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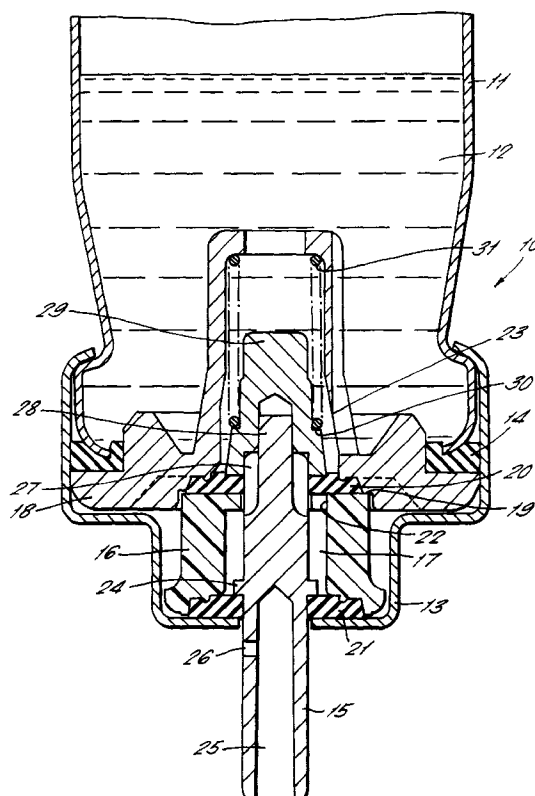
**29.10.1997 Bulletin 1997/44**(51) Int Cl.<sup>6</sup>: **B65D 83/54**(21) Application number: **97302729.5**(22) Date of filing: **22.04.1997**

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**DE FR GB IT**(30) Priority: **26.04.1996 GB 9608707**(71) Applicant: **Bespak plc****King's Lynn Norfolk PE30 2JJ (GB)**(72) Inventor: **Howlett, David****Kings Lynn, Norfolk 1AF (GB)**(74) Representative: **Alexander, Thomas Bruce et al****BOULT WADE TENNANT,****27 Furnival Street****London EC4A 1PQ (GB)**(54) **Improvements in or relating to valve for dispensers**

(57) A dispensing apparatus (10) is provided for dispensing a product (12) from a pressurised container comprising a metering valve. The valve comprises a valve body (16,18) defining a metering chamber (17), an outer annular seal (21) closing an outer end of the chamber (17), an inner annular seal (20) at an inner end of the chamber (17) and a valve stem (15) extending in sliding sealed relation through the chamber (17) and engaging at its inner end a valve stem member. Spring means (31) are provided urging the valve stem member (29) into sealing engagement with the inner seal (20) such that the chamber (17) is sealed, the valve stem (15) being manually movable against the action of the spring means (31) to unseat the valve stem member (29) into a first position in which a fluid inlet path is opened into the chamber (17) to enable filling of the chamber (17). The valve stem (15) being movable further to a second position in which the fluid inlet path is closed and a fluid outlet path from the chamber (17) is opened to enable the product to be dispensed from the chamber (17).

FIG. 1.

**EP 0 803 449 A1**

## Description

The invention relates to improvements in valves for dispensers for dispensing an accurately metered dose of a product.

The accuracy of the metered dose of an active drug is very important for dispensing drugs and medicaments and more attention is being paid nowadays to the consistent accuracy of every dose supplied by pharmaceutical dispensing means. One problem in particular which has been noted is the loss of prime. This is usually characterised by the measure of the product (i.e. the complete formulation) which is dispensed from the valve following storage in adverse conditions and/or for an extended duration. This can equate to storage of the dispenser with the valve pointing upwards for up to 24 hours as this replicates the more severe aspects of patient usage. If the total amount of formulation dispensed is reduced, then it also follows that the amount of active substance dispensed is also below specification.

There are a number of explanations for loss of prime. The first is simply that the liquid drains out of the metered volume of the valve (this is often referred to as "drain back") back into the storage container. The principal factors controlling such drain back would be the flow path geometry and fluid properties such as surface tension and viscosity. A common approach adopted to improve drain back is to either restrict this flow path, or make the route more tortuous.

