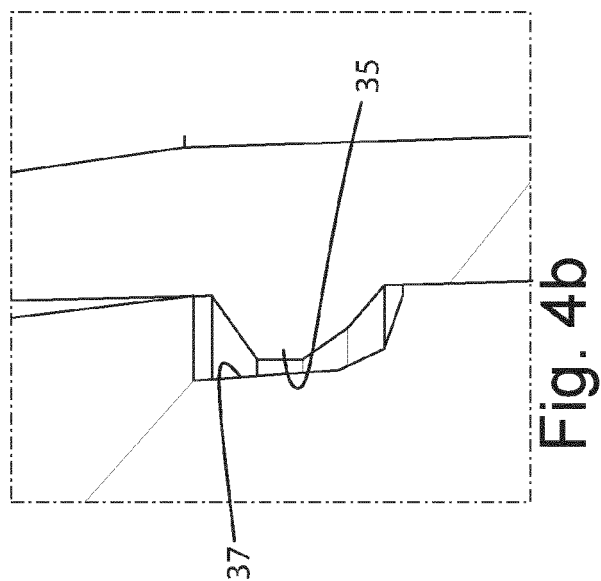
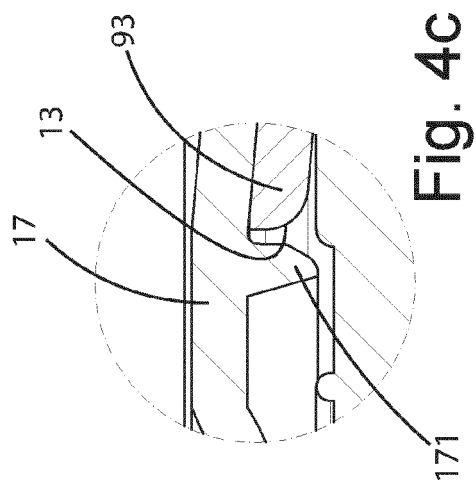
