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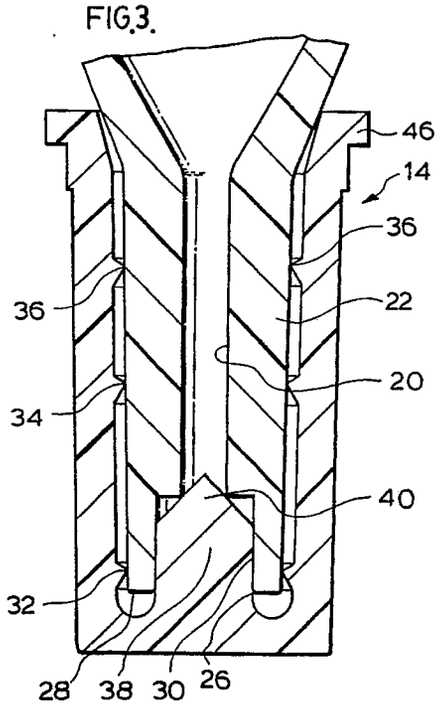
(54) Dropper construction.

(57) A dropper (10) for dispensing liquids in droplets of consistent size has a circular tip orifice (26) of predetermined diameter supplied with liquid via a capillary passage (20) of non-deformable diameter. Preferably, the dropper has a closure cap (14) of harder material than the tip (24) and is provided with an axially-directed projection (38) of complementary shape to a tip cavity (30) whereby upon closing the dropper the tip is remolded.

FIG.3.



EP 0 436 264 A1

DROPPER CONSTRUCTION

The present invention relates to a dropper construction for the discharge of drops from a reservoir of liquid.

For the oral administration of certain vaccines, such as poliomyelitis vaccine, it is necessary for a reliable and accurate dosage to be provided. In this regard, the World Health Organization now requires polio vaccine to be administered as two drops each of 0.05 ml. Unfortunately, there does not exist a dropper able to function reproducibly and accurately in this manner, although attempts have been made in the prior art. The absence of such a device has lead to the development of the present invention.

In accordance with the present invention, there is provided a novel dropper structure which is able to provide a reliable and consistent drop of liquid from a reservoir thereof within the body of the dropper. The reservoir is connected via a capillary passage to a tip from which the drops fall and which is capped when not in use.

In the present invention, it is essential for the capillary passage to have a fixed cross-sectional dimension which does not alter as a result of differences in pressure applied to the resiliently-flexible reservoir, so that the flow of liquid through the capillary passage is controlled by surface forces. In this way, irrespective of the pressure applied by hand to the reservoir to eject the liquid therefrom, within a reasonable range, the same volume of liquid is delivered to the tip.

The tip is dimensioned to have a diameter which corresponds to the volume of liquid to be ejected as a single drop from dropper. It is known that the weight of a droplet released from an orifice corresponds to the formula:

$W = 2\pi r ST f$

where W is the drop weight, r is the radius of the orifice, ST is the surface tension at the point of wetting and f is a connection factor which depends on the orifice radius and the material of construction of the tip.

Although standard textbooks provide information with respect to f, we have found this information to be incorrect. We have found that the connector factor f is determined by the relationship:

$f = 0.998 - 1.119X + 0.793X^2 + 0.1520X^3 - 0.265X^4$

where $X = arV^{-}0.33$

a = an empirical factor depending on tube material and solution.

r = orifice radius

V = drop volume

The invention is described further by way of illustration, with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of a dropper constructed in accordance with one embodiment of the invention;

Figure 2 is a close-up sectional view of the head of the dropper of Figure 1 illustrating the structure of the head and droplet formation;

Figure 3 is a close-up sectional view of the head of the dropper assembled with the cap;

Figure 4 is a close-up sectional view of an alternative form of the head of the dropper of Figure 1;

Figure 5 is a close-up sectional view of the head of the dropper of Figure 4 assembled with the cap;

Figure 6 is a perspective view of a typical prior art dropper structure which is improved by the structure of the invention;

Figure 7 is a part-sectional view of the dropper of Figure 6 assembled with its cap;

Figure 8 is another part-sectional view of the dropper of Figures 6 during drop formation;

Figure 9 is a close-up sectional view of a further alternative form of the head of the dropper of Figure 1; and

Figure 10 is a close-up sectional view of the head of the dropper of Figure 9 assembled with the cap.

Referring to the drawings, a dropper 10 comprises a dropper body 12 and a cap 14. The body 12 is molded as one piece in a seamless mold, so as to provide an entirely smooth external surface, particularly in the area of the tip, from any convenient polymeric material, such as low density polyethylene. The body 12 includes an elongate generally cylindrical reservoir 16 which is deformable by squeezing to eject drops of liquid, such as polio vaccine, from the reservoir 16. Usually, the reservoir contains a convenient multiple of unit doses. For example, with polio vaccine, the reservoir 16 typically contains 10 or 20 unit doses.