A second explanation is more complex and results from the thermodynamic properties of the liquified propellants normally employed in such dispensers and in particularly in metered dose inhalers. The propellants give off a vapour, consisting of molecules of substance. If the substance is in an enclosed space, as it is in a dispensing container, the pressure of the vapour will reach a maximum that depends on the nature of the substance and the temperature. Within the closed container, at room temperatures, such propellants are in an equilibrium state, in as much as molecules of the liquid are transforming into vapour at the same time as the reverse is occurring. The metered volume of product is connected to the bulk of the product and this vapourisation also occurs in the metering chamber. A significant expansion to the vapour state displaces liquid from the chamber, causing a loss of prime and this can occur if the dispenser is stored with the valve pointing either upwards or downwards. It is thought likely that the actual loss of prime occurs as a combination or interaction of these two phenomena.

It is therefore an object of the present invention to provide improved dispensing apparatus which eliminates or reduces these problems wherein the metered valve is sealed in the rest state of the valve.

According to the invention there is provided dispensing apparatus for dispensing a product from a pressurised container comprising a metering valve, said valve comprising a valve body defining a metering

chamber, an outer annular seal closing an outer end of said chamber, an inner annular seal at an inner end of said chamber, a valve stem extending in sliding sealed relation through the chamber and engaging at its inner end a valve stem member spring means urging the valve stem member into sealing engagement with the inner seal such that the chamber is sealed, the valve stem being manually movable against the action of the spring means to unseat the valve stem member into a first position in which a product inlet path is opened into the chamber to enable filling of the chamber, the valve stem being movable further to a second position in which the product inlet path is closed and a product outlet path from the chamber is opened to enable the product to be dispensed from the chamber.

The metering chamber is thus filled dynamically following deliveries of a dose by the user. Provided that the flow path into the chamber is significant, refilling is almost instantaneous, so the chamber only needs to be open for a short period of time. Once filled the chamber is fully closed and sealed as the valve comes to rest, preventing either drain back or equilibrium displacement as the creation of a vapour bubble in a closed chamber would necessitate an increase in pressure.

Preferably the fluid inlet path is provided by longitudinal slots in the inner end of said valve stem.

The fluid inlet path is alternatively provided by transverse apertures in the inner end of said valve stem.

The fluid inlet path may as a further alternative be provided by the external shaping of the inner end of the valve stem relative to the inner seal.

Preferably the valve stem is movable to an intermediate position between the first and second positions in which the fluid inlet and outlet paths close and the chamber is sealed.

The fluid outlet path may be provided by an orifice communicating with a hollow portion of the valve stem, defining an exit channel.

Preferred embodiments of the present invention are described, by way of example only, with reference to the accompanying drawings in which:-

Fig. 1 shows a cross sectional side elevation of dispensing apparatus according to the present invention;

Figs. 2 to 5 are cross sectional side elevations of the valve of the dispensing apparatus of Fig. 1 showing the valve stem in different states of depression;

Fig. 6 is a cross sectional side elevation of the valve of Fig. 1 undergoing filling; and

Figs. 7 to 9 are cross sectional side elevations of alternative valve configurations for the dispensing apparatus of Fig. 1.

Referring to Fig. 1, the dispensing apparatus 10 comprises a dispensing container 11 in which a product 12 is stored to be dispensed in metered doses. The product may be medicament or pharmaceutical in the form of a liquid or a drug substance normally in suspension or other excipients, or a product which is expelled using a liquified propellant such as a CFC or HFA or blends thereof.

A valve assembly is held in position to seal the dispensing container 11 by a closure or ferrule 13 which is crimped to the open neck of the container 11. The ferrule 13 is preferably of aluminium and an elastomeric sealing gasket 14 prevents leakage of the product 12 between the ferrule 13 and the container 11.

The valve assembly comprises a valve stem 15, preferably of a polymeric or metallic material, which extends co-axially within a valve body 16, 18 and extends from the body to be externally accessible and provides an outlet for the product 12. The valve body comprises a valve member 16, preferably also of a polymeric or metallic material, which defines a cylindrical metering chamber 17, and an housing 18. The valve member 16 has an aperture 22 in one end and is located in a shallow annular recess 19 in the housing 18 and an elastomeric sliding seal 20 (the inner seal 20) provides a liquid-tight seal therebetween.

A further elastomeric sliding seal 21 (the outer seal 21) is located between the opposite end of the valve member 16 and the ferrule 13 to prevent leakage of the product 12 between the ferrule 13 and the valve stem 15 from the chamber 17.

The valve stem 15 has a first section comprising a generally hollow section defining a dispensing channel 25. The hollow first section of the valve stem 15 has a port 26 communicating with the dispensing channel 25.