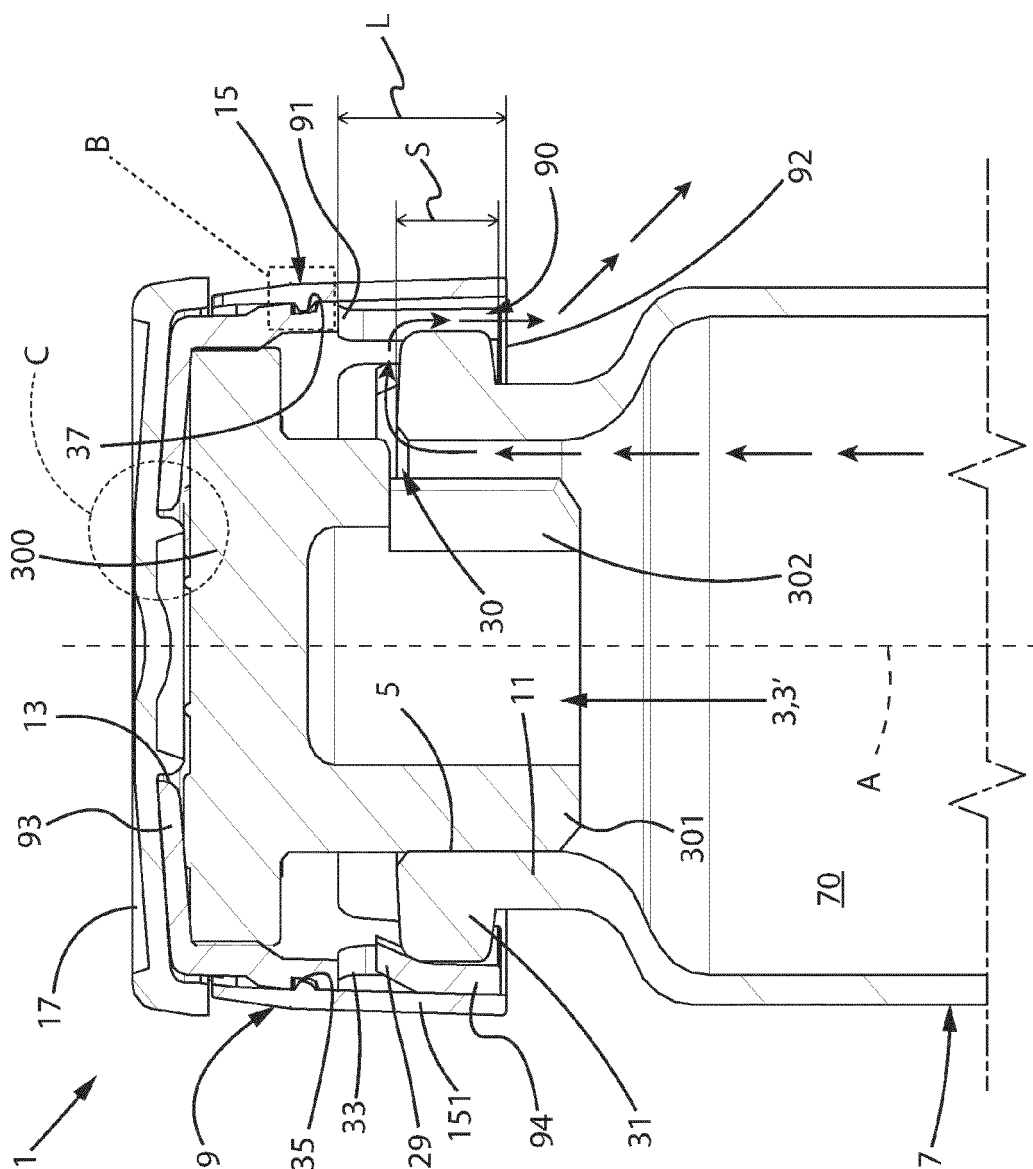
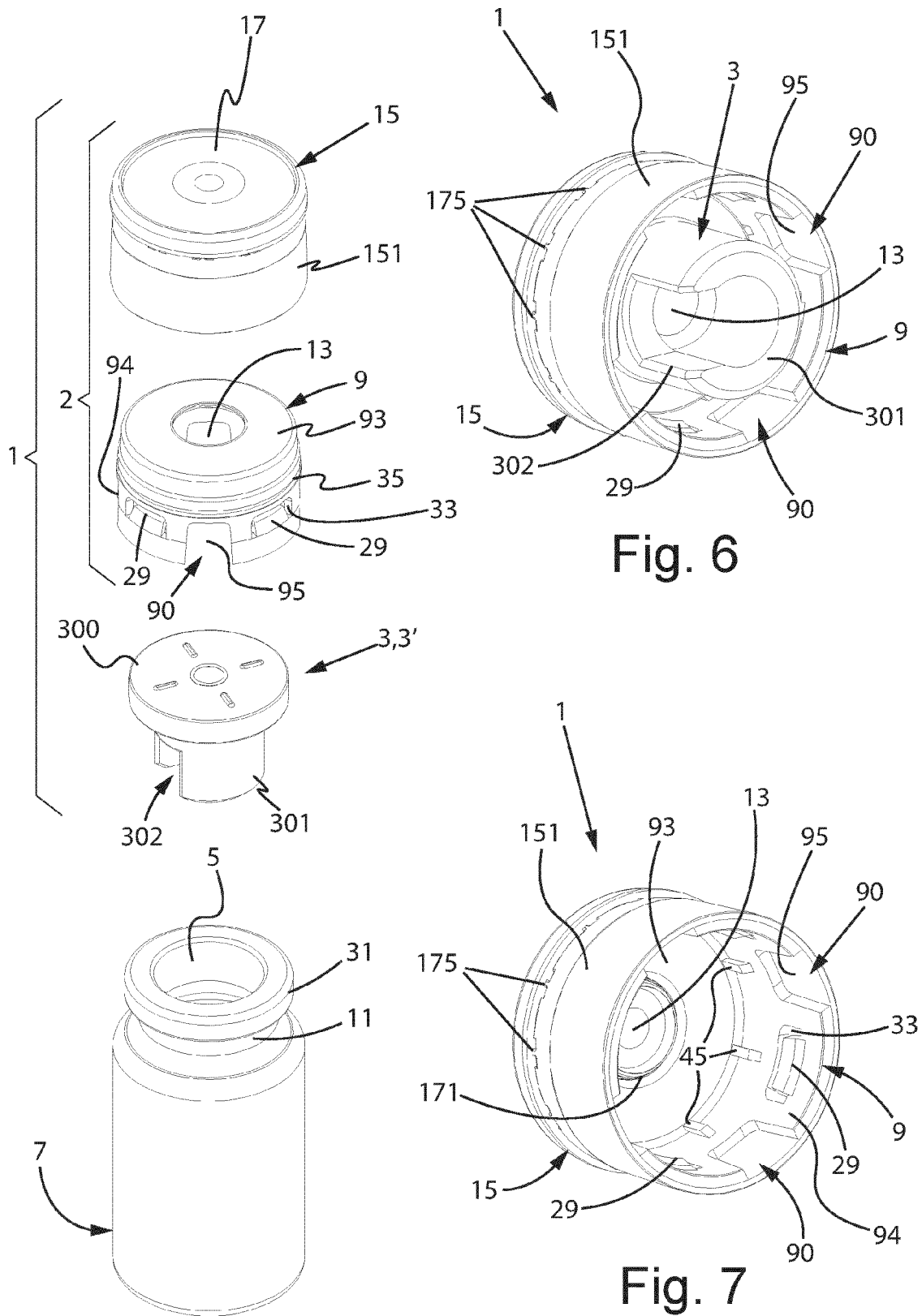


