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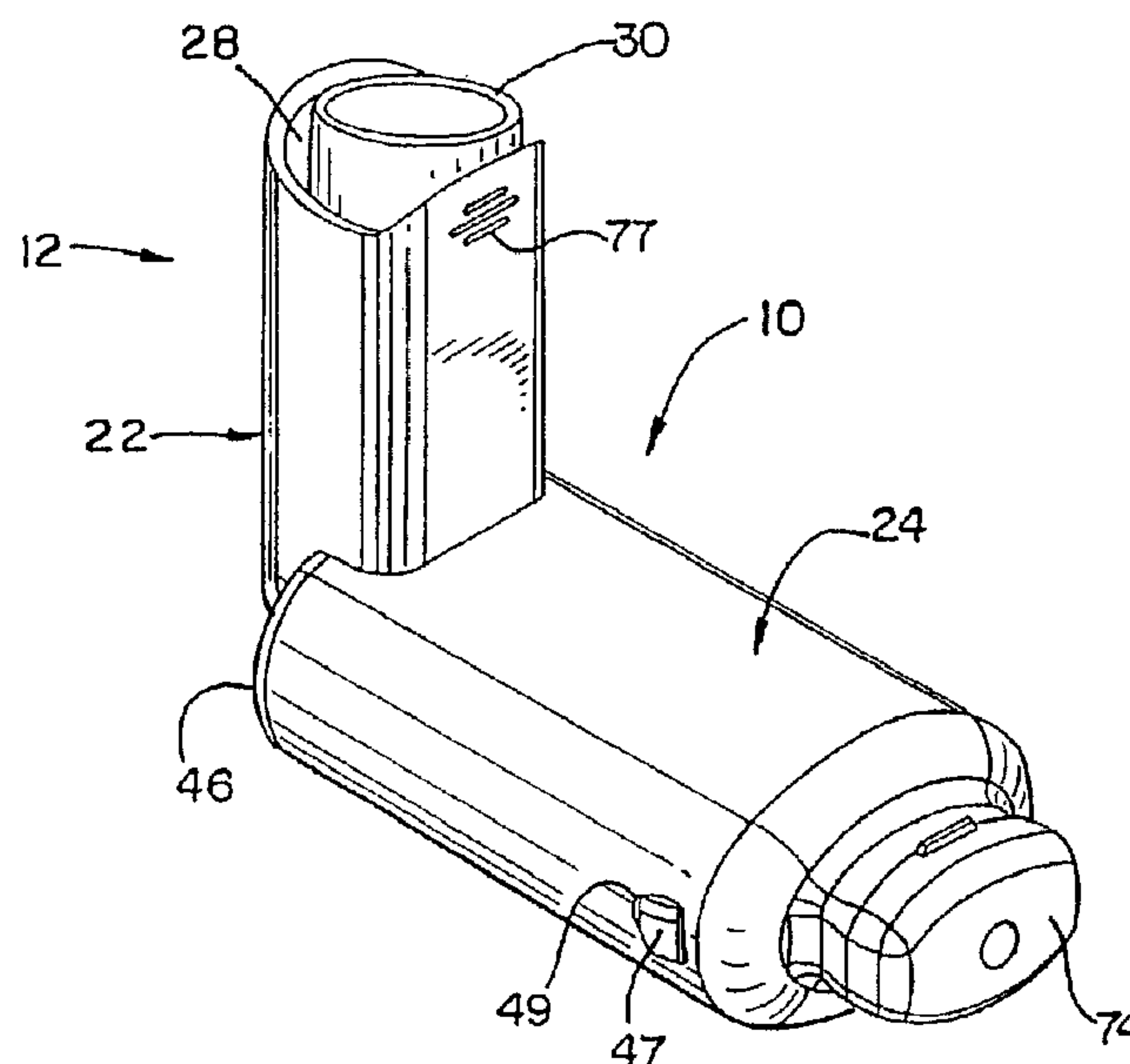
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(54) Titre : APPAREIL ET SYSTEME DE LIBERATION DE MEDICAMENT EN AEROSOL

(54) Title: AEROSOL MEDICATION DELIVERY APPARATUS AND SYSTEM



(57) **Abrégé/Abstract:**

An improved aerosol medication delivery apparatus and system. The aerosol medication delivery apparatus includes a canister-holding portion and a chamber housing. The canister-holding portion has a receptacle for receipt of a pMDI canister containing a medication and a propellant to provide the aerosol medication delivery system. The canister-holding portion has a discharge orifice communicating with the receptacle to direct an aerosol into an interior of the chamber housing at an input end thereof. The chamber housing also has an output end from which medication can be withdrawn by inhalation by a patient. According to one aspect, the aerosol delivery system includes a containment baffle located at the output end of the chamber housing to partially block the output. According to another aspect, the canister-holding portion and the chamber housing are coupled together by a mechanism that provides for the canister-holding portion to be retracted into the chamber housing for storage. The coupling mechanism also allows the canister-holding portion to be extracted from its storage position in the chamber housing and pivoted into position for use when dispensing medication. In another aspect, an aerosol medication apparatus includes a chamber housing with an input end to receive the discharge of a medication from a pMDI canister and an output end including a containment baffle that partially blocks the output end. The pMDI canister may be received in an elastomeric backpiece that is adapted to accommodate various sizes of actuator boot mouthpieces.



ABSTRACT

An improved aerosol medication delivery apparatus and system. The aerosol medication delivery apparatus includes a canister-holding portion and a chamber housing. The canister-holding portion has a receptacle for receipt of a pMDI canister containing a medication and a propellant to provide the aerosol medication delivery system. The canister-holding portion has a discharge orifice communicating with the receptacle to direct an aerosol into an interior of the chamber housing at an input end thereof. The chamber housing also has an output end from which medication can be withdrawn by inhalation by a patient. According to one aspect, the aerosol delivery system includes a containment baffle located at the output end of the chamber housing to partially block the output. According to another aspect, the canister-holding portion and the chamber housing are coupled together by a mechanism that provides for the canister-holding portion to be retracted into the chamber housing for storage. The coupling mechanism also allows the canister-holding portion to be extracted from its storage position in the chamber housing and pivoted into position for use when dispensing medication. In another aspect, an aerosol medication apparatus includes a chamber housing with an input end to receive the discharge of a medication from a pMDI canister and an output end including a containment baffle that partially blocks the output end. The pMDI canister may be received in an elastomeric backpiece that is adapted to accommodate various sizes of actuator boot mouthpieces.

AEROSOL MEDICATION DELIVERY APPARATUS AND SYSTEM

FIELD OF THE INVENTION

This invention relates to a portable aerosol medication delivery apparatus and system for administering a desired respirable dosage of a medication in aerosol form to a patient's lungs by oral inhalation.

BACKGROUND OF THE INVENTION

The use of aerosol medication delivery systems to administer medication in aerosol form to a patient's lungs by inhalation is well known in the art.

Conventional aerosol medication delivery systems include pressurized metered-dose inhalers (pMDIs). Conventional pMDIs typically have two components: a canister component in which the medication particles are stored under pressure in a suspension or solution form and a receptacle component used to hold and actuate the canister. The canister component typically includes a valved outlet from which the contents of the canister can be discharged. Aerosol medication is dispensed from the pMDI by applying a force on the canister component to push it into the receptacle component thereby opening the valved outlet and causing the medication particles to be conveyed from the valved outlet through the receptacle component and discharged from an outlet of the receptacle component. Upon discharge from the canister, the medication particles are "atomized" forming an aerosol. It is intended that the patient coordinate the discharge of aerosolized medication with his or her inhalation so that the medication particles are entrained in the patient's inspiratory flow and conveyed to the lungs. Typically, pMDIs have used propellants, such as chlorofluorocarbons (CFCs), to pressurize the contents of the canister and to propel the medication particles out of the outlet of the receptacle component.

Although conventional pMDIs have been widely used to provide many patients with the benefits of aerosol medication, conventional pMDIs have certain drawbacks. For example, an objective of aerosol therapy has been the optimization of the mass percentage of the respirable dose of an aerosol medication in order to optimize deposition in a patient's lungs to achieve a full therapeutic effect with the

1 least possible side-effects. Conventional pMDIs may not have always been able to
2 meet this objective.

3 One drawback associated with conventional pMDIs relates to the discharge
4 velocity of the aerosol particles. Medication particles are stored under considerable
5 pressure in the pMDI canister and as a consequence, their velocity may be high upon
6 discharge.

7 Among other things, the effect of high velocity contributes to a significant
8 number of aerosol medication particles impacting and depositing in the patient's
9 oropharynx and upper airway rather than continuing their pathway through the upper
10 airway and into the lungs. Such impaction and deposition may result in a significant
11 portion of the medication dose being systemically absorbed or ingested. As
12 documented in the literature [J. L. Rau, "Respiratory Care Pharmacology", 4th ed.
13 (1994, Mosby) at pp. 256-261; K. Meeran, A. Hattersley, J. Burrin, R. Shiner, K.
14 Ibbertson K., "Oral and Inhaled Corticosteroids Reduce Bone Formation as Shown by
15 Plasma Osteocalcin Levels", *Am. J. Respir. Crit. Care Med* 151:333-336], systemic
16 absorption or ingestion of aerosol medication may cause a patient adverse side-effects,
17 particularly when the aerosol medication is a corticosteroid. Some of these adverse
18 side-effects include pharyngeal candidiasis, hoarseness, and adrenal suppression.

19 The high velocity of the aerosol medication particles may also accentuate the
20 difficulty of a significant number of patients, particularly the very young and elderly,
21 to coordinate actuation of the pMDI with inhalation of the aerosol medication
22 particles generated. Failure to coordinate the actuation and inhalation maneuvers and
23 failure to inhale slowly, have been documented by the literature [S.P. Newman,
24 "Aerosol Deposition Considerations in Inhalation Therapy" *Chest* / 88 / 2 / August,
25 1985 / Supplement] as contributing to a significant reduction in the number of aerosol
26 medication particles inspired and deposited in a patient's lungs.

27 Impaction and deposition of aerosol medication particles on a patient's
28 oropharynx and upper airway may also contribute to an unpleasant taste in a patient's
29 mouth, particularly with certain medication solution or suspension formulations such
30 as flunisolide.

31 In addition to high particle velocity, a significant number of large non-

1 respirable medication particles may be produced upon discharge as a result of the
2 medication suspension or solution formulation as well as the atomization process. As
3 mentioned above, conventional pMDIs have used CFCs to propel the medication out
4 of the pMDI actuator outlet. In view of environmental concerns with CFCs, there has
5 been a growing interest in using non-CFC propellants, such as hydrofluoroalkanes
6 (HFAs).

7 Accordingly, it is an object of the invention to provide for the delivery of
8 respirable medication particles from a pMDI canister with a device that overcomes the
9 disadvantages of the prior art.

10 It is another object to provide a device which reduces the need for a patient to
11 coordinate activation of a pMDI canister with inhalation.

12 It is a further object to provide a device that reduces the delivery of non-
13 respirable medication particles from a pMDI canister to a patient.

14 It is yet another object to provide a device that reduces the impaction of
15 medication particles on a patient's oropharynx and upper airway.

16 It is still another object to provide a device for the delivery of aerosol
17 medication from a pMDI canister that uses an HFA propellant instead of a CFC
18 propellant.

19 20 SUMMARY OF THE INVENTION

21 In order to address the above noted objectives, as well as other objectives, the
22 present invention provides an improved aerosol medication delivery apparatus. The
23 aerosol medication delivery apparatus includes a canister-holding portion and a
24 chamber housing. The canister-holding portion has a receptacle for receipt of a pMDI
25 canister containing a medication and a propellant. The canister-holding portion has a
26 discharge orifice communicating with the receptacle to direct an aerosol into an
27 interior of the chamber housing at an input end thereof. The chamber housing also
28 has an output end from which medication can be withdrawn by inhalation by a patient.
29 The canister-holding portion and the chamber housing are coupled together by a
30 mechanism that provides for the canister-holding portion to be retracted into the
31 chamber housing for storage. The coupling mechanism also allows the canister-

1 holding portion to be extracted from its storage position in the chamber housing and
2 pivoted into position for use when dispensing medication. According to one aspect of
3 the present invention, the aerosol delivery system includes a containment baffle
4 located at the output end of the chamber housing to partially block the output end.

5 According to another aspect, the canister-holding portion and the chamber
6 housing are coupled together by a mechanism that provides for the canister-holding
7 portion to be retracted into the chamber housing for storage. The coupling mechanism
8 also allows the canister-holding portion to be extracted from its storage position in the
9 chamber housing and pivoted into position for use when dispensing medication.

10 In another aspect, an aerosol medication delivery apparatus includes a chamber
11 housing with an input end and an output end. The input end receives the discharge of a
12 medication from a pMDI canister and the output end includes a containment baffle
13 that partially blocks the output end. The pMDI canister is received in an elastomeric
14 backpiece that is adapted to accommodate various sizes of actuator boot mouthpieces.
15

16 BRIEF DESCRIPTION OF THE DRAWINGS

17 FIG. 1 is a perspective view of an aerosol medication delivery system in
18 accordance with an embodiment of the present invention.