The generally cylindrical reservoir 16, which is heat-sealed closed by heat seal 18 at one end, communicates with a capillary passage 20 in a neck 22 of the dropper body 12. The capillary passage 20 has a uniform diameter along its length which is dimensioned to permit flow therethrough by capillary effect only. The neck 22 is formed of relatively thick material in comparison to the diameter of the capillary

passage 20, to resist deformation of the diameter of the capillary passage 20 as ejecting pressure is applied to the reservoir 16, so as to provide a uniform flow of liquid from the reservoir 16 through the capillary passage 20 irrespective of the pressure applied by hand to the reservoir 16 within a reasonable range. The flow is controlled primarily by surface forces in the passage 20.

Located at the downstream end of the neck 22 is a tip 24. The tip 24 has a circular orifice 26 which is of a diameter to ensure that each liquid drop which falls from the orifice 26 always contains the same predetermined volume of liquid. The tip 24 has an entirely smooth surface 28 of contact with the liquid and a cylindrical or slightly tapered cavity 30 extending into the tip 24 to the passage 20. The orifice 26 thereby is defined by a sharp right angle edge.

The cap 14 also is molded as a one-piece construction from a polymeric material and is intended to function as a fluid-tight end closure for the body 12 when the dropper 10 is not in use, so that liquid is not lost from the reservoir 16, nor can contaminants enter the liquid reservoir.

The cap 14 includes a series of circular ridges 32, 34, 36 which are integrally molded to the internal surface of the cap 14 and arranged to grip the outer surface of the neck 22 when the cap 14 is positioned in its closing position. An axially inwardly directed projection 38 from the end wall of the cap 14 is arranged to project accurately into the cavity 30 of the tip 24 when the cap 14 is in its closed position.

The projection 38 has a diameter and shape such that it snugly fits into the cavity 30 when the cap 14 is assembled to the body 12 so that the external surface of the projection 38 engages the internal surface of the cavity 30. The projection 38 includes a tapered nose portion 40 which projects into and engages the orifice 42 at the downstream end of the capillary passage 20 when the cap 14 is fully assembled to the body 12, thereby preventing liquid flow out of the passage 20.

One of the ridges, namely ridge 32, is arranged to engage the tip portion 24 of the dropper 10 so that the walls of the cylindrical cavity 30 are gripped between that ridge 32 and the projection 38. The cap 14 is generally formed of harder polymeric material than the tip 24, so that insertion of the projection 38 into the cavity 30 of the tip 24 and gripping of the wall of the cavity 30 between the projection 38 and the ridge 32, in effect, remolds the tip 24 each time the cap 14 is put on the dropper 10. This arrangement ensures that the shape of the tip 24, and, in particular, the size and shape of the orifice 26, is maintained and hence the drop of liquid falling from the tip 24 is consistently of the same volume, irrespective of the rate at which such droplets are formed and fall from the tip 24.

The cap 14 has an outer surface having longitudinally-extending ridges which permit the cap 14 to be gripped readily for removal from the body 12 and reassembly with the body 12. The cap 14, at its open end, has a radially-extending rim 46, which facilitates machine assembly of the cap 14 to the body portion 12 prior to filling the reservoir 16 with liquid and formation of the heat seal 18.

Figures 4 and 5 show some variation to the structure shown in Figures 2 and 3. As seen therein, the capillary passage 20 may be made shorter than the length of the neck 22, to provide a cavity 47 in the neck. This modification does not affect the effectiveness of the device, but enables molding of the dropper 10 to be more readily effected.

In addition, an annular shoulder 48 is cut into the periphery of the surface 28, leaving a ring with sharp right angle edges, which produces improved drop uniformity with certain materials.

At the present time, oral polio vaccine is dispensed from a tube of uniform diameter as three drops per dose. One attempt to provide a more consistent volume of droplet is illustrated in Figures 4 to 6. However, the dropper 100 illustrated therein is not effective in this regard, for a number of reasons. As can be seen, as initially provided, the body 102 has a membrane closure to the reservoir 106. The cap 108 has a prong 110 which is intended to pierce the membrane to permit liquid to be dispensed from the reservoir 106. Unfortunately, this piercing action does not produce a consistent opening and leaves ragged edge remnants of the membrane in the orifice 112. This problem is avoided in the structure of this invention.