Fig. 4



மேற்கூறியவற்றைப் பற்றி





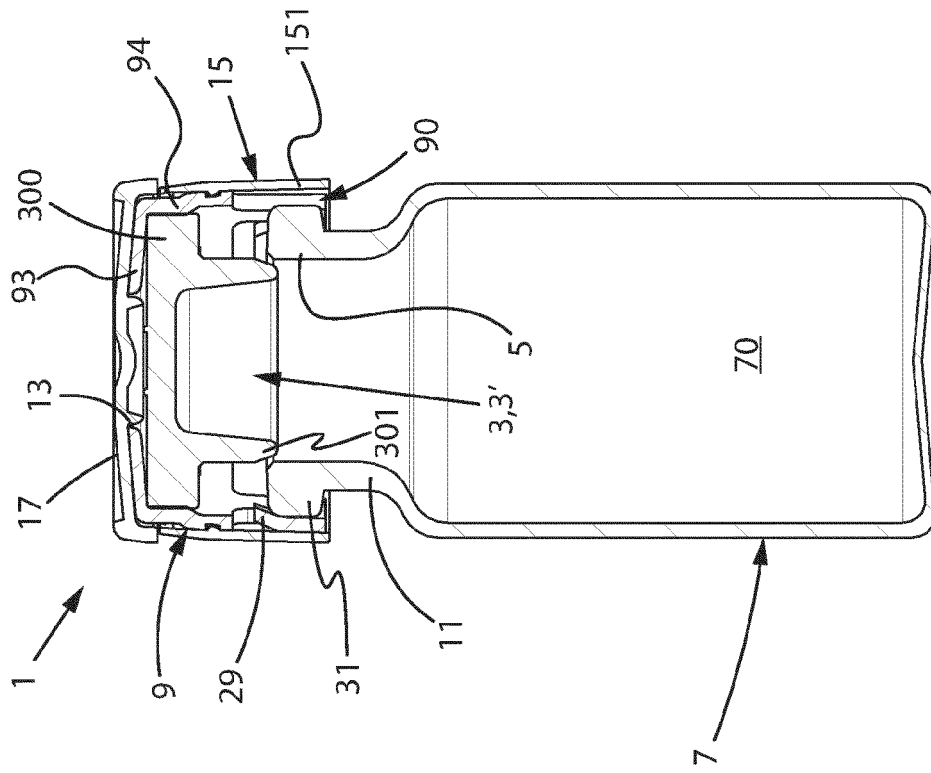


Fig. 9