The valve stem 15 also has a second section, one end of which is formed with longitudinal grooves 27 and a spigot 28. Positioned over this spigot 28 is a cap 29. The cap 29 has a flanged section 30 which provides an abutment for a return spring 31 which is located between the cap 29 and the base of the housing 18. The valve stem 15 also has a radially extending annular flange 24 located between the port 26 and the grooves 27.

The spring 31 is preferably of stainless steel and is biased to urge the flange 24 on the valve stem 15 into sealing contact with the outer seal 21.

In use, the valve stem 15 is displaced axially relative to the valve assembly against the bias of the spring 31, as shown in Fig. 2. As this occurs the stem 15 slides through the outer seal 21 and the inner seal 20 and the top of the stem grooves 27 pass through the aperture 22 in the valve member 16.

Further travel of the stem 15, as shown in Fig. 3, causes the stem grooves 27 to be fully located and sealed within the inner seal 20, thus isolating the metering chamber 17 from the product 12 within the container 11.

Further depression of the valve stem 15, as shown

in Fig. 4, causes the port 26 to pass through the outer seal 21 completely, into a position where it is in contact with the contents of the metering chamber 17. The preferred propellant systems used with the dispensing apparatus of the present invention are liquified gases or combinations thereof with boiling temperatures significantly below room temperature. As a result the product 12 boils evacuating the contents of the chamber 17 through the port 26 into the dispensing channel 25 as shown by the arrows in Fig. 4.

When the force on the valve stem 15 is released, the return spring 31 causes the stem 15 to return towards its rest position sliding through the inner and outer seals 20 and 21. When the stem grooves 27 pass through the inner seal 20 and contact the metering chamber 17, as shown in Fig. 5, the liquid product 12 is transferred into the metering chamber 17, as shown by the arrows, at a high rate due to the pressure differential. The potential for filling the metering chamber 17 exists for the duration that the grooves 27 bridge the inner seal 20 and prior to creation of the seal between the cap 29 and the inner seal 20.

Once the valve stem 15 is back in its rest position, as shown in Fig. 1, the seal created at the interface of the stem cap 29 and the inner seal 20 isolates the volume of product 12 in the metering chamber 17 from the rest of the product 12 in the container 11. This liquid-tight seal prevents the loss of product 12 from the metered volume in the metering chamber 17 and thus prevents loss of prime regardless of the orientation of the dispensing apparatus.

Fig. 6 illustrates a preferred pressure filling route for the valve assembly at the maximum point of displacement of the valve stem 15. The product 12 passes through the dispensing channel 25 of the valve stem 15, through the port 26 and into the metering chamber 17. The product 12 then passes through the aperture 22 in the end of the valve member 16 and forces the inner sliding seal 20 to deflect allowing the product 12 to escape into the housing 18, through the channel 23 and into the container 11, as shown by the arrows.

An alternative embodiment of the invention is shown in Fig. 7 which incorporates the more traditional flatter ferrule 13 and operates essentially the same as Fig. 1.

An alternative embodiment shown in Fig. 8 shows a similar arrangement to that of Fig. 7, but where the stem grooves 27 have been replaced with an annular clearance 37 which performs the same function.

In the embodiment shown in Fig. 9, a similar arrangement is shown, but where the clearance 37 has been replaced with two radial ports 38, 39 of large cross sectional area in an extension 40 of the cap 29. The ports 38, 39 are connected via an axial transfer duct 41 and perform the re-filling operation of the same manner as the stem grooves 27.