In addition, the dropper 100 is molded in a two-part mold, which leaves a visible mold part line 114. The presence of this mold part line 114, which is of inconsistent dimension, adjacent to and extending into the droplet-forming orifice 116 leads to inconsistency of droplet size. By molding the dropper 10 with smooth walls, this inconsistency problem is overcome. In addition, the prior art dropper 100 has no mechanism for remolding the tip.

Figures 9 and 10 show further variation to the structure shown in Figures 2 and 3. As seen therein, the capillary passage 20 is made very short, thereby lengthening the cavity 47 in the neck. By providing this structure, molding of the dropper 10 is even more readily effected without adversely affecting the effectiveness of the device.

As in the arrangement of Figures 9 and 10, an annular shoulder 48 is cut into the periphery of the surface 28, leaving a ring with sharp right angle edges, which produces improved drop uniformity with certain materials. In addition the orifice 26 is provided in conical form, with the cap projection being formed

with a complimentarily-shaped surface, again for ease of molding without adversely affecting the effectiveness of the device.

The invention is illustrated further by the following example:

Droppers 10 were molded from low density polyethylene. The body 12 was formed from the low density polyethylene sold by USI Chemicals under the trademark "PETROTHENE R" grade NA226 while the cap 14 was molded from PETROTHENE grade NA201, a harder polyethylene.

The dropper 10 was dimensioned with a body length of 66.5 mm, a reservoir diameter of 10.7 mm, a capillary passage diameter of 1.5 mm, a tip diameter of 5.3 mm, an orifice diameter of 3 mm and an overall length of capillary passage and cavity of 13.5 mm. These dimensions and materials are intended to provide droplets of consistent size 0.05 ml ± 0.005 ml.

Two runs were made and two droppers chosen at random from a batch filled with polio virus vaccine having a density of 1.2057 g/ml. Drops were ejected from each dropper and the weight of liquid in each drop determined. The results are reproduced in the following Table:

TABLE

TUBE # 1		TUBE # 2	
WT (gms)		WT (gms)	
	.056		.052
	.054		.049
	.059		.059
	.062		.060
	.061		.055
	.062		.054
	.058		.054
	.060		.053
	.063		.056
	.056		.054
	.060		.063
	.059		.057
	.060		.059
	.065		.056
	.060		.060
	.055		.060
	.062		.059
	.058		.059
	.064		.060
	.059		.059
	.061		.056
	.060		.054
	.061		.058
	.052		.055
	.061		.058
	.061		.055
	.060		.055
	.058		.058
	.057		.058
	.058		.055
	.051		.064
	.052		.056
	.058		.064
	.059		.056
	.060		.065
	.063		.060
	.056		.061
	.058		.063
	.067	Average:	.057
	.059	Coefficient of Variation:	6.2%
	.054		
	.060		
	.052		
	.068		
Average:	.059		
Coefficient of Variation:	6.4%		

For the volume of liquid in each drop, the individual determined amount is divided by the density (1.2057). For Tube # 1, the total number of droplets was 44, representing 22 two-drop doses, the average weight of the droplets was 0.059 g and the average volume of the droplets was 0.049 ml. The coefficient of variation (ie the ratio between the standard deviation of the measurements and the average measurement)

was quite small, 6.4%.

For Tube # 2, the total number of droplets was 38, representing 19 two-drop doses, the average weight of the droplets was 0.057 g and the average volume of the droplets was 0.048 ml. The coefficient of variation for this group was only 6.2%. These results show the consistency of droplet size obtained using the dropper arrangement of the present invention.

In summary of this disclosure, the present invention provides a novel dropper arrangement which ensures a consistent droplet size to be maintained. Modifications are possible within the scope of this invention.

Claims

1. A dropper for dispensing liquids in droplets comprising a reservoir (16) for said liquid within the body (12) of the dropper (10); a neck (22) extending from the reservoir to a tip (24); and a passage (20) formed through said neck (22) communicating with said reservoir (16) and said tip (24), characterized in that said passage (20) is a capillary passage, said neck (22) has a sufficient thickness in the region of said passage (20) to avoid deformation under the influence of the pressure of liquid flowing through said passage (20), and said tip (24) has a circular orifice (26) of diameter corresponding to the volume of liquid required in each droplet.

2. A dropper as claimed in Claim 1, wherein the tip (24) includes a cavity (30) extending from the downstream end of the capillary passage (20) to the orifice (26).

3. A dropper as claimed in Claim 2, wherein said cavity (30) has a uniform diameter along its length.

4. A dropper as claimed in Claim 2, wherein said cavity (30) is slightly outwardly tapered towards its downstream end.

5. A dropper as claimed in any one of Claims 2 to 4, wherein the tip (24) has a smooth flat end wall (28) and the cavity (30) defines with the end wall (28) a sharp perpendicular edge to the orifice (26).