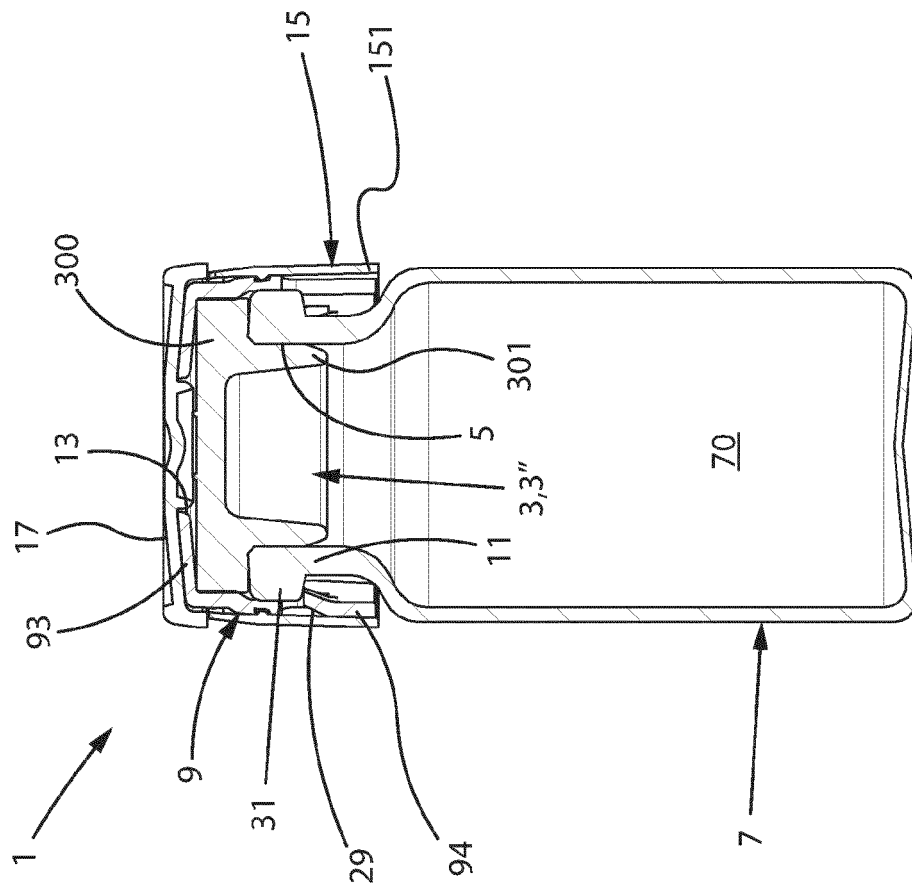


Fig. 8

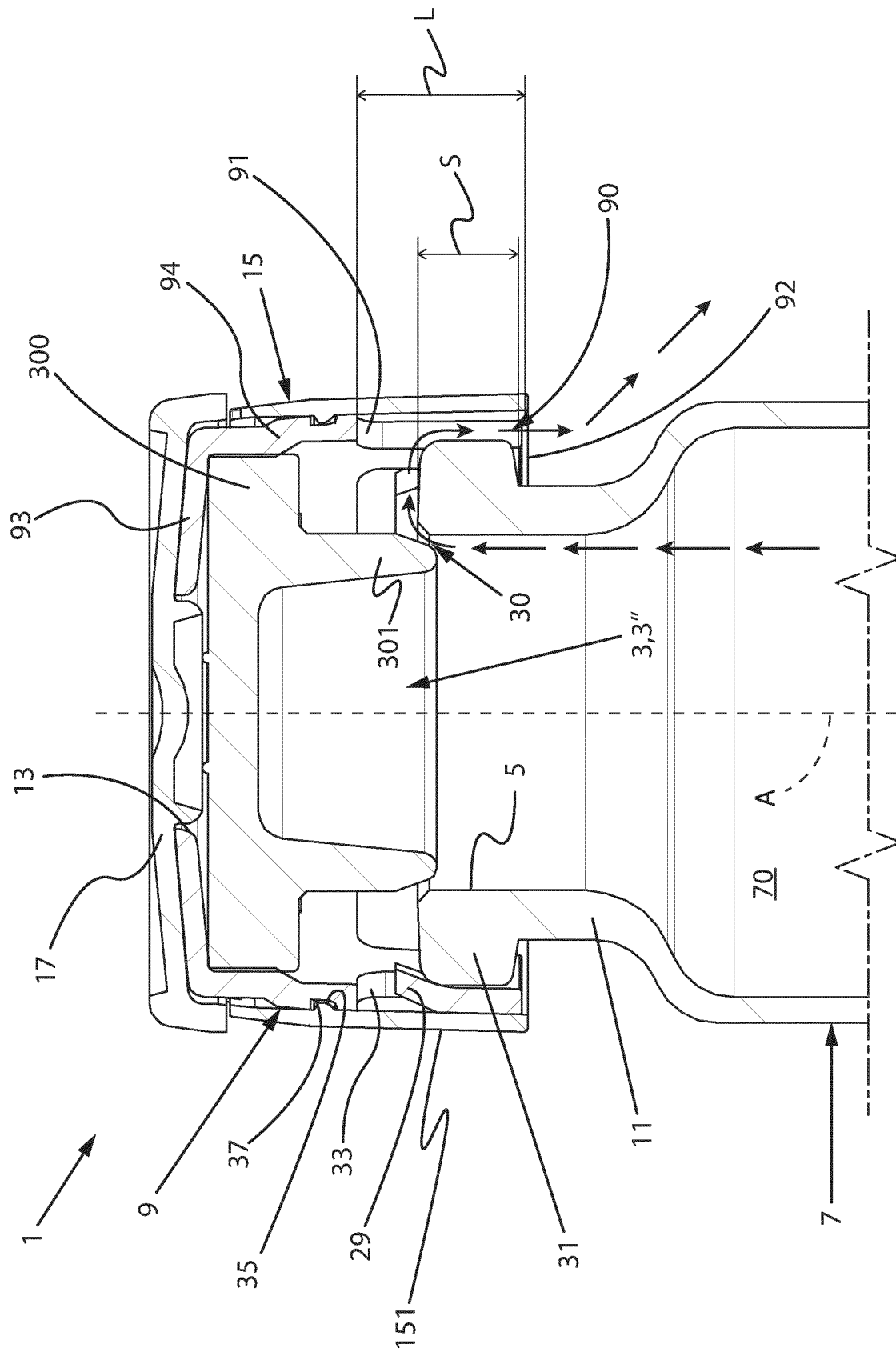