19 FIG. 2 is an exploded view of the aerosol medication delivery system of FIG.
20 1.

21 FIG. 3 is a side view of the aerosol medication delivery system of FIG. 1.

22 FIG. 4 is a side sectional view of the aerosol medication delivery system of
23 FIG. 1.

24 FIG. 5 is a front view of the canister-holding portion shown in FIG. 1.

25 FIG. 6 is a sectional view of the canister-holding portion of FIG. 5 taken along
26 line 6—6'.

27 FIG. 7 is a side view of the downstream housing portion in FIG. 1.

28 FIG. 8 is an end view of the downstream housing portion shown in FIG. 7.

29 FIG. 9 is a sectional view of the downstream housing portion shown in FIG. 8
30 taken along line 9—9'.

31 FIG. 10 is a sectional view of the embodiment in FIG. 1 in a retracted position.

1 FIG. 11 is an enlarged sectional view of an inside upstream portion of the
2 chamber housing of FIG. 1 showing part of the coupling mechanism.

3 FIG. 12 is a perspective view of an aerosol medication delivery system in
4 accordance with another embodiment of the present invention.

5 FIG. 13 is an end view of the embodiment of FIG. 12.

6 FIGS. 14-16 each show an end view of an alternative embodiment of the
7 containment baffle shown in FIG. 8.

8 FIG. 17 is a side sectional view of another alternative embodiment of the
9 aerosol medication delivery apparatus of FIG. 1.

10 FIG. 18 is an end view of the embodiment shown in FIG. 17

11 FIG. 19 is a side sectional view of yet another alternative embodiment of the
12 aerosol medication delivery apparatus of FIG. 1.

13 FIG. 20 is an end view of the containment baffle of the embodiment of FIG.
14 19.

15 FIG. 21 is a side sectional view of yet another alternative embodiment of the
16 aerosol medication delivery apparatus of FIG. 1.

17 FIG. 22 is an end view of the containment baffle of the embodiment of FIG.
18 21.

19
20 DETAILED DESCRIPTION OF THE
21 PRESENTLY PREFERRED EMBODIMENTS

22 **I. General**

23 FIGS. 1-11 show an embodiment of an aerosol medication delivery apparatus
24 10. The apparatus 10 comprises a pMDI canister-holding portion (or dispenser) 22
25 coupled to a chamber housing portion 24. The delivery apparatus 10 together with a
26 pMDI canister 30 form an aerosol therapy system 12.

27 The canister-holding portion 22 has a generally rectangular cross-sectional
28 shape that defines a receiving area or receptacle 28 for receipt therein of the pMDI
29 canister 30. The receiving area 28 is suited for conventional pMDI canisters of well-
30 known construction. The pMDI canister 30 contains a medication suspension or
31 solution under pressure. In the present embodiment, an HFA propelled medication

1 suspension or solution formulation is used. In one embodiment, the liquid medication
2 is flunisolide. Other propellants and other medications may also be used.

3 Referring to FIG. 6, the pMDI canister 30 has a stem 32 that permits a portion
4 of the medication suspension or solution to be discharged therefrom upon application
5 of a force on the stem 32. When the pMDI canister 30 is located in the receiving area
6 28 of the canister-holding portion 22, the canister stem 32 is positioned in a vertical
7 channel or well 34 formed in the bottom of the canister-holding portion 22. When the
8 stem 32 of the canister 30 is located in the vertical channel 34, ambient air can pass
9 into the chamber via a passageway 33. A horizontal passage 35 communicates with
10 the vertical channel 34. The horizontal passage 35 leads to a discharge orifice 36
11 located opposite from the vertical channel 34.
12

13 II. Chamber Housing

14 Referring to FIG. 6, the discharge orifice 36 forms the passage by which
15 medication particles from the pMDI canister 30 can exit the canister holding portion
16 22 and enter into the chamber housing portion 24. The chamber housing 24 has an
17 input end 46 and an output end 48 that define the ends of an interior space 39.

18 Referring to FIGS. 2 - 4, in a present embodiment, the chamber housing
19 portion 24 is formed of two parts: a main housing portion 43 and a downstream
20 portion 45. The main housing portion 43 and the downstream portion 45 together
21 define the interior space 39 of the chamber housing portion 24. The downstream
22 portion 45 has retaining fingers 47 that engage in slots 49 on each side of the main
23 housing portion 43. In the embodiment shown, the main housing portion 43 and the
24 downstream portion 45 easily snap together and can be easily disconnected for
25 cleaning.

26 Referring to FIG. 2, the main housing portion 43 has a curved cross section.
27 In a present embodiment, the curved cross-section has a complex geometry formed of
28 a plurality of radii to form a convenient, easy-to-use shape.
29

30 III. Containment Baffle/Mouthpiece

31 Referring to FIGS. 2 and 7-9, a containment baffle 51 is located in the

1 downstream portion 45 at the outlet of the chamber housing 24. The containment
2 baffle 51 is located centrally and forms a distal wall 53 of the downstream portion 45.
3 The containment baffle 51 is positioned so as to partially block the output end 48.
4 The containment baffle 51 reduces the velocity or flow rate or both of the aerosol
5 medication particles on axis 42 of the chamber housing 24. A mouthpiece 55 is
6 located on the outside of the downstream portion 45 and includes the containment
7 baffle 51 at an outlet end thereof.

8 As shown in FIGS. 7-9, the containment baffle 51 has a concave-shaped center
9 portion 62. In the embodiment shown, the perimeter of the concave-shaped center
10 portion 62 of the containment baffle 51 has generally straight vertical sides 57A and
11 57B, a curved top side 57C, and a curved bottom side 57D. The perimeter of the
12 concave-shaped center portion 62 of the containment baffle 51 conforms generally in
13 shape to the cross-sectional shape of the mouthpiece 55. The concave-shaped center
14 portion 62 of the containment baffle 51 is aligned with a central axis 42 of the
15 chamber housing 24 and is directly in line with the discharge orifice 36. Aerosol
16 medication particles that have a flow path away from the axis of symmetry 42 tend to
17 have a velocity that is lower than that of particles near to the axis of symmetry. The
18 center portion 62 of the containment baffle 51 reduces the forward, on-axis velocity
19 and simultaneously acts as an impaction surface for on-axis projectile aerosol
20 medication particles. At the same time the center portion 62 allows slower moving
21 aerosol medication particles to migrate towards the sides 52 of the chamber housing
22 24. The forward velocity of the aerosol medication particles away from the axis 42
23 along the chamber length is also reduced by the outer portion 66 of the containment
24 baffle 51 that is concentric with the concave shaped center portion 62.

25 Positioned between the center and outer portions 62 and 66 is an inhalation
26 opening area 70. In the embodiment, the inhalation opening area 70 is defined by four
27 openings 70A-70D. The openings are arcuate in shape and conform to the periphery
28 of the central portion 62. Each of the openings 70 has a length of approximately 9
29 mm and a width of approximately 2 mm. The size, shape and number of openings
30 may vary depending on the medication suspension or solution formulation and/or
31 propellant used.

1 In a present embodiment, the aerosol delivery apparatus 10 includes a cap 74
2 which can be placed over the mouthpiece 55 to prevent contaminants from entering
3 the interior space 39. The cap 74 serves to protect the mouthpiece 55 and keep it
4 relatively clean.

6 **IV. Operation**

7 To use the aerosol delivery apparatus 10 for delivery of an aerosol medication,
8 the canister-holding portion 22 and chamber housing 24 are arranged as shown in
9 FIG. 1. The cap 74 is removed and the pMDI canister 30 is located in the receiving
10 area 28 with the stem 32 inserted into the channel 34 formed in the bottom of the
11 receiving area 28 as shown in FIG. 6. As mentioned above, the apparatus 10 receives
12 the pMDI canister 30 which is operated conventionally (i.e. by pressing down on the
13 pMDI canister 30 which is located stem-side-down in the receiving area 28). Upon
14 depression of the stem 32, the medication suspension or solution formulation in the
15 pMDI canister 30 is discharged out of an opening 33 at the tip of the stem 32. As the
16 medication suspension or solution formulation flows through the horizontal channel
17 35 and out of the discharge orifice 36, the propellant and suspending liquid or solvent
18 evaporate and the medication particles are discharged in aerosol form into the
19 surrounding environment inside the chamber volume 39. Upon discharge from the
20 pMDI canister 30, the medication particles in the aerosol plume may have an average
21 speed, size distribution and/or flow rate that may not be ideal for direct inhalation by a
22 patient. However, once the aerosol medication is inside the chamber volume 39, the
23 proportion of larger non-respirable particles available on inhalation is minimized and
24 the dose of respirable particles is optimized. The aerosol medication particles are
25 withdrawn therefrom by having the patient, whose mouth is around the mouthpiece
26 55, inhale through the inhalation opening area 70. The aerosol medication particles
27 will then flow through the inhalation opening area 70 and into the patient's mouth.

29 **V. Retraction for Storage**

30 A further feature of the aerosol medication apparatus 10 is that it can be
31 retracted for convenient storage and portability. For this purpose, the chamber

1 housing 24 is coupled to the canister-holding portion 22 via a coupling mechanism 94
2 as shown in FIG. 11. The coupling mechanism 94 permits the aerosol medication
3 delivery apparatus 10 to be compactly stored by pivoting the canister-holding portion
4 22 from the position of FIGS. 1-4 to a horizontal position and then pushing the
5 canister-holding portion 22 so that it translationally moves into the chamber housing
6 24 as shown in FIG. 10.

7 Referring to FIG. 11, the pivoting and translational movement is accomplished
8 by the structure of the coupling mechanism 94. In particular, the coupling mechanism
9 94 includes a pair of slots 96 formed in the chamber housing 24, wherein each slot 96
10 has an open end 98 and a closed end 100. As shown in FIG. 5, the canister-holding
11 portion 22 has a pair of pegs 102, attached thereto. In addition, the interior portion of
12 the chamber housing 24 has multiple parallel tracks 104 (shown in FIG. 10) which
13 guide the canister-holding portion 22 into the chamber housing 24.

14 To connect the chamber housing 24 and the canister-holding portion 22
15 together, a top end 109 of the canister-holding portion 22 is first inserted into the
16 output end 48 of the chamber housing 24 and translationally moved towards and past
17 the input end 46 so that the pegs 102 are inserted into the open ends 98 of the
18 corresponding slots 96. Each of the pegs 102 can then translationally move within its
19 respective slot 96 to the closed end 100 thereof. Thus, the canister-holding portion 22
20 is telescopically received within the chamber housing 24 during translational
21 movement and is able to move from the retracted position of FIG. 10 to an extended
22 position. At the extended position, both pegs 102 contact the closed ends 100 of their
23 corresponding slots 96 and the canister-holding portion 22 is then allowed to pivot to
24 the position of FIG. 4 so that the patient can use the apparatus 10. The end of the
25 canister-holding portion 22 is curved so as to allow it to pivot relative to the chamber
26 housing 24. The foregoing coupling and retraction mechanism allow for easy use,
27 transport, and lower manufacturing costs.

28 To facilitate handling by the patient, a plurality of ribs 77 may be located
29 along the front and rear sides of the canister-holding portion 22 close to the top edge
30 109 thereof. These ribs 77 remain exposed when the canister-holding portion 22 is
31 retracted into the chamber portion 24 so that the patient can use these ribs to help grip

1 the end of the canister-holding portion 22 in order to withdraw it from the chamber
2 portion 24. After use by the patient, the cap 74 can be placed back over the
3 mouthpiece 55.

4 5 **VI. Advantages of Disclosed Embodiment**

6 With the embodiment disclosed above, the end result of combining the
7 specified inhalation opening area 70, the chamber housing 24, and the containment
8 baffle 51 is to administer a controllable and desired respirable dose of aerosol
9 medication to a patient for inhalation into the lungs. Further, the disclosed
10 embodiment provides advantages over prior devices in that it incorporates an
11 integrated actuator and is easier to use and is easier to store and carry given its smaller
12 size.

13 An advantageous feature of the disclosed embodiment is provided by the
14 containment baffle 51. As mentioned above, the velocity of the aerosol medication
15 particles nearest the axis of symmetry 42 will typically be greater than that of aerosol
16 medication particles that are located further from the axis 42. The velocity of the
17 aerosol medication particles near the axis 42 may be so large as to reduce the
18 effectiveness of delivering the medication to the patient because it will cause a
19 significant portion of the aerosol medication particles to impact on the oropharyngeal
20 region and upper airway where they have no therapeutic value and, in the case of
21 medication such as corticosteroids, may give rise to adverse side-effects. The
22 containment baffle 51 overcomes this potential problem by isolating the patient's
23 mouth from the location at which the greatest risk of high velocity impaction may
24 occur. The containment baffle provides this solution in a manner that is relatively
25 inexpensive and easy to manufacture.

26 The disclosed aerosol medication delivery apparatus optimizes the deposition
27 of respirable aerosol medication particles in a patient's lungs to provide a desired
28 therapeutic effect. The aerosol medication delivery apparatus also reduces the
29 importance of coordination between the actuation and inhalation maneuvers and
30 reduces or eliminates possible side-effects caused by aerosol medication formulations
31 consisting of corticosteroids. The aerosol medication delivery apparatus also reduces

1 or eliminates the unpleasant taste associated with aerosol medication formulations
2 such as flunisolide and allows for convenient portability and quick use.