6. A dropper as claimed in any one of Claims 2 to 5, wherein a further cavity (47) is formed in said neck (22) at the downstream end of said reservoir (16) and said capillary passage extends from said further cavity (47) to said cavity (30).

7. A dropper as claimed in any one of Claims 2 to 6 including a closure cap (14) for fitting over the neck (22) and tip (24) to provide a fluid tight closure when the dropper (10) is in use, said closure cap (14) being formed of harder material than the tip (24) and having an axially-directed projection (38) of a complementary shape to that of the cavity (30) of the tip (24) to be received in snug fit into the cavity (30) whereby the tip (24) is remolded upon closing the dropper.

8. A dropper as claimed in Claim 7, wherein the axially-directed projection (38) includes a tapered nose portion (40) which extends into the downstream end of the capillary passage (20) and engages a shoulder (42) at the downstream end of the passage (20) to prevent liquid flow therethrough when the cap (14) provides the fluid tight closure.

9. A dropper as claimed in Claim 7 or 8, wherein the closure cap (14) has a radially inwardly extending annular ridge (32) arranged to engage the outer wall of the tip (24) to grip the cavity (30) between the ridge (32) and the axially-directed projection (38) when the cap (14) provides the fluid tight closure.

10. A dropper as claimed in any one of the preceding claims, including a clsoure cap (14) having a plurality of radially inwardly extending annular ridges (32, 34, 36) arranged to engage the outer surface of the neck (22) in interference fit to provide a fluid tight closure when the dropper is not in use.

FIG.1.

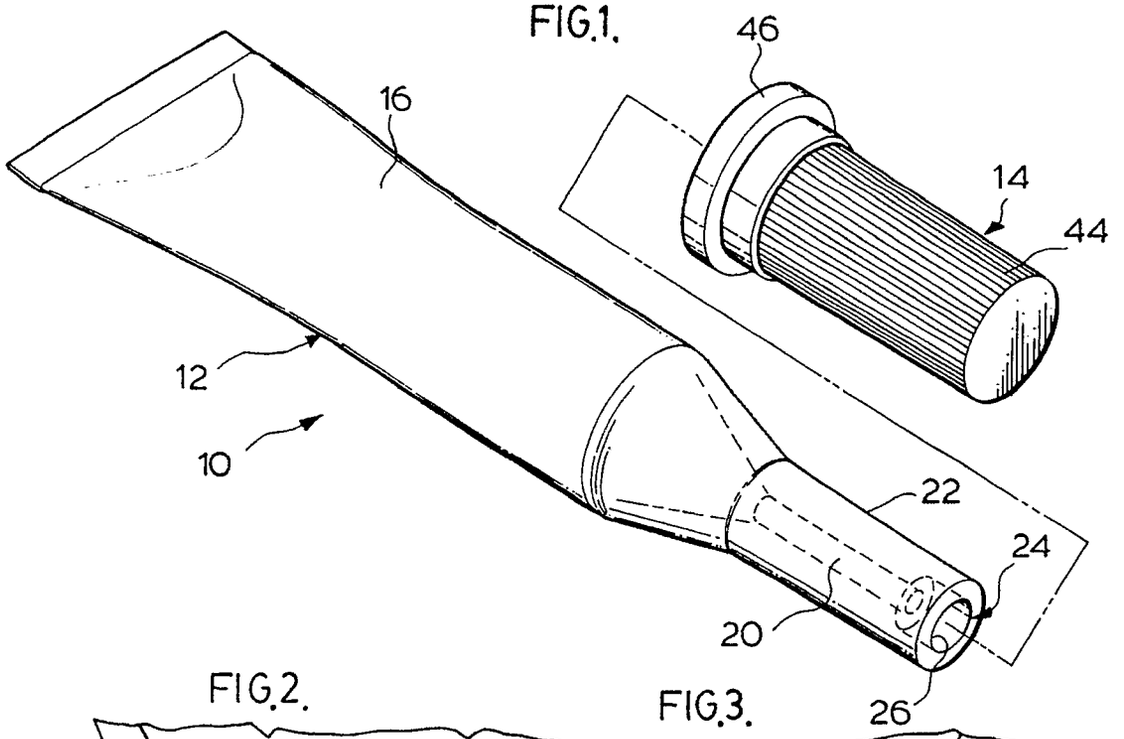


FIG.2.