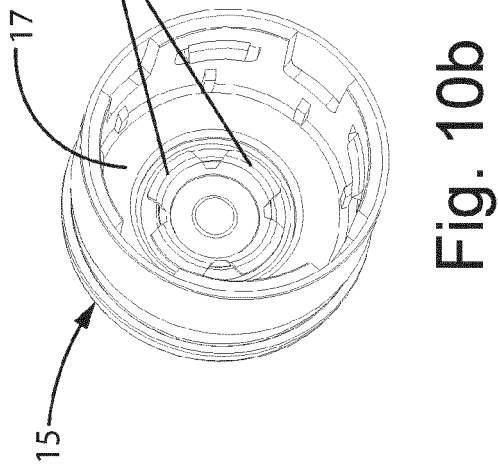
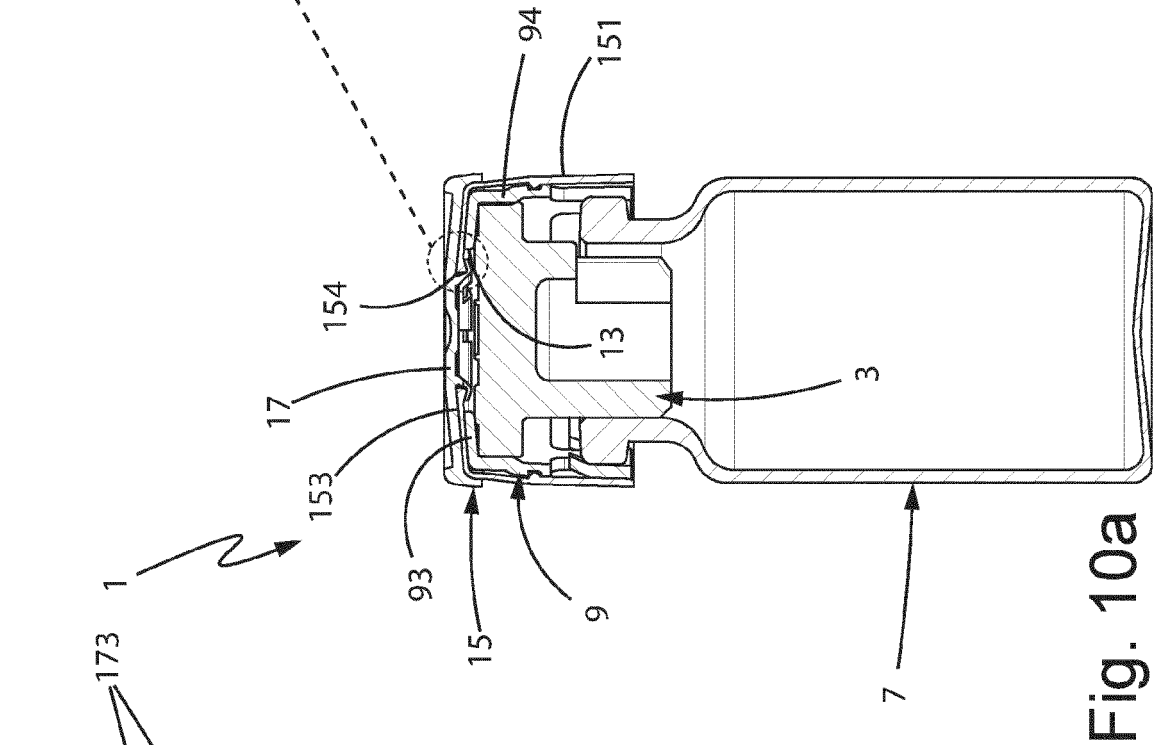
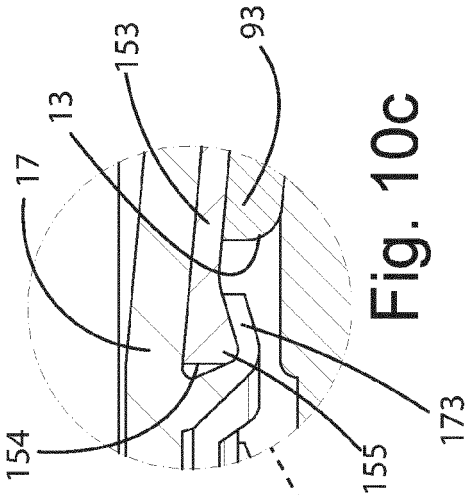