3 In the case of pMDIs that use HFA as a propellant for flunisolide, the present
4 embodiment provides a particular advantage. Through use of the present
5 embodiment, the respirable dosage of flunisolide delivered to the patient can be
6 controlled in a manner to closely conform to the dosage of flunisolide that had been
7 delivered using conventional prior art systems that used prior propellants, such as
8 CFC. In this manner, the dosage of flunisolide can be consistently maintained,
9 thereby benefiting administration of such medication to patients.

10 The shape, size, and number of openings in the inhalation opening area may
11 vary in order to ensure the administration of a desired respirable dose of a specific
12 pMDI formulation. Upon discharge the on-axis aerosol medication particles, which
13 are generally non-respirable and have a higher inertia than the respirable particles,
14 collide with the interior center portion of the containment baffle resulting in a
15 reduction in the number of larger (non-respirable) aerosol medication particles, and
16 the division of larger (non-respirable) aerosol medication particles into smaller
17 respirable particles.

18 By sealing off (except for the inhalation opening area) the output end of the
19 chamber, the containment baffle contributes to maintaining a high pressure zone in the
20 chamber which allows for the deflection of most slower moving respirable aerosol
21 medication particles away from the containment baffle and into the chamber for
22 containment until inhaled by the patient through the inhalation opening area. The
23 containment of the respirable aerosol medication particles in the chamber provides the
24 patient with more time to inhale the aerosol medication particles and, therefore,
25 reduces the importance of exact coordination between the discharge maneuver and
26 inhalation.

27 28 **VII. Exemplary embodiment**

29 In one exemplary embodiment, shown in FIGS. 1-11, the canister-holding
30 portion 22 is approximately 7.5 cm in height and is approximately 2.5 by 2.5 cm in
31 cross section. The chamber housing 24 is approximately 8 cm in length and has an

1 oval-shaped cross section with dimensions of approximately 49 mm by 33 mm. The
2 mouthpiece 55 is approximately 1.5 cm in length. The canister-holding portion, the
3 chamber housing, and the end cap are formed of a suitable hard, durable plastic, such
4 as polypropylene. The discharge orifice 36 has a diameter of approximately 0.011
5 inches. In a present embodiment, the containment baffle 51 has a width of
6 approximately 27 mm and a height of approximately 15 mm at the center and 5 mm
7 at the side edges.

8 For purposes of this embodiment, it is assumed that the pMDI canister
9 contains a 0.06% w/v to 0.24% w/v mixture of liquid medication, such as flunisolide
10 in ethanolic solution and HFA as a propellant. It is understood that the pMDI canister
11 30 can also contain other liquids and other mixtures without departing from the spirit
12 of the invention.

13 14 **VIII. Alternative embodiments**

15 Referring to FIGS. 12 and 13, another embodiment of an aerosol delivery
16 apparatus 110 is shown. This embodiment is similar to the embodiment shown in
17 FIGS. 1-11 and like components are labeled with the same numerals. In the
18 embodiment of FIGS. 12 and 13, the containment baffle 151 is located at an upstream
19 end of the passageway defined in the mouthpiece 55. The containment baffle 151 in
20 this embodiment is convex in shape and diverts flow around an on-axis trajectory. In
21 the embodiment of FIGS. 12 and 13, a chamber housing 124 has four squared-off
22 sides 125, 126, 127, and 128. The squared-off sides may facilitate gripping of the
23 device.

24 Referring to FIGS. 14-16, there are depicted alternative embodiments of the
25 containment baffle. In FIG. 14, a containment baffle 251 has a screen-like structure
26 forming a plurality of openings defined between a crisscrossed mesh 252. The surface
27 area provided by the mesh 252, combined with the relatively small areas of the
28 openings, serves to prevent aerosol particles having a high velocity from passing to
29 the patient. In FIG. 15, a containment baffle 351 has a plurality of small circular
30 openings formed around a periphery of a solid central portion 362. Like the previous
31 embodiments, the embodiment of FIG. 15 provides a surface area 362, combined with

1 the relatively small openings, serves to prevent aerosol particles having a high
2 velocity from passing to the patient. In FIG. 16, a containment baffle 451 has four
3 relatively large openings formed around the periphery a solid dish-shaped central
4 portion 462. The dish-shaped central portion 462 is connected to the remainder of the
5 chamber body by one or more ribs 463. Like the previous embodiments, the
6 embodiment of FIG. 16 provides a surface area 462, that serves to prevent aerosol
7 particles having a high velocity from passing to the patient.

8 Referring to FIGS. 17 and 18, there is shown an alternate embodiment 512 of
9 an aerosol delivery apparatus. The embodiment of FIGS. 17 and 18 includes an
10 aerosol delivery apparatus 510. The apparatus 510 includes a chamber housing 524
11 which defines an interior space 539. The apparatus 510 does not include an integrated
12 canister-holding portion. Instead, the chamber housing 524 has a backpiece 527. The
13 backpiece 527 is made of an elastomeric material and is fitted over the upstream end
14 of the chamber housing 524. The backpiece 527 has an opening 529 located centrally
15 therein. The opening 529 is sized to receive the mouthpiece end of a separate pMDI
16 actuator boot. In a preferred embodiment, the opening 529 is sized so that the
17 mouthpiece of the pMDI actuator boot fits snugly into the opening 529. Because the
18 backpiece 527 is formed of an elastomeric material, it is resilient and the opening 529
19 in the backpiece can be stretched, thereby enabling it accommodate actuator boot
20 mouthpieces of various sizes and shapes. The backpiece 527 may be similar to the
21 backpiece described in U.S. Pat. No. 4,470,412 or in Ser. No. 08/248,716, the entire
22 disclosure of which is incorporated by reference herein.

23 Located at a downstream end of the chamber housing 524 is a mouthpiece 555.
24 Also located at the downstream end of the chamber housing 524 is a containment
25 baffle 551. The containment baffle 551 may be similar to the containment baffle 51 in
26 the above described embodiment. Located around the periphery of the containment
27 baffle center portion 562 is an inhalation opening area 570. The inhalation opening
28 area 570 includes four arcuate shaped openings. In the embodiment of FIGS. 17 and
29 18, the containment baffle 551 is located at the downstream end of the mouthpiece
30 555, although in alternative embodiments, the containment baffle may be located at
31 the upstream end of the mouthpiece or anywhere along the length of the mouthpiece.

1 With the embodiment of FIGS. 17 and 18, the patient inserts the actuator boot
2 mouthpiece into the opening 529 and inserts the pMDI canister into the actuator boot.
3 The patient presses down on the pMDI canister to cause a plume of aerosol
4 medication to be discharged from the stem of the pMDI canister out of the mouthpiece
5 of the actuator boot and into the interior space 539. The patient inhales the aerosol
6 from the interior space 539 via the mouthpiece 555 of the apparatus 510.

7 Another embodiment of the aerosol medication delivery apparatus is shown in
8 FIGS. 19 and 20. An aerosol delivery apparatus 610 includes a chamber housing 624
9 defining an interior space 639. The apparatus 610 also includes an elastomeric
10 backpiece 627 which may be similar to the backpiece in the embodiment shown in
11 FIGS. 17 and 18. The apparatus 610 includes a containment baffle 651. The
12 containment baffle 651 is located at the downstream end of the chamber housing 624
13 just upstream of the mouthpiece 655. The containment baffle 651 includes an
14 inhalation opening area 670 located around the periphery of the containment baffle
15 651. In the embodiment of FIGS. 19 and 20, the containment baffle 651 may be
16 formed of a single piece of material with the chamber housing 624. The mouthpiece
17 655 may be formed of a separate piece of material that is coupled to the downstream
18 end of the chamber housing 624. The embodiment of FIGS. 19 and 20 may be used in
19 a similar manner as the embodiment of FIGS. 17 and 18.

20 Still another embodiment of the aerosol medication delivery apparatus is
21 shown in FIGS. 21 and 22. This embodiment of the aerosol delivery apparatus is
22 particularly suited for use by a mechanically ventilated patient (i.e. a patient using a
23 ventilator). In FIG. 21, an aerosol delivery apparatus 710 includes components that
24 are similar to the previous embodiments, in particular the embodiment of FIGS. 17
25 and 18. A chamber housing 724 defines an interior space 739. The apparatus 710 is
26 intended to be positioned in a ventilator circuit, in particular in the air passageway that
27 provides inspiratory air flow from a ventilator to the patient. The chamber housing
28 724 includes a first opening 727 located in a first tubular extension 728 extending
29 from the upstream end 746 of the chamber housing 724 and a second opening 755
30 located in a second tubular extension 756 that extends from the downstream end 748
31 of the chamber housing 724. The first opening 727 connects to tubing 731 that leads

1 to the ventilator (not shown) and the second opening 755 leads to tubing, a mask, a
2 mouthpiece, or other suitable means (not shown) of providing air from the ventilator
3 to the patient. Located at the upstream end of the chamber 724 is a receptacle 722. At
4 the bottom of the receptacle 722 is a well 734 adapted to receive the stem of a pMDI
5 canister. The well 734 extends into a rib 735 that extends across the entrance into the
6 interior space 739 of the chamber housing 724. The rib 735 may be located at or
7 along the extension 728. The rib 735 includes a discharge opening 736 that
8 communicates with the well 734. The discharge opening 736 is oriented toward the
9 interior space 739. The receptacle 722, the rib 735, and the discharge opening 736 are
10 integrated with the chamber housing 724 forming part of the aerosol delivery
11 apparatus 710, (i.e. the receptacle and chamber housing form an integrated unit). In
12 one embodiment the receptacle 722, the rib 735, and the discharge opening 736 are
13 formed of the same piece of material as the chamber housing 724, or alternatively,
14 they may be formed of separate pieces. Further disclosure regarding an integrated
15 chamber housing and canister receptacle is included in U.S. Pat. No. 5,012,804.

16 Located at the downstream end 748 of the chamber 724 is a containment baffle
17 751. The containment baffle 751 may be located at the downstream end of the
18 chamber housing 724 or along the extension 756. The containment baffle 751
19 includes an inhalation opening area 770 located around the periphery of the
20 containment baffle 751.

21 The embodiment of FIGS. 21 and 22 may be used in a similar manner as the
22 device disclosed in U.S. Pat. No. 5,012,804. The apparatus 710 may be positioned in
23 the inspiratory flow path from the ventilator to the patient when the patient is initially
24 placed on the ventilator. The apparatus 710 is then left in place until needed.
25 Alternatively, the apparatus 710 may be positioned in the inspiratory flow path of the
26 ventilator circuit just prior to when a dose of aerosol medication is to be delivered to a
27 ventilated patient. A pMDI canister is positioned in the receptacle 722 and actuated.
28 The medication from the pMDI canister is conveyed with the inspiratory flow from
29 the ventilator to the patient. As in the previously described embodiments, the
30 containment baffle 751 reduces on-axis non-respirable particles.

1 The invention may be embodied in other forms than those specifically
2 disclosed herein without departing from its spirit or essential characteristics. The
3 described embodiments are to be considered in all respects only as illustrative and not
4 restrictive, and the scope of the invention is commensurate with the appended claims
5 rather than the foregoing descriptions.

1 WE CLAIM:

2 1. An aerosol medication delivery apparatus for use with a pMDI canister
3 having medication and a propellant contained therein under pressure, wherein the
4 pMDI canister has a discharge orifice from which the medication and propellant can
5 be discharged forming an aerosol, the apparatus comprising:

6 a chamber housing having an input end and an output end and defining an
7 interior space, wherein said input end receives the medication discharged from the
8 discharge orifice of the pMDI canister into said interior space and wherein the
9 medication can be withdrawn from said interior space by inhalation by a patient from
10 the output end; and

11 a containment baffle located at said output end to partially block said output
12 end.

13
14 2. The aerosol delivery apparatus of Claim 1 wherein said containment
15 baffle is surrounded by an inhalation area including at least one opening and wherein
16 said inhalation area is located concentrically with said containment baffle.

17
18 3. The aerosol delivery apparatus of Claim 1 wherein said containment
19 baffle is aligned with said discharge orifice.

20
21 4. The aerosol delivery apparatus of Claim 1 further comprising:
22 a backpiece located on the input end of the chamber housing, said backpiece
23 including an opening located therein to receive a mouthpiece of an actuator boot of
24 the pMDI canister.

25
26 5. The aerosol delivery apparatus of Claim 1 wherein said containment
27 baffle defines an inhalation opening area located around a periphery thereof.

28
29 6. The aerosol delivery apparatus of Claim 5 wherein said inhalation
30 opening area comprises four arcuate-shaped openings.

31

1 7. The aerosol delivery apparatus of Claim 1 wherein said containment
2 baffle is located at an upstream end of a mouthpiece extending from said output end
3 of said chamber housing portion.

4
5 8. The aerosol delivery apparatus of Claim 1 wherein said containment
6 baffle is located at a downstream end of a mouthpiece extending from said output end
7 of said chamber housing portion.

8
9 9. The aerosol delivery apparatus of Claim 1 further comprising:
10 a receptacle coupled to the chamber housing at an upstream portion thereof;
11 a well located in a bottom of said receptacle, said well communicating with
12 said discharge orifice;

13 and further wherein said chamber housing portion includes a first opening at
14 said input end coupled to a ventilator circuit and a second opening at said output end
15 leading to the patient.