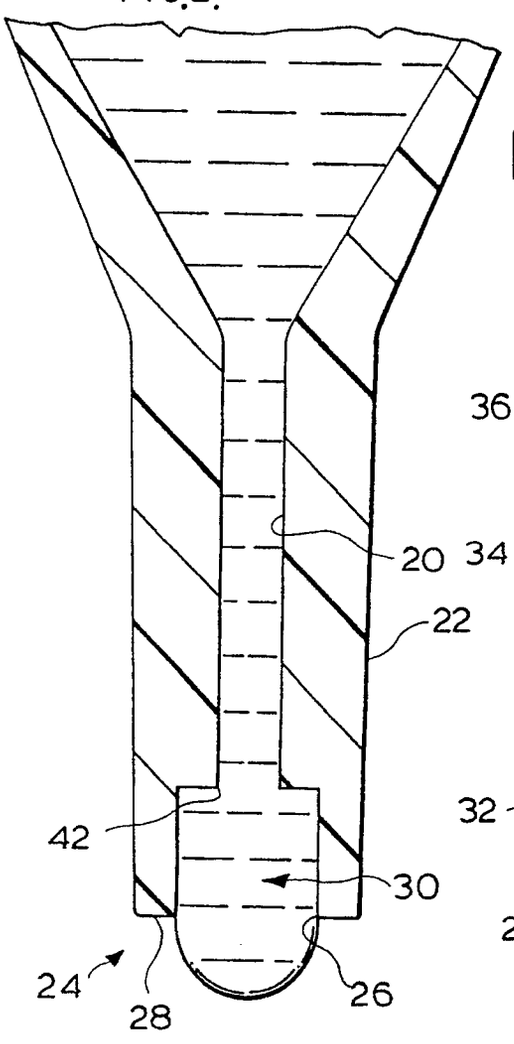


FIG.3.

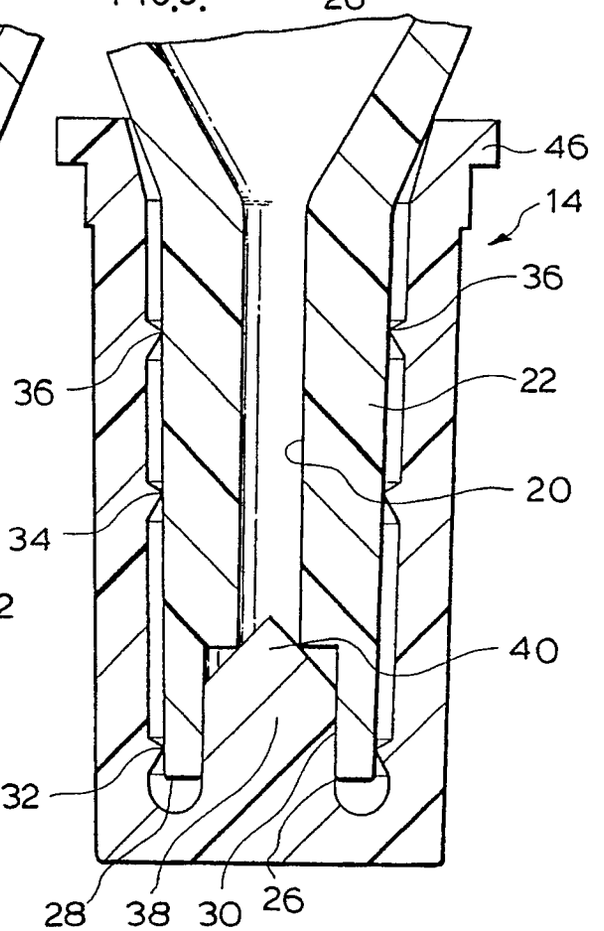


FIG.4.