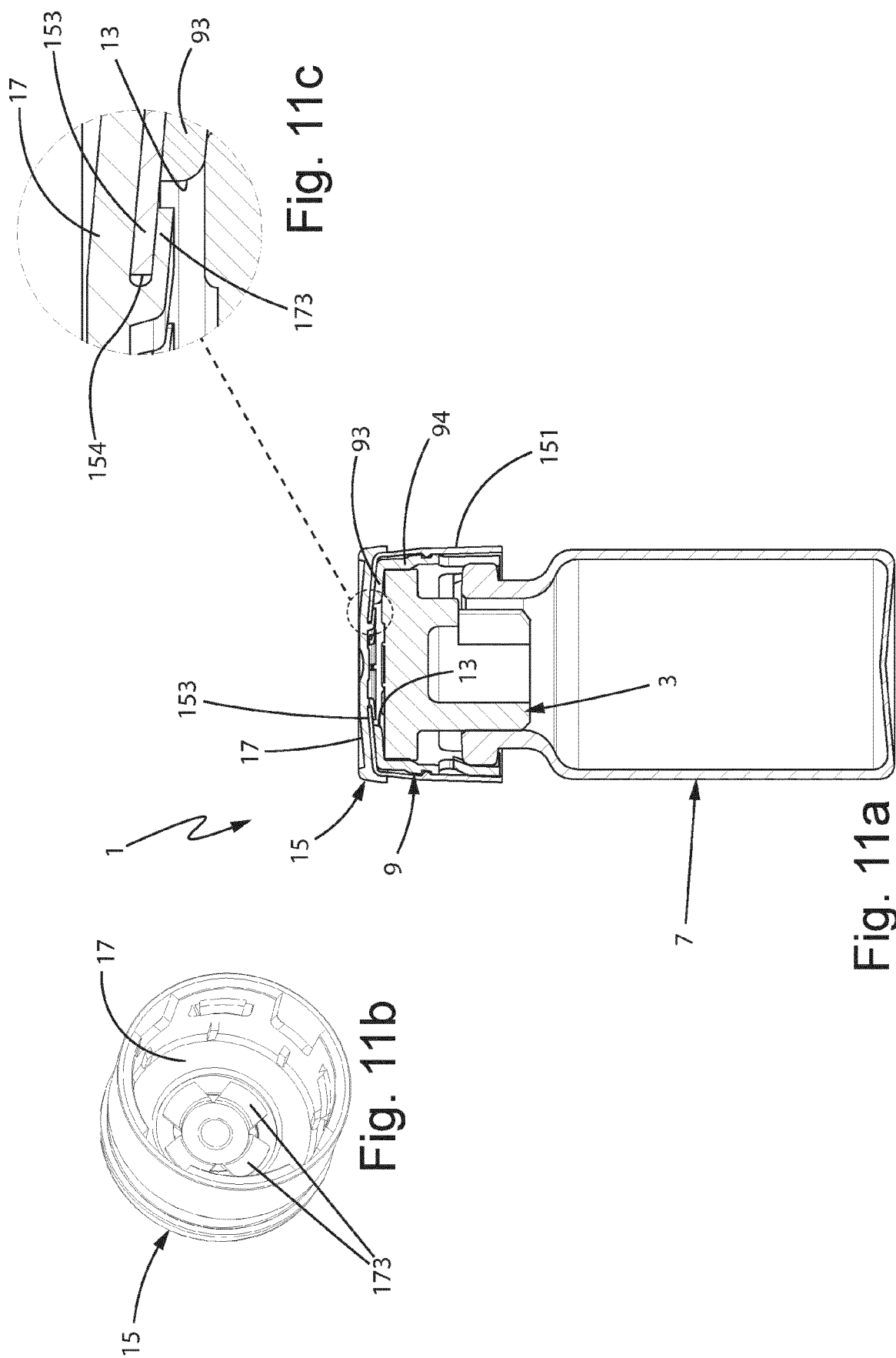
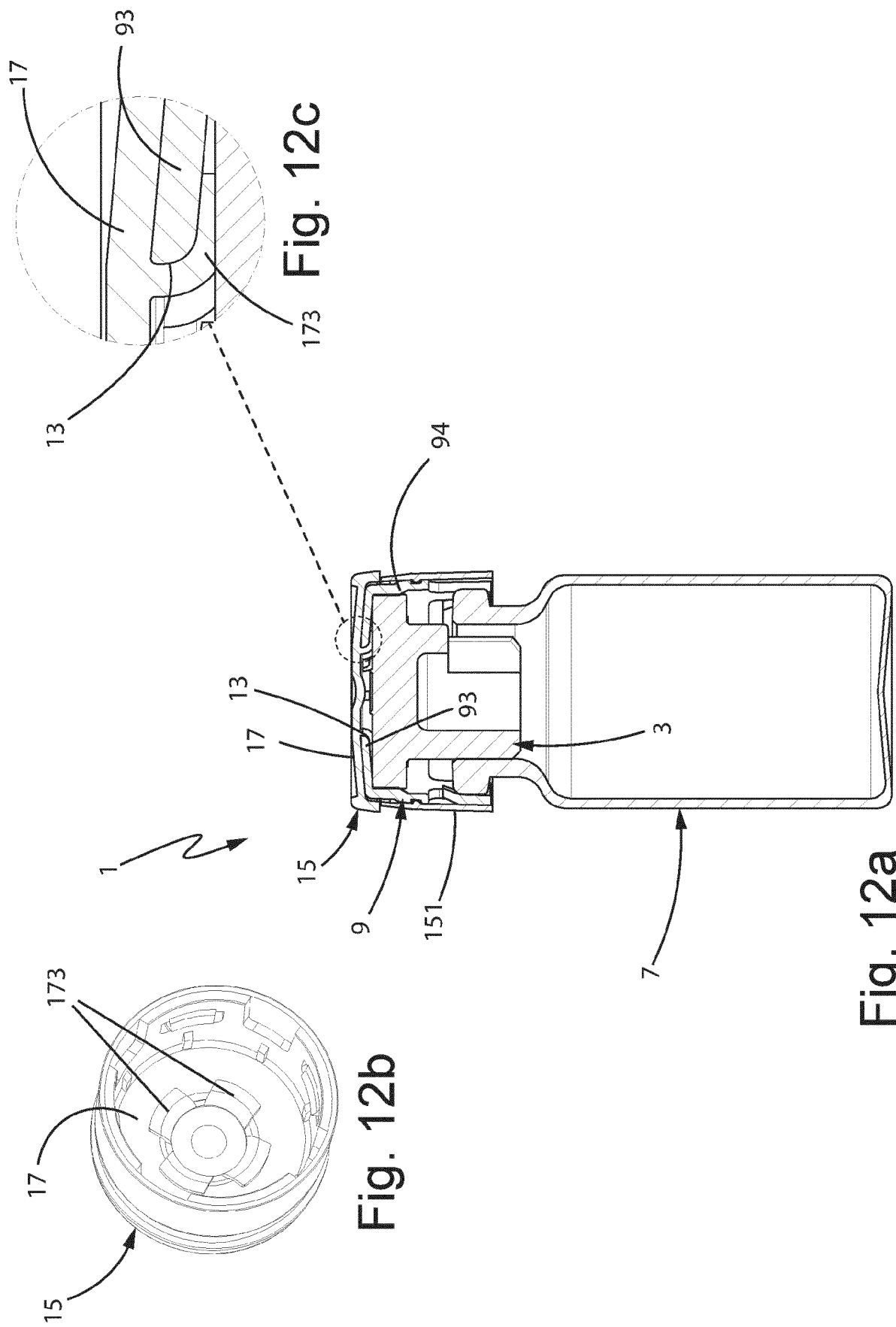