16
17 10. The aerosol delivery apparatus of Claim 9 wherein said receptacle and
18 chamber housing are formed of an integrated unit.

19
20 11. An aerosol medication delivery apparatus comprising:
21 a canister-holding portion comprising a receptacle for receipt therein of a
22 pMDI canister, wherein the pMDI canister has medication and a propellant contained
23 therein under pressure, said canister-holding portion having a discharge orifice
24 communicating with said receptacle to receive the medication and propellant from
25 said pMDI canister;

26 a chamber housing having an input end and an output end from which
27 medication can be withdrawn by a patient, said chamber housing defining an interior
28 space wherein said discharge orifice of said canister-holding portion communicates
29 with said interior space at said input end; and

30 a containment baffle located at said output end to partially block said output
31 end.

1
2 12. The aerosol delivery apparatus of Claim 11 wherein said containment
3 baffle is concave-like in shape as viewed from the interior space.

4
5 13. The aerosol delivery apparatus of Claim 11 wherein said containment
6 baffle includes at least one opening located concentrically adjacent thereto.

7
8 14. The aerosol delivery apparatus of Claim 11 wherein said containment
9 baffle is aligned with said discharge orifice.

10
11 15. An aerosol therapy system comprising:
12 the aerosol delivery apparatus of Claim 11; and
13 a pMDI canister of medication having a stem, wherein said canister is located
14 at least in part within said receptacle.

15
16 16. The aerosol delivery system of Claim 15 wherein said canister contains
17 HFA.

18
19 17. The aerosol delivery system of Claim 15 wherein said medication
20 includes flunisolide.

21
22 18. The aerosol delivery apparatus of Claim 11 wherein said containment
23 baffle is convex-like in shape as viewed from the interior space.

24
25 19. The aerosol delivery apparatus of Claim 11 wherein said chamber
26 housing has squared-off sides.

27
28 20. The aerosol delivery apparatus of Claim 11 wherein said containment
29 baffle defines an inhalation opening area located around a periphery thereof.

30
31 21. The aerosol delivery apparatus of Claim 20 wherein said inhalation

1 opening area comprises four arcuate-shaped openings.
2

3 22. The aerosol delivery apparatus of Claim 11 wherein said containment
4 baffle comprises a solid center portion located along a central axis of said chamber
5 housing.
6

7 23. The aerosol delivery apparatus of Claim 11 wherein said containment
8 baffle comprises a center portion having a plurality of openings formed through a
9 periphery thereof.
10

11 24. The aerosol delivery apparatus of Claim 11 wherein said containment
12 baffle comprises a screen-like mesh defining a plurality of openings therethrough.
13

14 25. The aerosol delivery apparatus of Claim 11 wherein ambient air can
15 pass into said interior space when a pMDI canister is located in said canister-holding
16 portion.
17

18 26. The aerosol delivery apparatus of Claim 11 wherein said containment
19 baffle has curved top and bottom sides and straight vertical sides.
20

21 27. The aerosol delivery apparatus of Claim 11 wherein said containment
22 baffle includes a center portion coupled to said chamber housing by a plurality of ribs.
23

24 28. The aerosol delivery apparatus of Claim 11 wherein said containment
25 baffle is located at an upstream end of a mouthpiece extending from said output end
26 of said chamber housing portion.
27

28 29. The aerosol delivery apparatus of Claim 11 wherein said containment
29 baffle is located at a downstream end of a mouthpiece extending from said output end
30 of said chamber housing portion.
31

1 30. The aerosol delivery apparatus of Claim 11 further comprising:
2 a mechanism coupling said canister-holding portion and said chamber housing
3 providing for said canister-holding portion to be retracted into said chamber housing
4 for storage and to be extended out of said chamber housing and pivoted into position
5 for use in dispensing medication.

6
7 31. An aerosol medication delivery apparatus comprising:
8 a canister-holding portion comprising a receptacle for receipt therein of a
9 pMDI canister, wherein the pMDI canister has medication and a propellant contained
10 therein under pressure, said canister-holding portion having a discharge orifice
11 communicating with said receptacle to receive the medication and propellant from
12 said pMDI canister;

13 a chamber housing having an input end and an output end from which
14 medication can be withdrawn by a patient, said chamber housing defining an interior
15 space wherein said discharge orifice of said canister-holding portion communicates
16 with said interior space at said input end;

17 a mechanism coupling said canister-holding portion and said chamber housing
18 providing for said canister-holding portion to be retracted into said chamber housing
19 for storage and to be extended out of said chamber housing and pivoted into position
20 for use in dispensing medication; and

21 a containment baffle located at said output end to partially block said open
22 output end.

23
24 32. The aerosol delivery apparatus of Claim 31 wherein said containment
25 baffle is concave-like in shape as viewed from the interior space.

26
27 33. The aerosol delivery apparatus of Claim 31 wherein said containment
28 baffle includes at least one inhalation opening area located concentrically adjacent
29 thereto.

30
31 34. The aerosol delivery apparatus of Claim 31 wherein said containment

1 baffle is axially aligned with said discharge orifice.

2
3 35. An aerosol therapy system comprising:
4 the aerosol delivery apparatus of Claim 31; and
5 a pMDI canister of medication having a stem, wherein said canister is located
6 at least in part within said receptacle.

7
8 36. The aerosol delivery system of Claim 35 wherein said canister contains
9 HFA.

10
11 37. The aerosol delivery system of Claim 35 wherein said medication
12 includes flunisolide.

13
14 38. The aerosol delivery apparatus of Claim 31 wherein said containment
15 baffle defines an inhalation opening area located around a periphery thereof.

16
17 39. The aerosol delivery apparatus of Claim 38 wherein said inhalation
18 opening area comprises four arcuate-shaped openings.

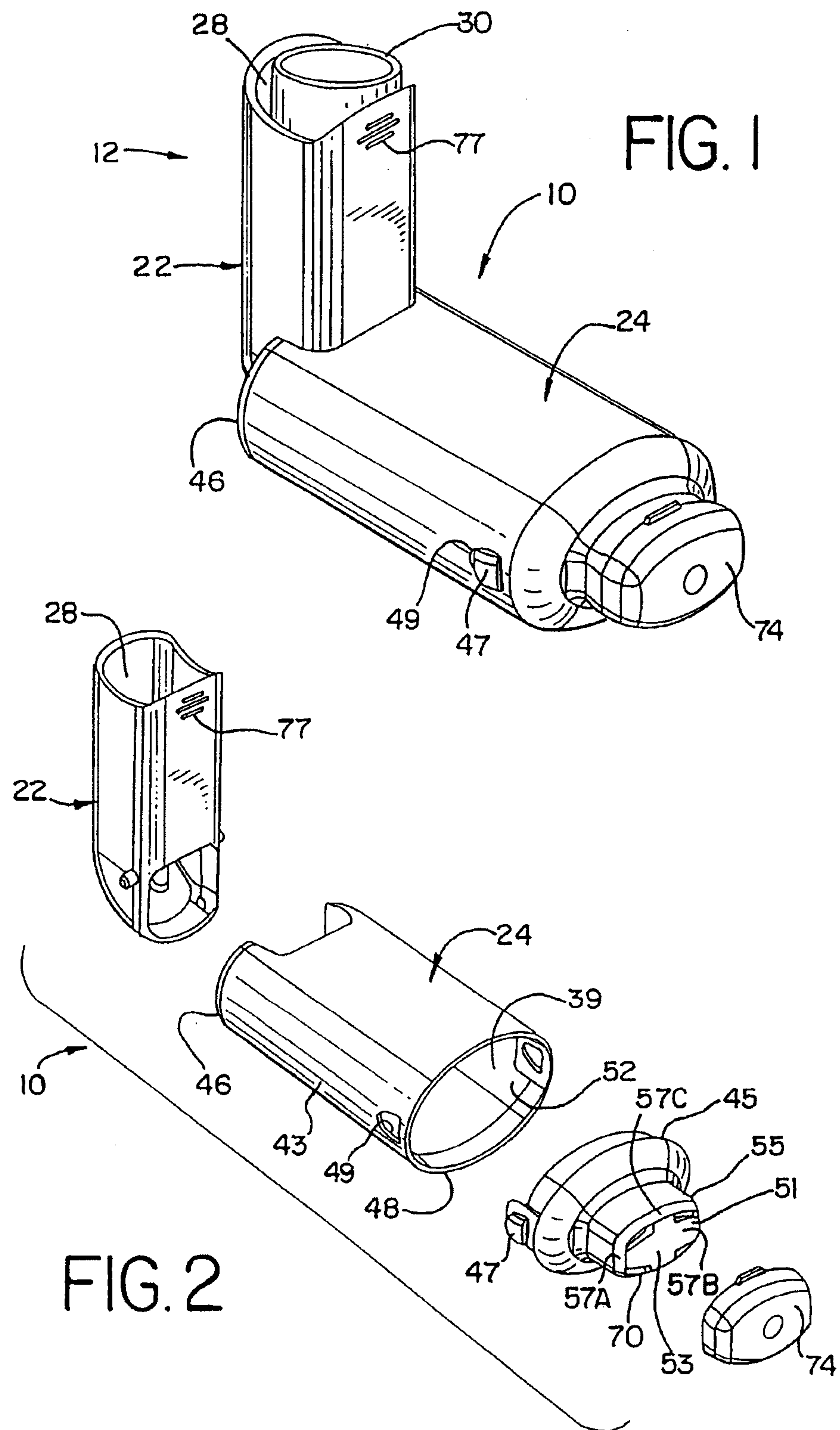
19
20 40. The aerosol delivery apparatus of Claim 31 wherein said containment
21 baffle comprises a solid center portion located along a central axis of said chamber
22 housing.

23
24 41. The aerosol delivery apparatus of Claim 31 wherein ambient air can
25 pass into said interior space when a pMDI canister is located in said canister-holding
26 portion.

27
28 42. The aerosol delivery apparatus of Claim 31 wherein said containment
29 baffle has curved top and bottom sides and straight vertical sides.

30
31 43. The aerosol delivery apparatus of Claim 31 wherein said containment

- 1 baffle is located at a downstream end of a mouthpiece extending from said output end
- 2 of said chamber housing portion.