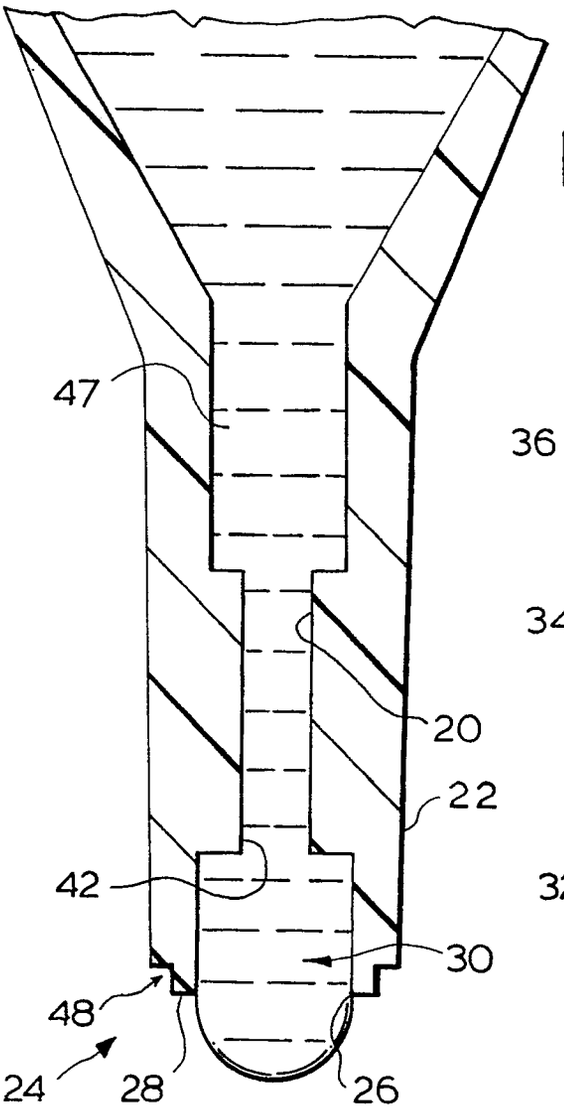
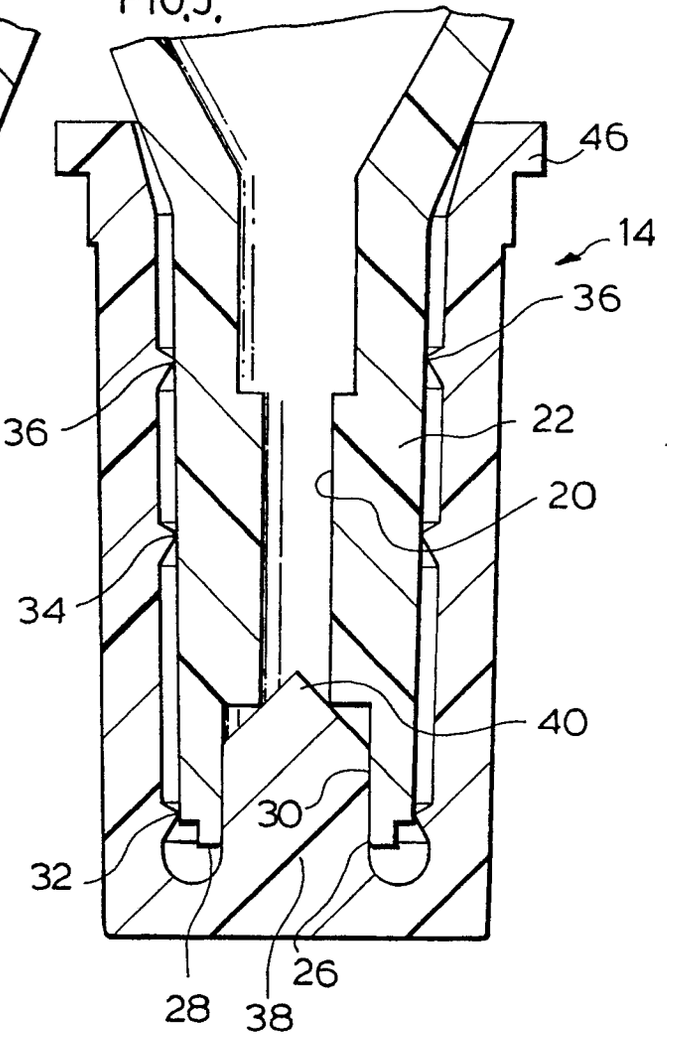


FIG.5.