Fig. 9a











## EUROPEAN SEARCH REPORT

Application Number

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EPO FORM 1503 03.82 (P04C01)

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
Y	US 5 314 084 A (FOLTA CHRISTOPHER M [US] ET AL) 24 May 1994 (1994-05-24) * figures 1-13 *	1-10	INV. B65D51/24
Y	FR 2 893 922 A1 (BIOCORP RECH ET DEV SA [FR]) 1 June 2007 (2007-06-01) * figures 1-14 *	2-6, 9	
Y	IT MI20 110 789 A1 (IBSA INST BIOCHIMIQUE SA) 10 November 2012 (2012-11-10) * see element 12c; figures 6, 7 *	1-10	
Y	US 8 777 031 B2 (ANEAS ANTOINE [FR]; WEST PHARM SERV DRUG RES LTD [DE]) 15 July 2014 (2014-07-15) * figures 1-6, 8 *	2-6, 9	
Y	US 8 839 971 B2 (ANEAS ANTOINE [FR]; WEST PHARM SERV DRUG RES LTD [DE]) 23 September 2014 (2014-09-23) * figures 3-9 *	2-6, 9	TECHNICAL FIELDS SEARCHED (IPC)
Y	US 2013/240476 A1 (ANEAS ANTOINE [FR]) 19 September 2013 (2013-09-19) * figures 3-9 *	2-6, 9	B65D
The present search report has been drawn up for all claims			
Place of search <b>The Hague</b>		Date of completion of the search <b>8 November 2023</b>	Examiner <b>Dominois, Hugo</b>
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ..... & : member of the same patent family, corresponding document	