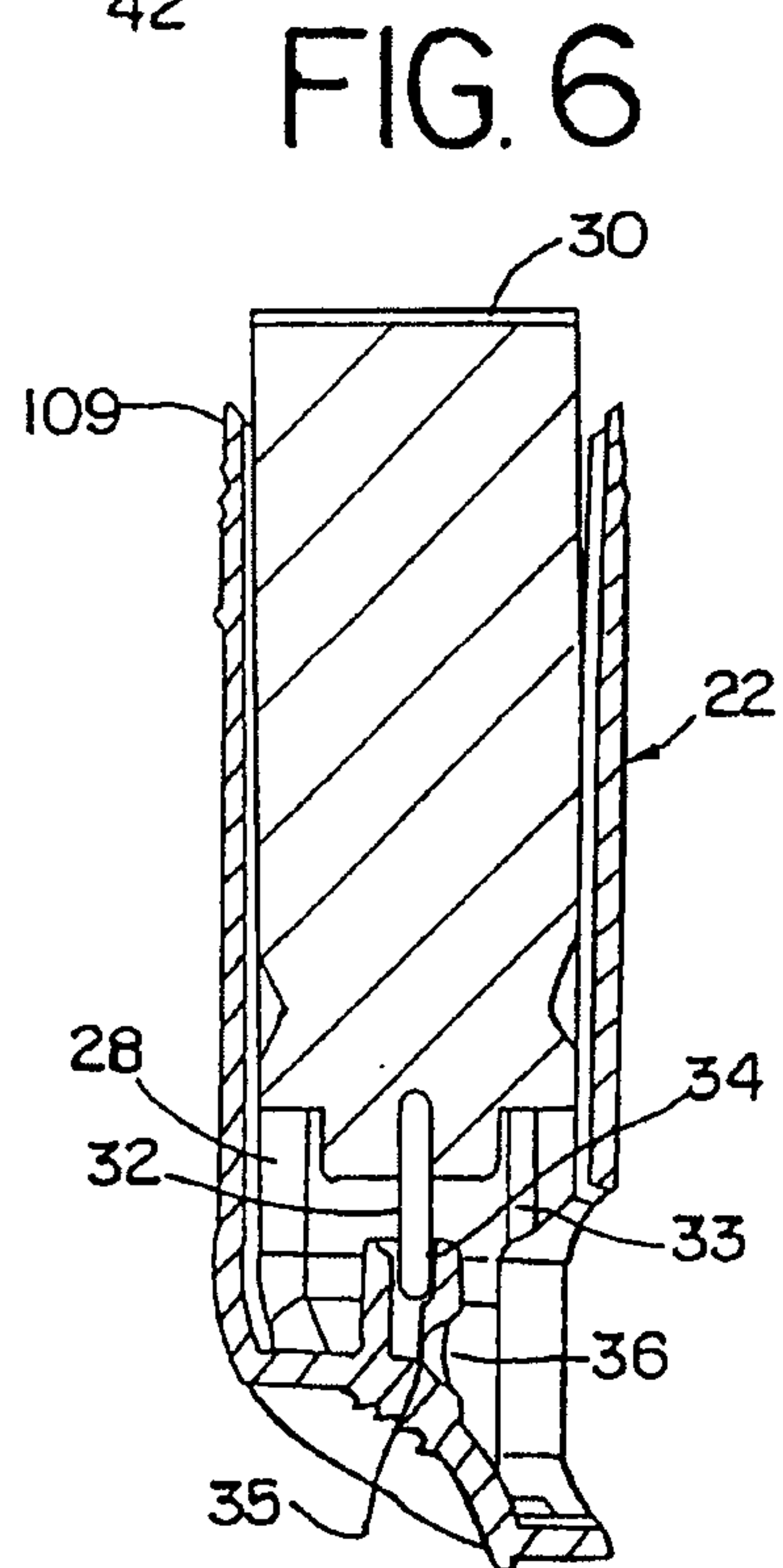
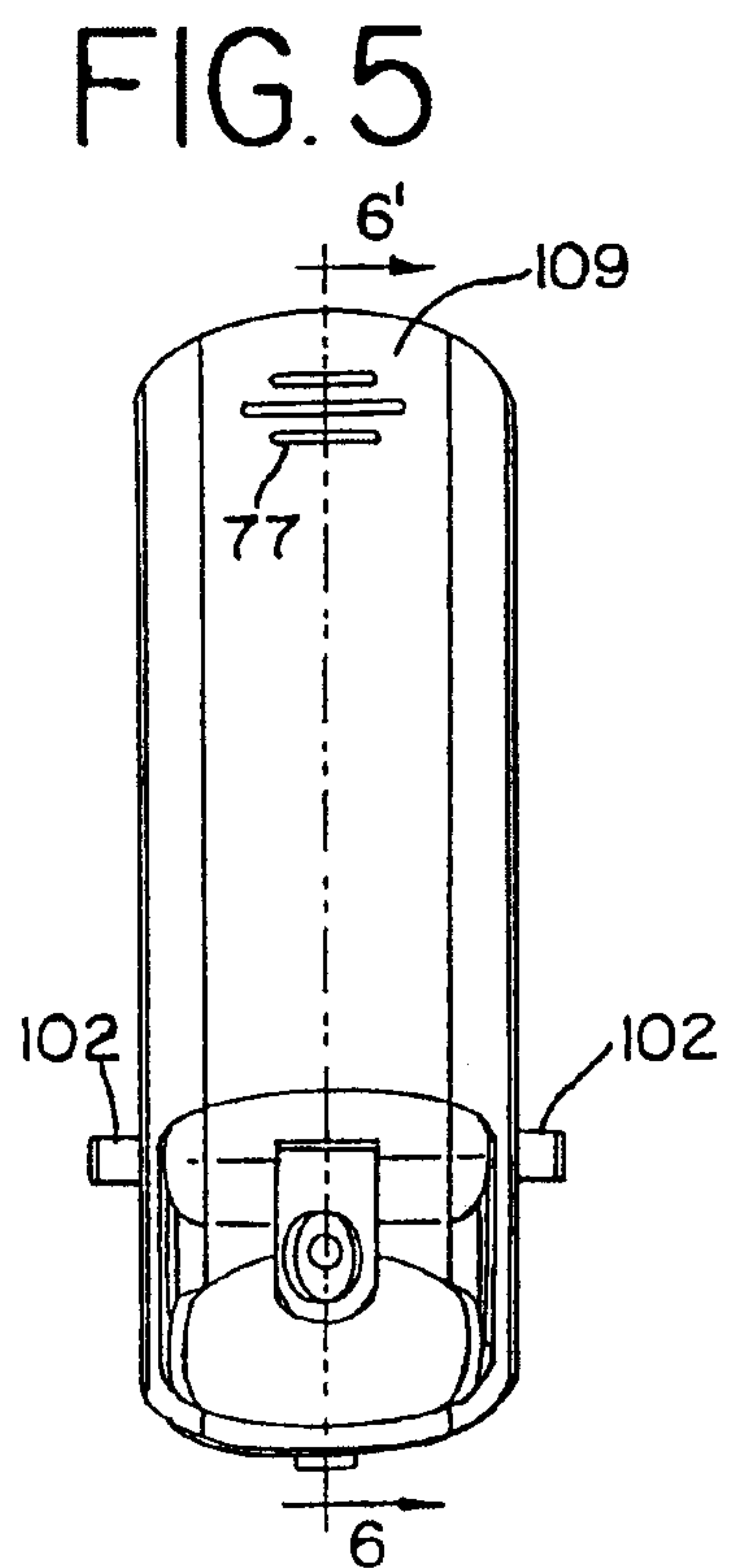
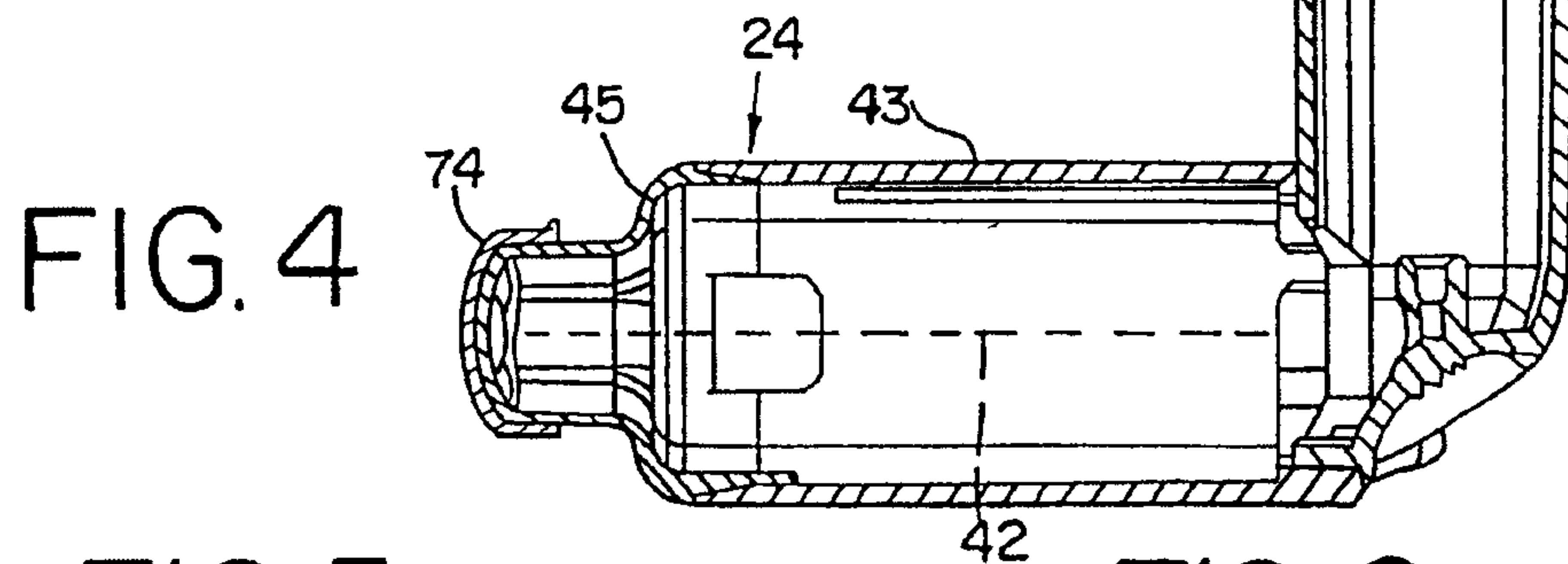
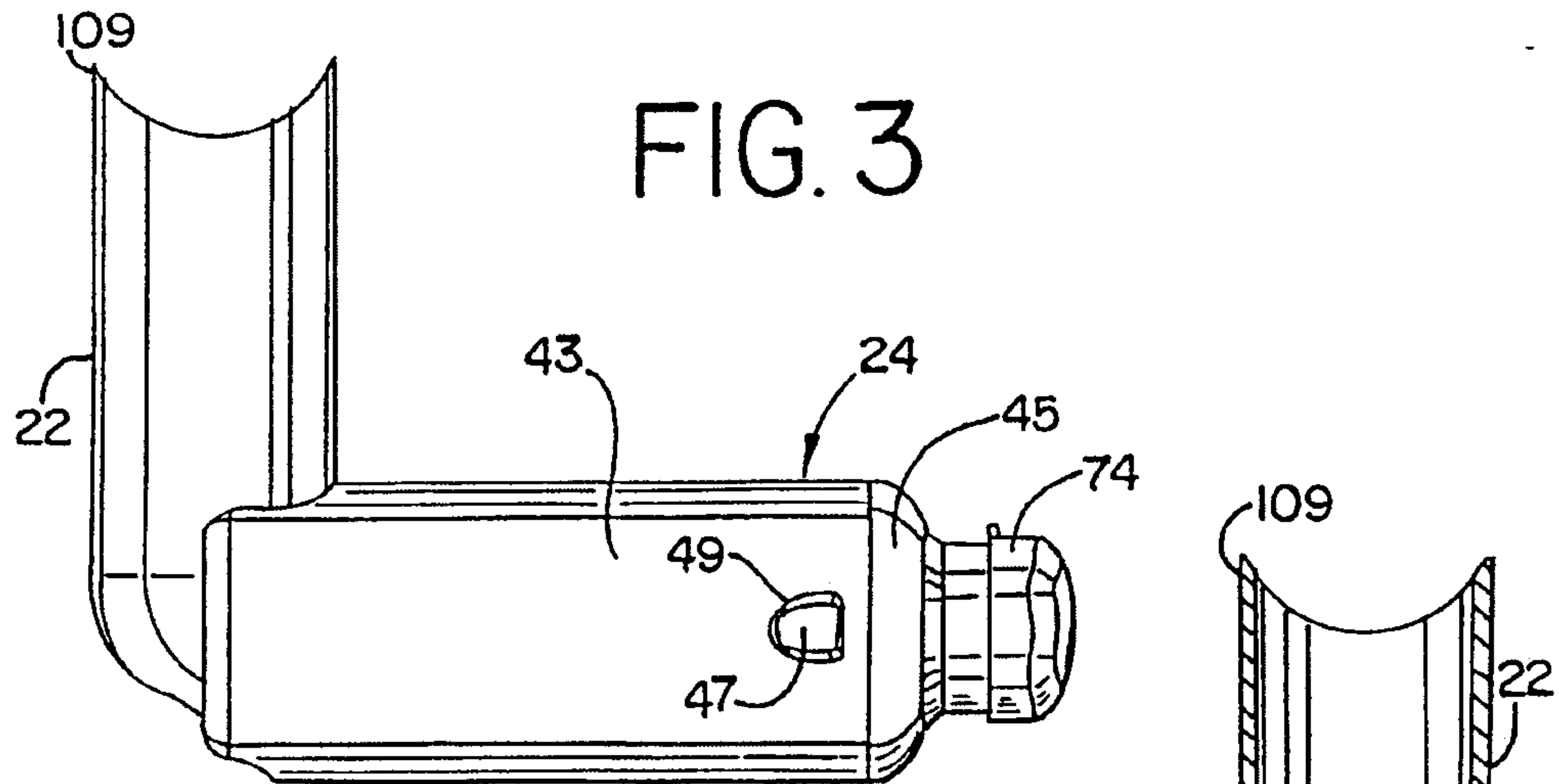