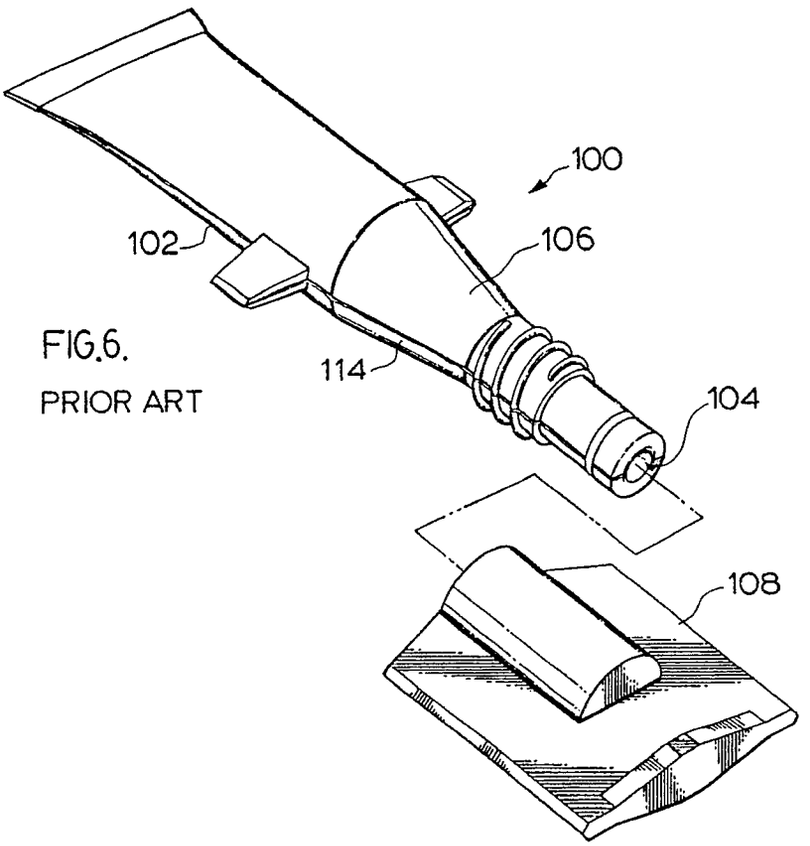


FIG.6.
PRIOR ART

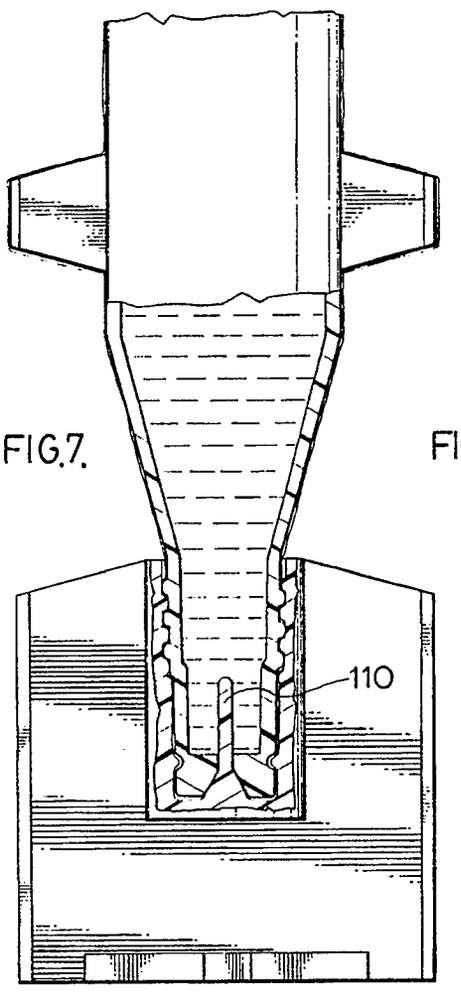


FIG.7.

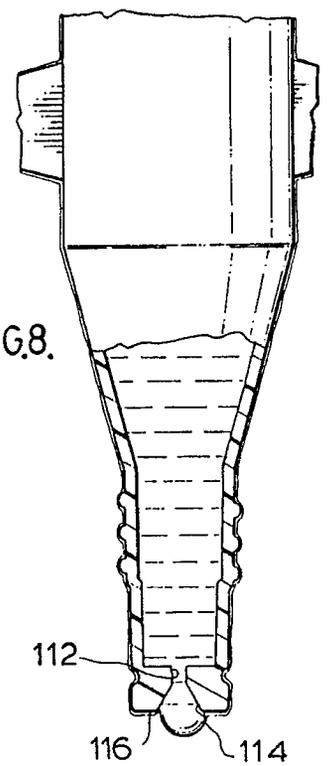


FIG.8.