**Claims**

1. Dispensing apparatus (10) for dispensing a product (12) from a pressurised container (11) comprising a metering valve, said valve comprising a valve body (16, 18) defining a metering chamber (17), an outer annular seal (21) closing an outer end of said chamber (17), an inner annular seal (20) at an inner end of said chamber (17), a valve stem (15) extending in a sliding sealed relation through the chamber (17) and engaging at its inner end a valve stem member (29), spring means (31) urging the valve stem member (29) into sealing engagement with the inner seal (20) such that the chamber (17) is sealed, characterised in that the valve stem (15) being manually movable against the action of the spring means (31) to unseat the valve stem member (29) into a first position in which a fluid inlet path is opened into the chamber (17) to enable filling of the chamber (17), the valve stem (15) being movable further to a second position in which the fluid inlet path is closed and a fluid outlet path from the chamber is opened to enable the product (12) to be dispensed from the chamber (17).  
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10  
15  
20  
25
2. Dispensing apparatus as claimed in claim 1 in which the fluid inlet path is provided by longitudinal slots (27) in the inner end of said valve stem (15).  
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3. Dispensing apparatus as claimed in claim 1 in which the fluid inlet path is provided by transverse apertures (38, 39) in the inner end of said valve stem (15).  
35
4. Dispensing apparatus as claimed in claim 1 in which the fluid inlet path is provided by the external shaping of the inner end of the valve stem (15) relative to the inner seal (20).  
40
5. Dispensing apparatus as claimed in claim 1 in which the valve stem (15) is movable to an intermediate position between the first and second positions in which the fluid inlet and outlet paths are closed and the chamber (17) is sealed.  
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6. Dispensing apparatus as claimed in claim 1 in which the fluid outlet path is provided by an orifice (26) communicating with a hollow portion (25) of the valve stem (15), defining an exit channel.  
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FIG. 1

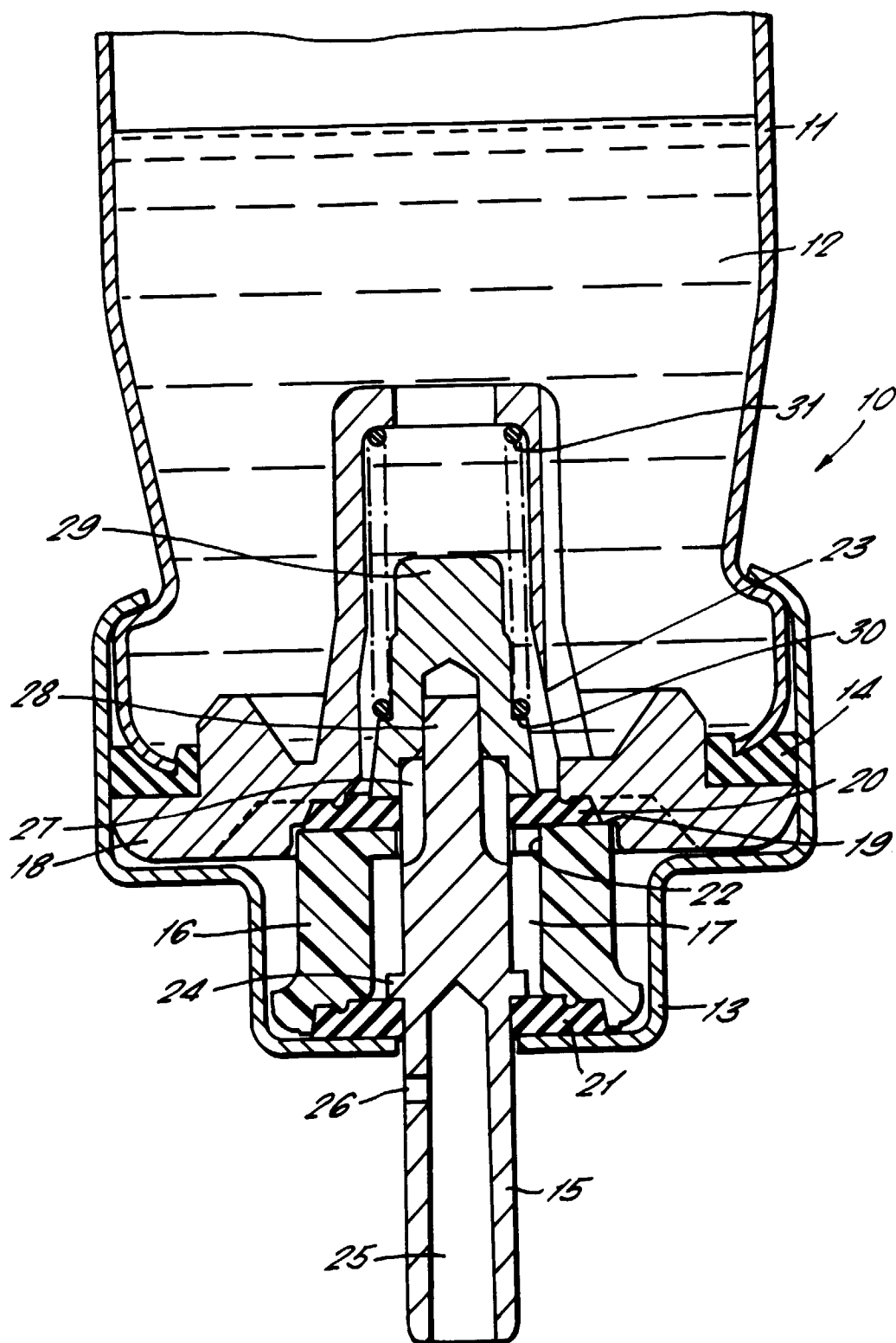


FIG. 2.