FIG. 7

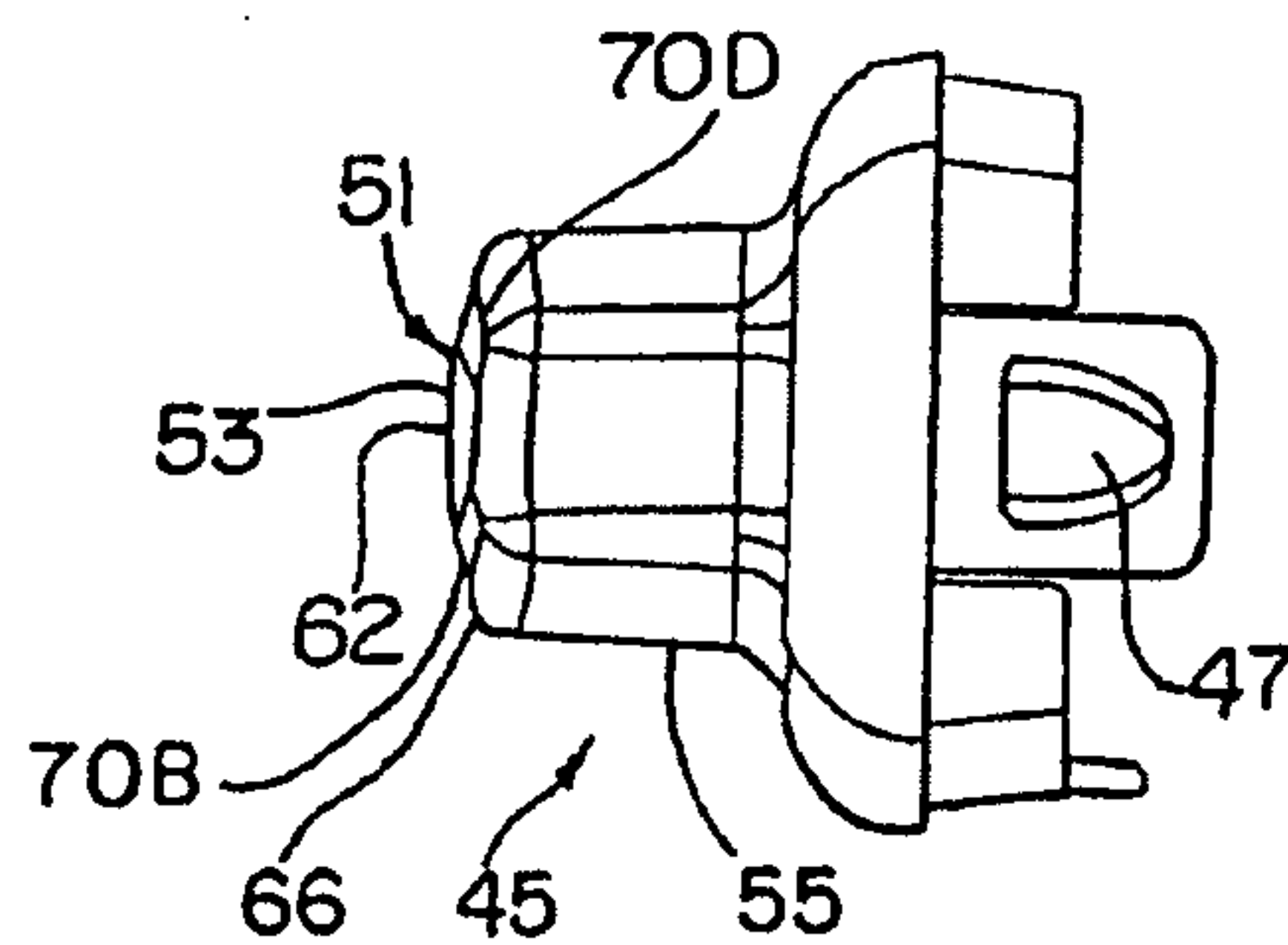


FIG. 8

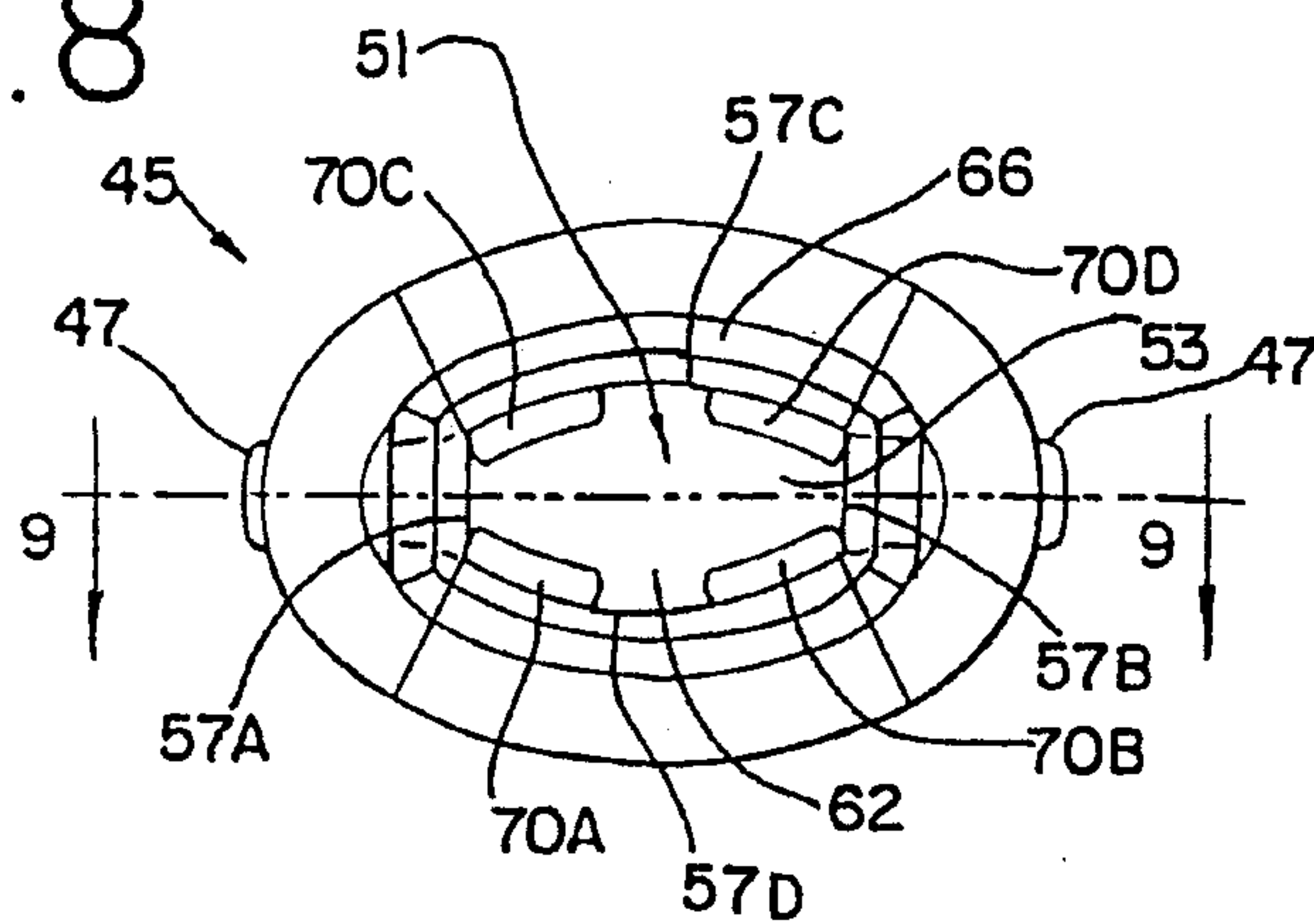


FIG. 9

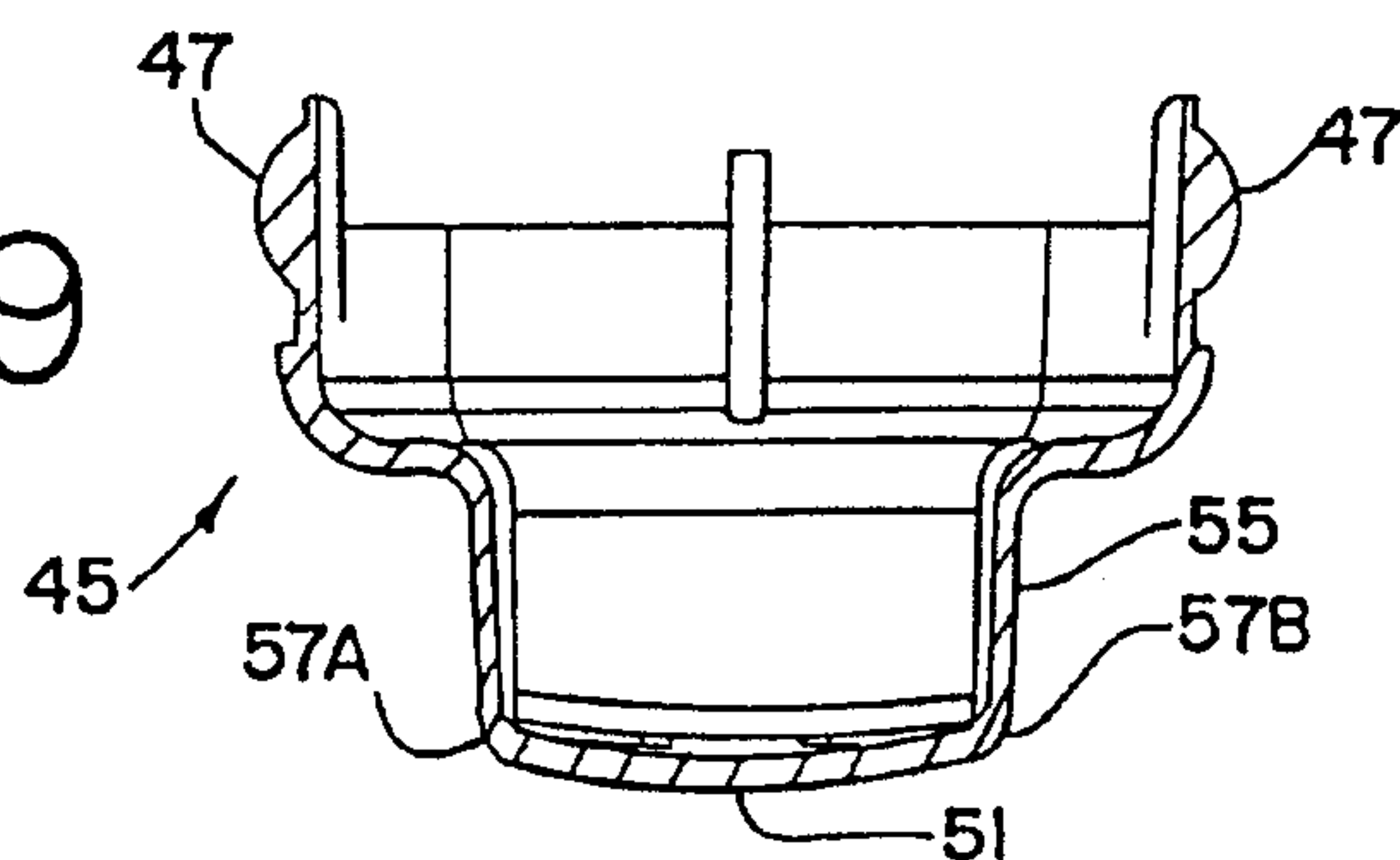


FIG. 10

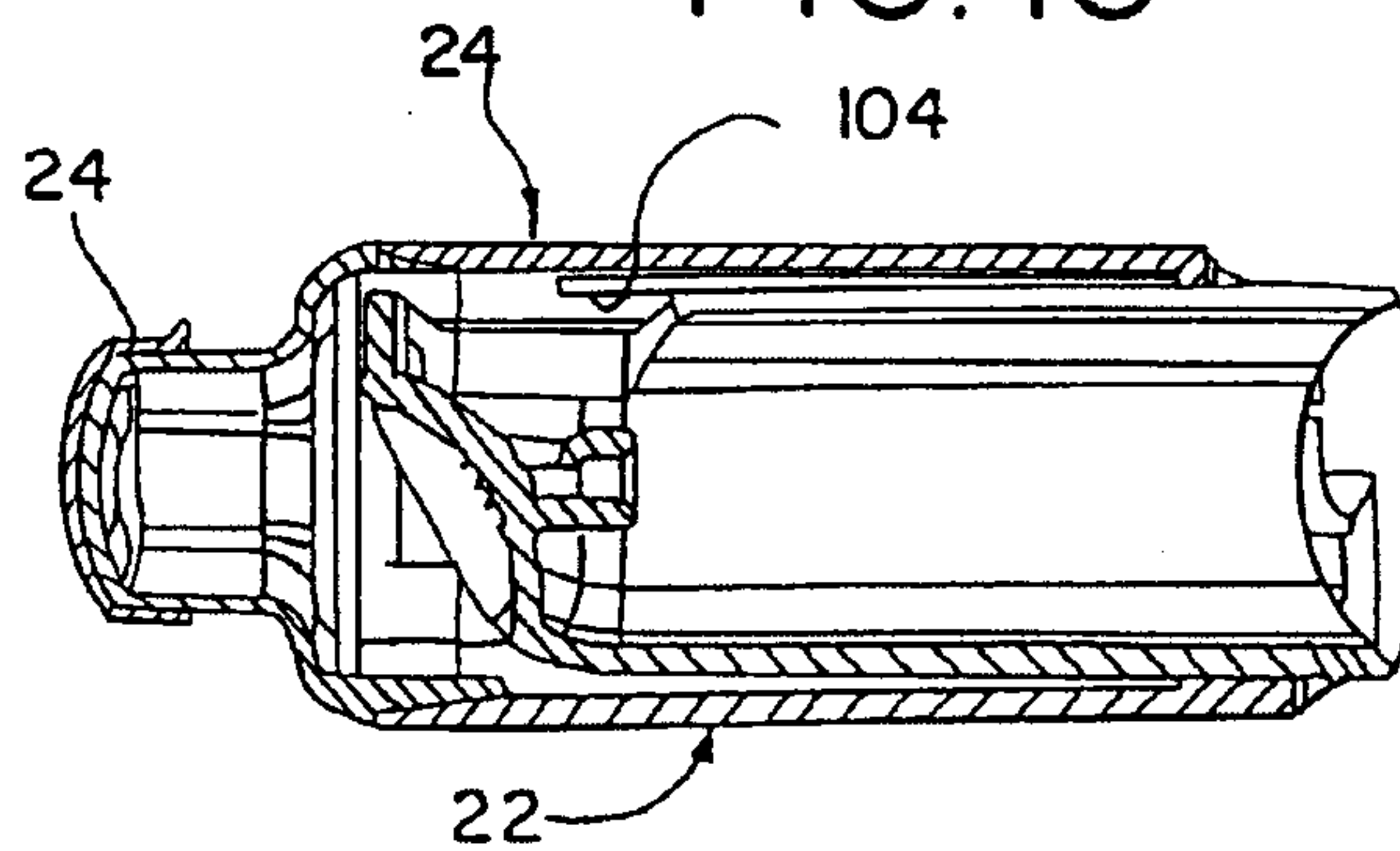