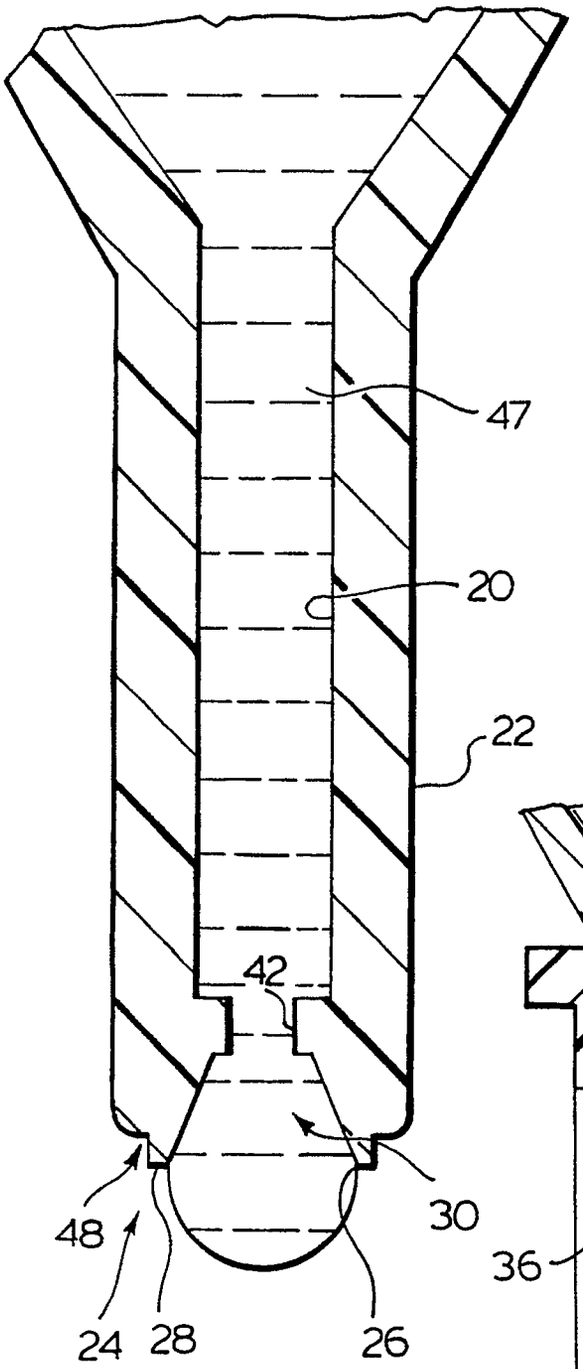
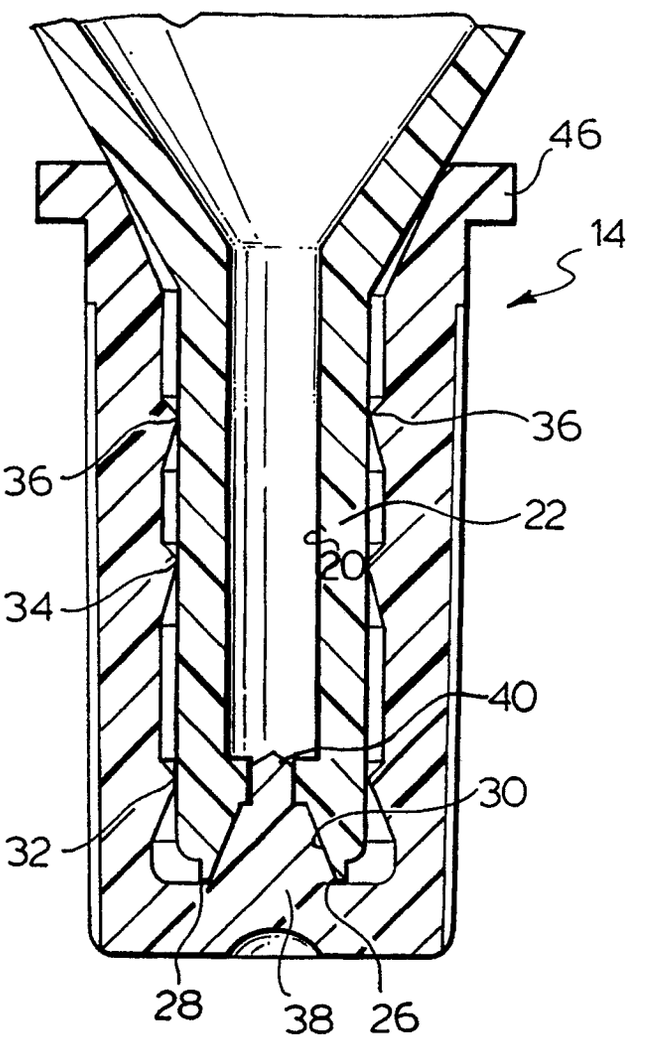


FIG.9.

FIG.10.



European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 90 30 0015

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	EP-A-0 255 492 (CAPSULIT) * Column 2, lines 10-20; figure 1 *	1-3,5,6	B 65 D 47/18
Y		4	
Y	WO-A-8 400 707 (A.H.S.C.) * Figure 6 *	4	
A	US-A-2 798 644 (ROOT) * Figures *	1	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

B 65 D
B 01 L

~~The present search report has been drawn up for all claims~~

Place of search	Date of completion of the search	Examiner
THE HAGUE	30-07-1990	NEWELL P.G.

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

EPO FORM 1503 03.82 (P0401)

European Patent Office

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

☐ All claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for all claims.

☐ Only part of the claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid,

namely claims:

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

x LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirement of unity of invention and relates to several inventions or groups of inventions,

namely:

1. Claims 1-6: Dropper construction to give consistent drop by forming cap capillary passage and cylindrical tip cavity.

2. Claims 7-10: Cap for dropper, with axial projection to re-mould internal tip cavity in order to control drop size.

These are two different "inventive concepts" which do not meet the requirements for unity of invention.

☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid,

namely claims:

☒ None of the further search fees has been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims,

namely claims: 1-6