**ANNEX TO THE EUROPEAN SEARCH REPORT  
ON EUROPEAN PATENT APPLICATION NO.**

EP 23 18 1167

08-11-2023

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on  
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
<b>US 5314084 A</b>	<b>24-05-1994</b>	<b>AU 5083993 A</b>	<b>15-03-1994</b>
		<b>CA 2142905 A1</b>	<b>03-03-1994</b>
		<b>DE 69302476 T2</b>	<b>10-10-1996</b>
		<b>EP 0655042 A1</b>	<b>31-05-1995</b>
		<b>HK 1007722 A1</b>	<b>23-04-1999</b>
		<b>JP 3514760 B2</b>	<b>31-03-2004</b>
		<b>JP H08500563 A</b>	<b>23-01-1996</b>
		<b>US 5314084 A</b>	<b>24-05-1994</b>
		<b>WO 9404424 A1</b>	<b>03-03-1994</b>
-----			
<b>FR 2893922 A1</b>	<b>01-06-2007</b>	<b>CN 101316769 A</b>	<b>03-12-2008</b>
		<b>FR 2893922 A1</b>	<b>01-06-2007</b>
-----			
<b>IT MI20110789 A1</b>	<b>10-11-2012</b>	<b>NONE</b>	
-----			
<b>US 8777031 B2</b>	<b>15-07-2014</b>	<b>AU 2009213918 A1</b>	<b>20-08-2009</b>
		<b>CA 2714618 A1</b>	<b>20-08-2009</b>
		<b>CN 101952179 A</b>	<b>19-01-2011</b>
		<b>CY 1113066 T1</b>	<b>13-04-2016</b>
		<b>EP 2242701 A1</b>	<b>27-10-2010</b>
		<b>ES 2387600 T3</b>	<b>27-09-2012</b>
		<b>FR 2927316 A1</b>	<b>14-08-2009</b>
		<b>JP 5364869 B2</b>	<b>11-12-2013</b>
		<b>JP 2011511741 A</b>	<b>14-04-2011</b>
		<b>PL 2242701 T3</b>	<b>31-10-2012</b>
		<b>US 2011000872 A1</b>	<b>06-01-2011</b>
		<b>WO 2009101354 A1</b>	<b>20-08-2009</b>
-----			
<b>US 8839971 B2</b>	<b>23-09-2014</b>	<b>AT E473931 T1</b>	<b>15-07-2010</b>
		<b>AU 2008240577 A1</b>	<b>30-10-2008</b>
		<b>BR PI0807479 A2</b>	<b>13-05-2014</b>
		<b>CA 2677408 A1</b>	<b>30-10-2008</b>
		<b>CN 101626958 A</b>	<b>13-01-2010</b>
		<b>CY 1112759 T1</b>	<b>10-02-2016</b>
		<b>EP 2125548 A1</b>	<b>02-12-2009</b>
		<b>ES 2347208 T3</b>	<b>26-10-2010</b>
		<b>FR 2912384 A1</b>	<b>15-08-2008</b>
		<b>JP 5102312 B2</b>	<b>19-12-2012</b>
		<b>JP 2010517885 A</b>	<b>27-05-2010</b>
		<b>PL 2125548 T3</b>	<b>30-11-2010</b>
		<b>US 2010050575 A1</b>	<b>04-03-2010</b>
		<b>WO 2008129144 A1</b>	<b>30-10-2008</b>
-----			
<b>US 2013240476 A1</b>	<b>19-09-2013</b>	<b>CN 103384632 A</b>	<b>06-11-2013</b>
		<b>EP 2643232 A1</b>	<b>02-10-2013</b>
		<b>FR 2967655 A1</b>	<b>25-05-2012</b>

EPO FORM P0459

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ANNEX TO THE EUROPEAN SEARCH REPORT  
ON EUROPEAN PATENT APPLICATION NO.

EP 23 18 1167

5 This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.  
The members are as contained in the European Patent Office EDP file on  
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

08-11-2023

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		US 2013240476 A1	19-09-2013
		WO 2012069538 A1	31-05-2012
-----			

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82