FIG. 12

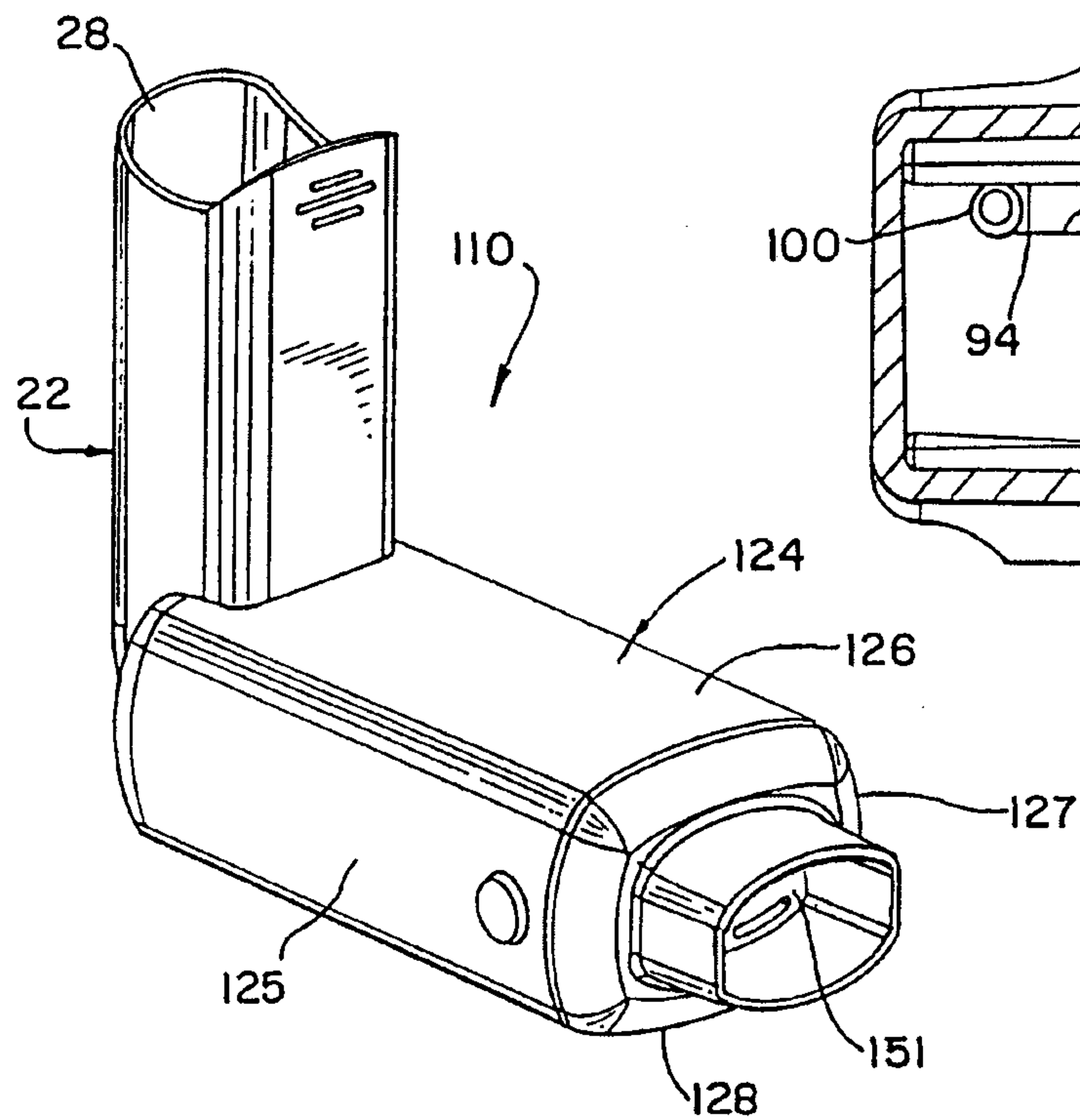


FIG. 11

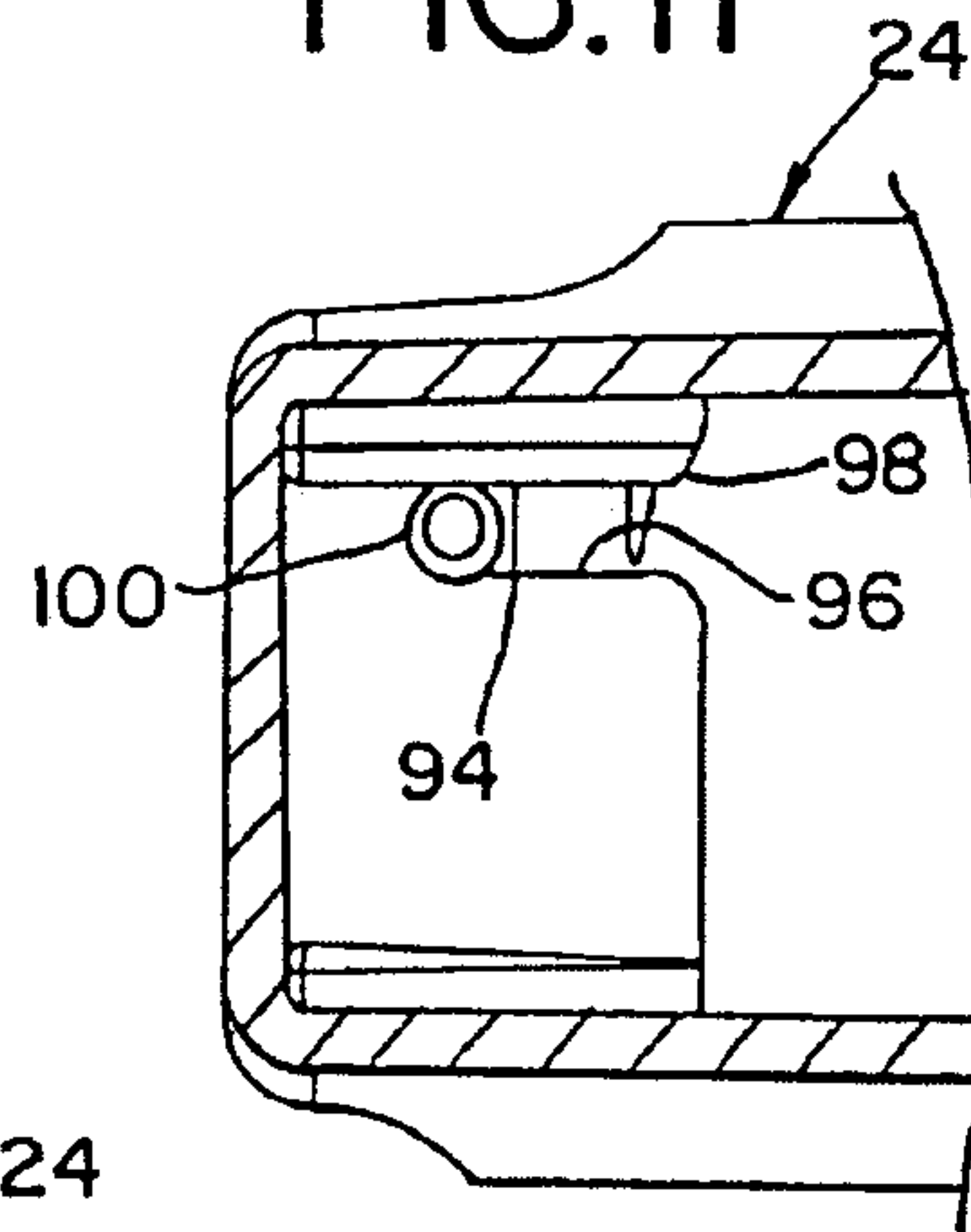


FIG. 13

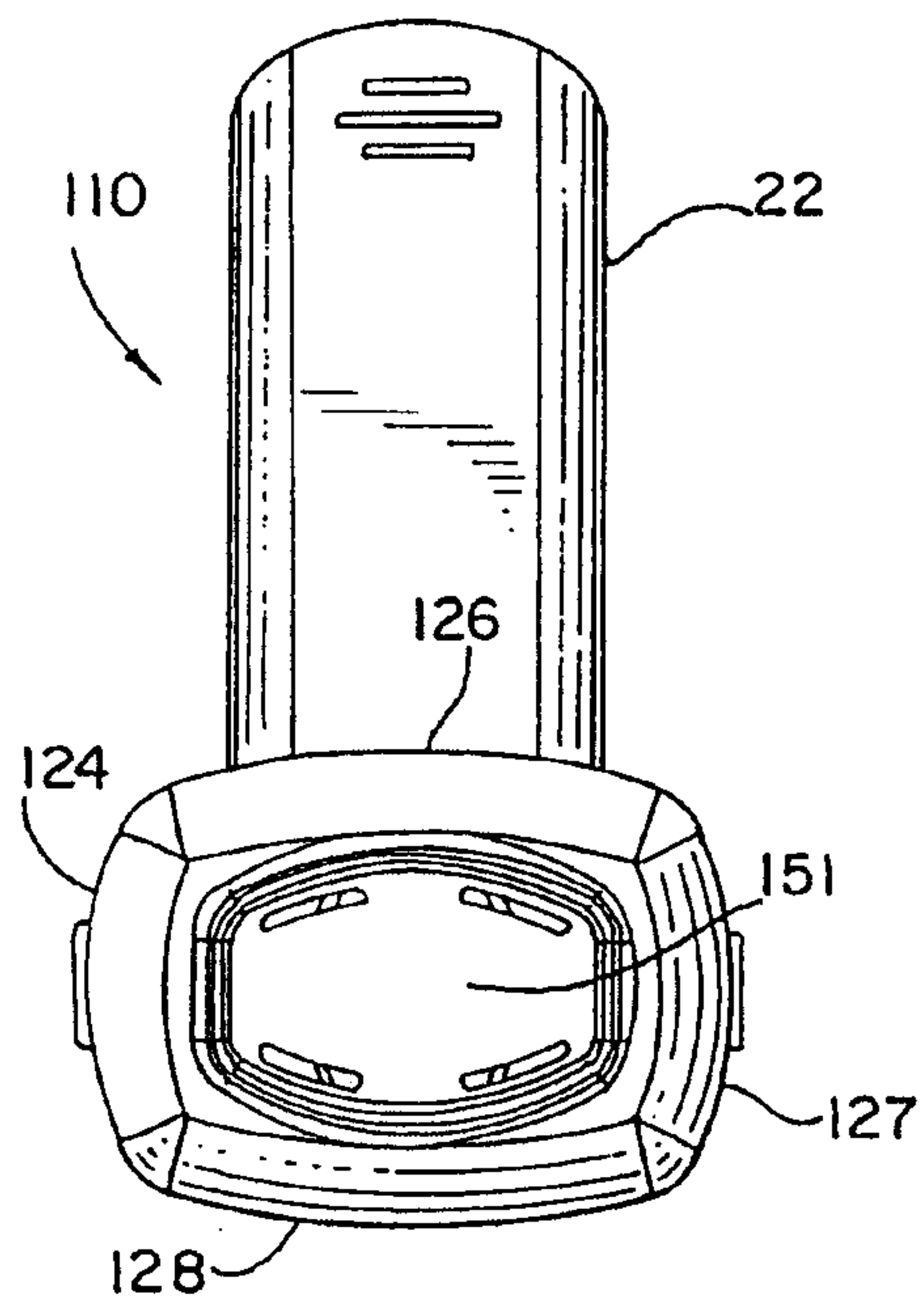


FIG. 14

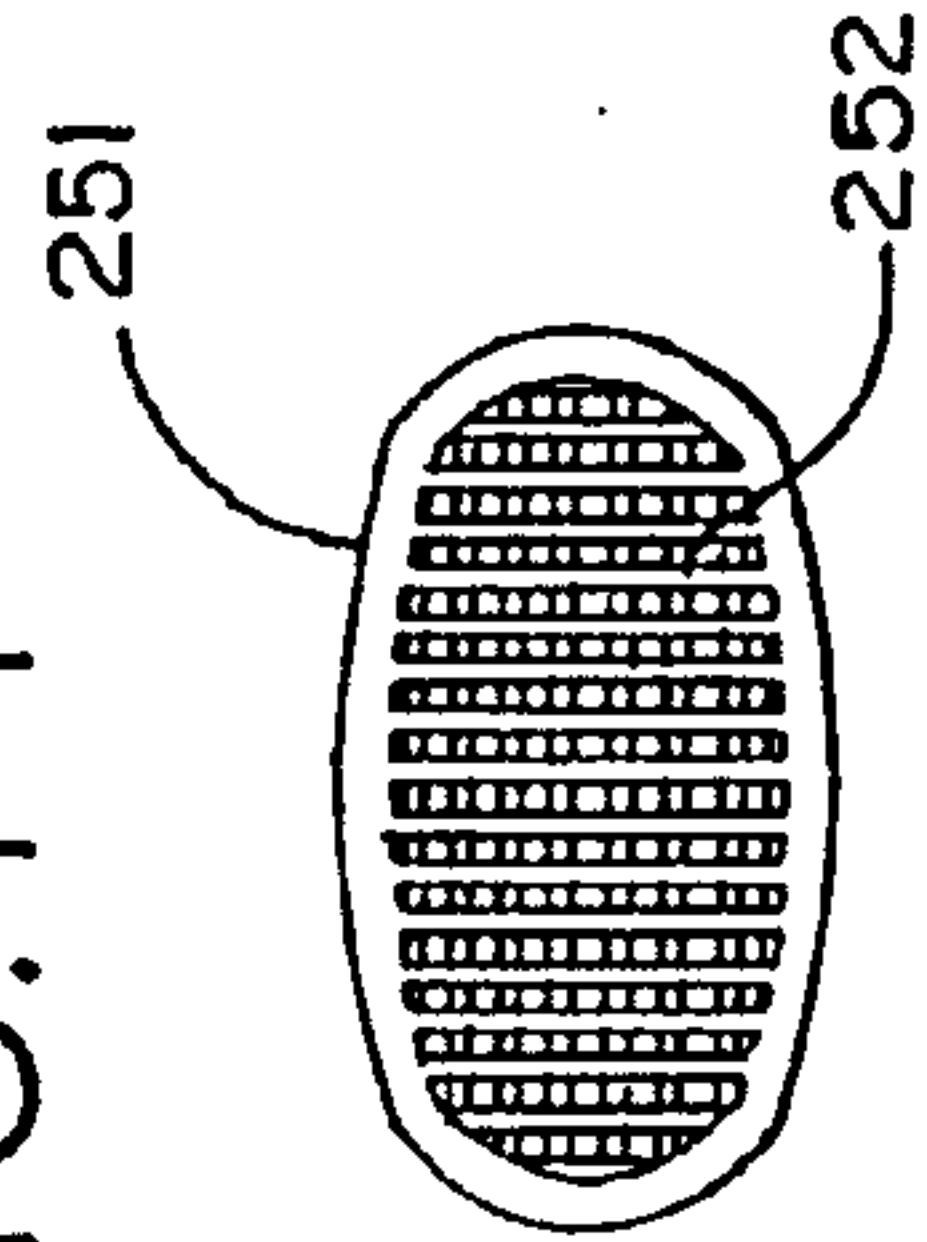


FIG. 15

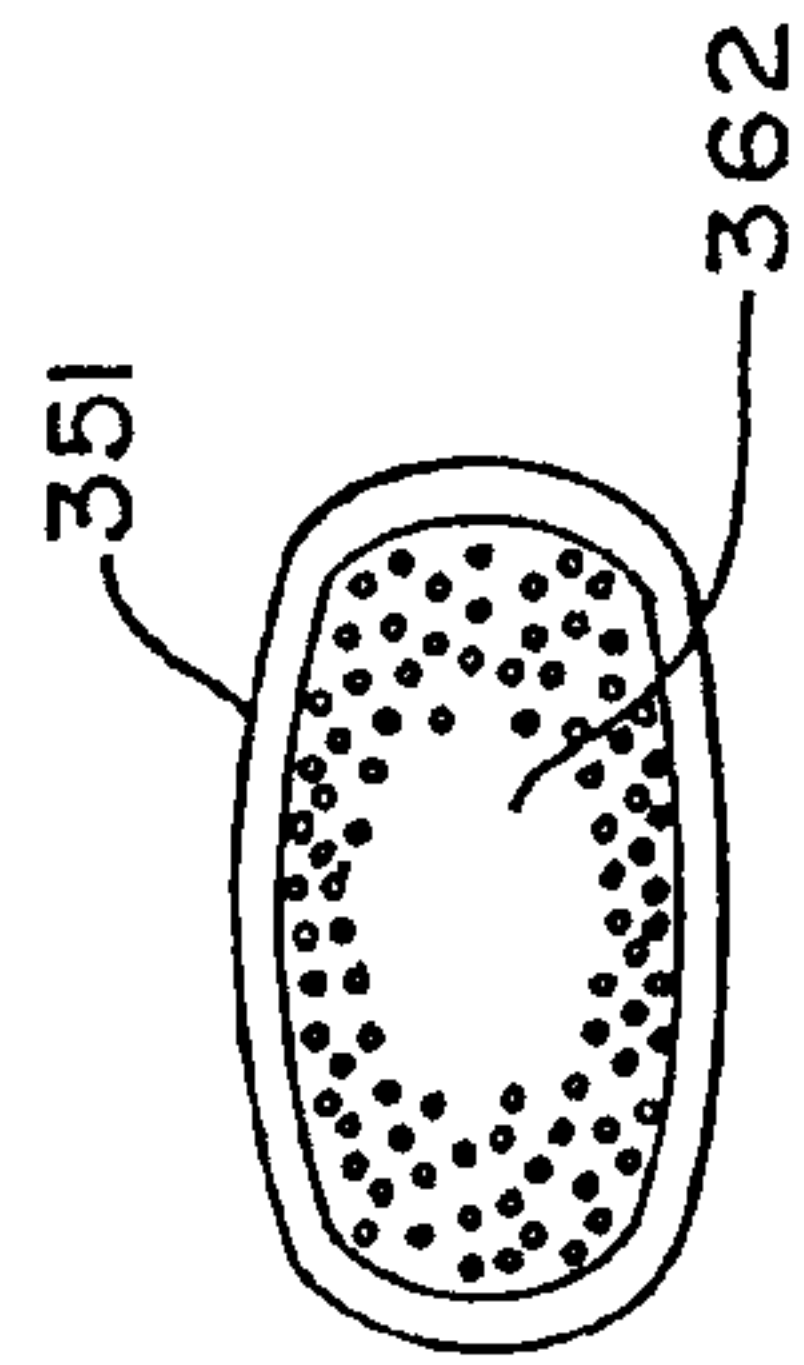


FIG. 16

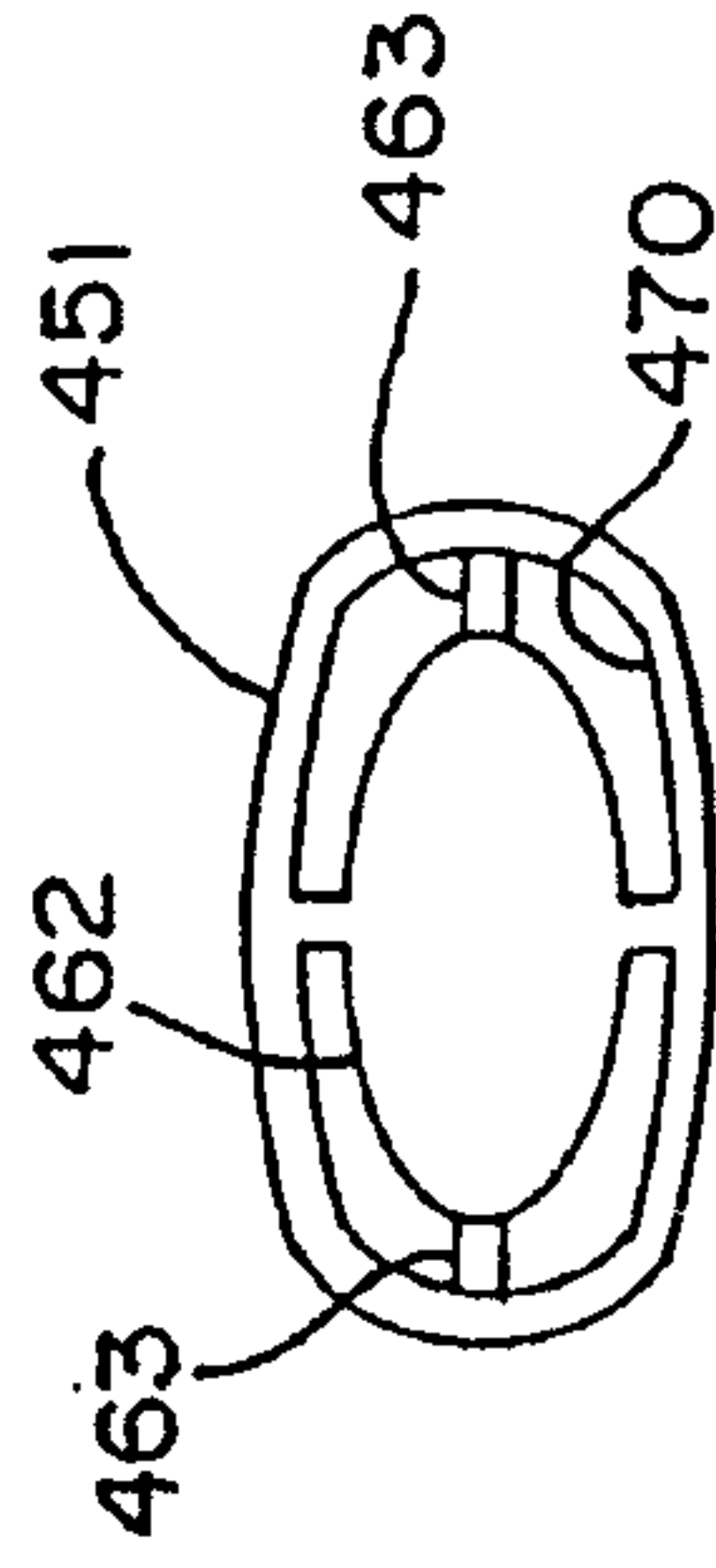


FIG. 17

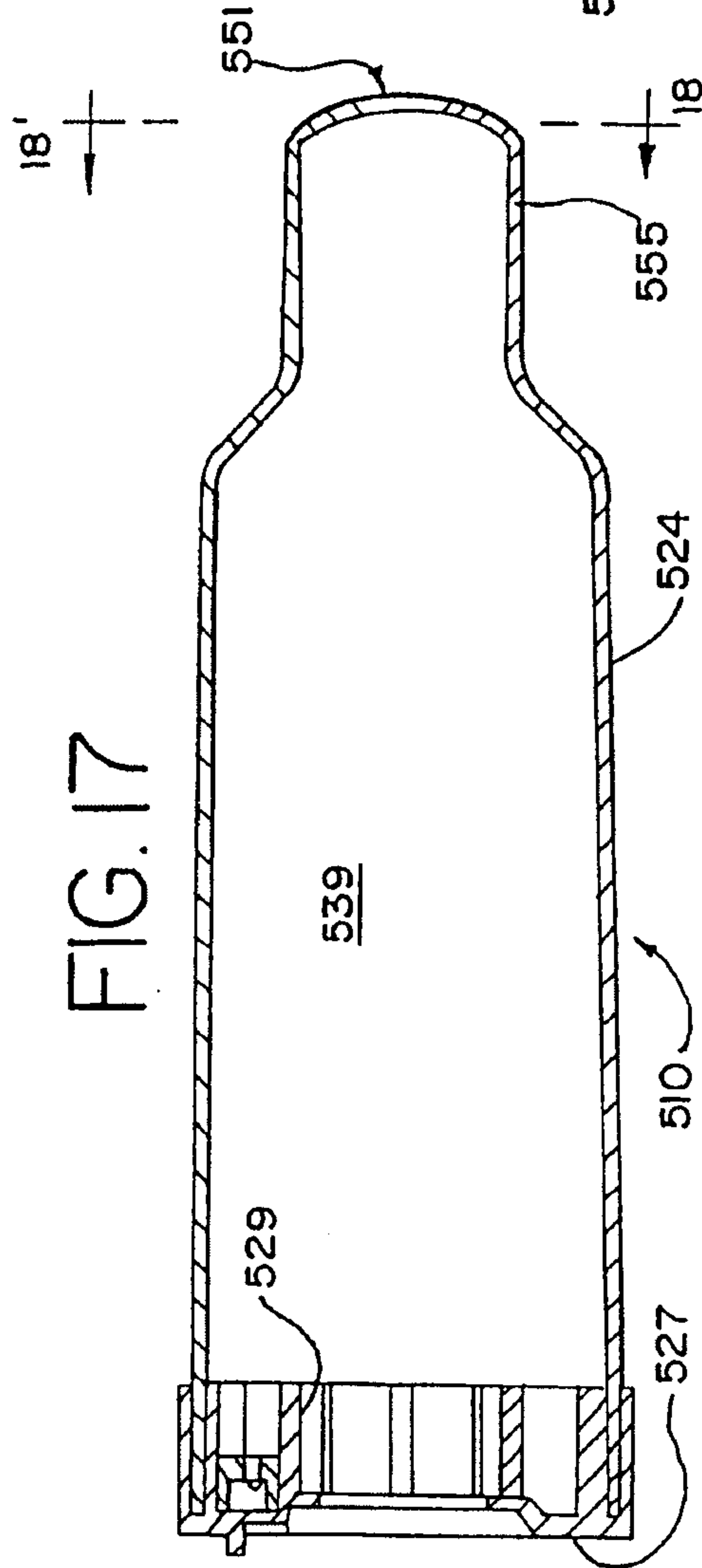


FIG. 18