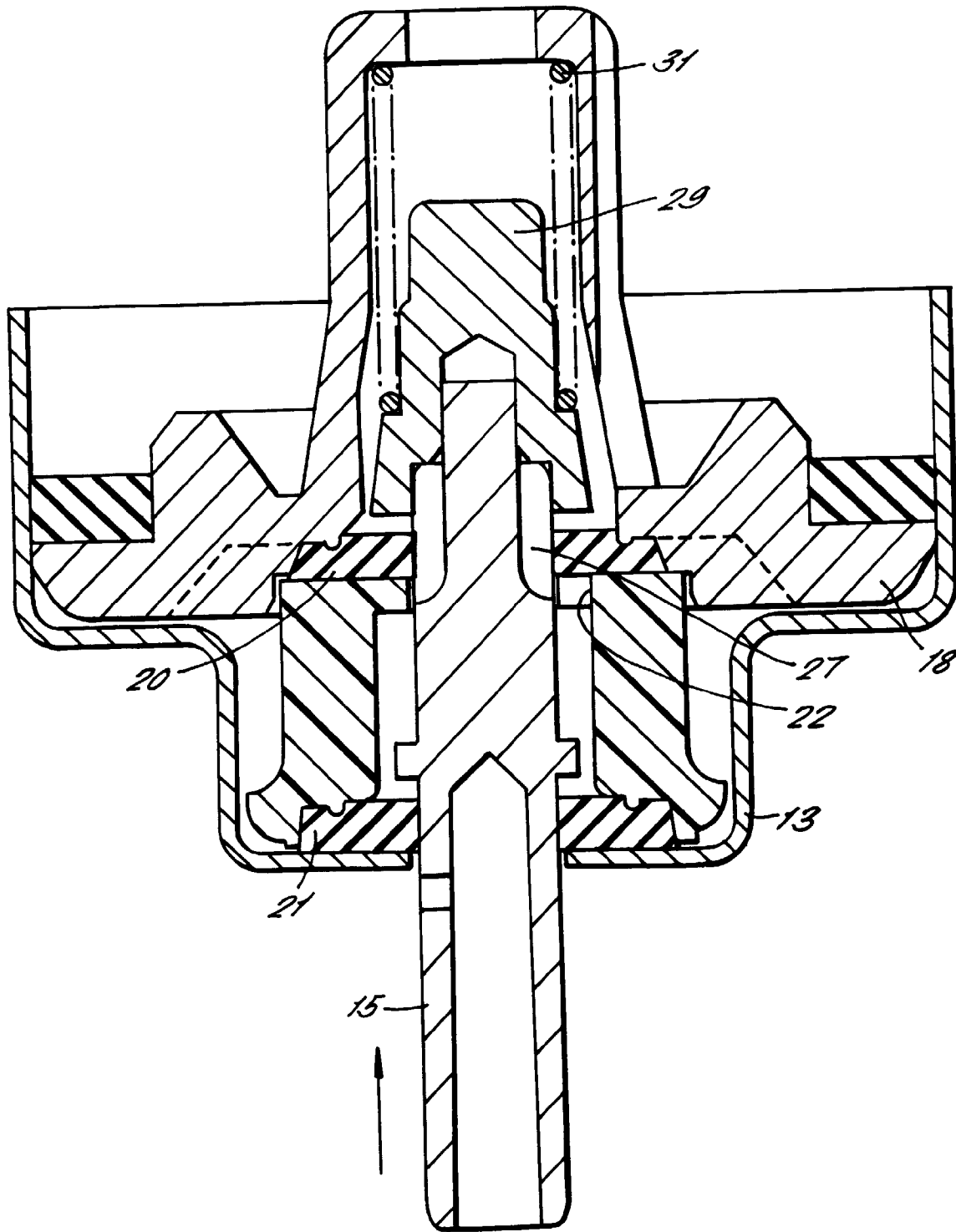


FIG. 3.

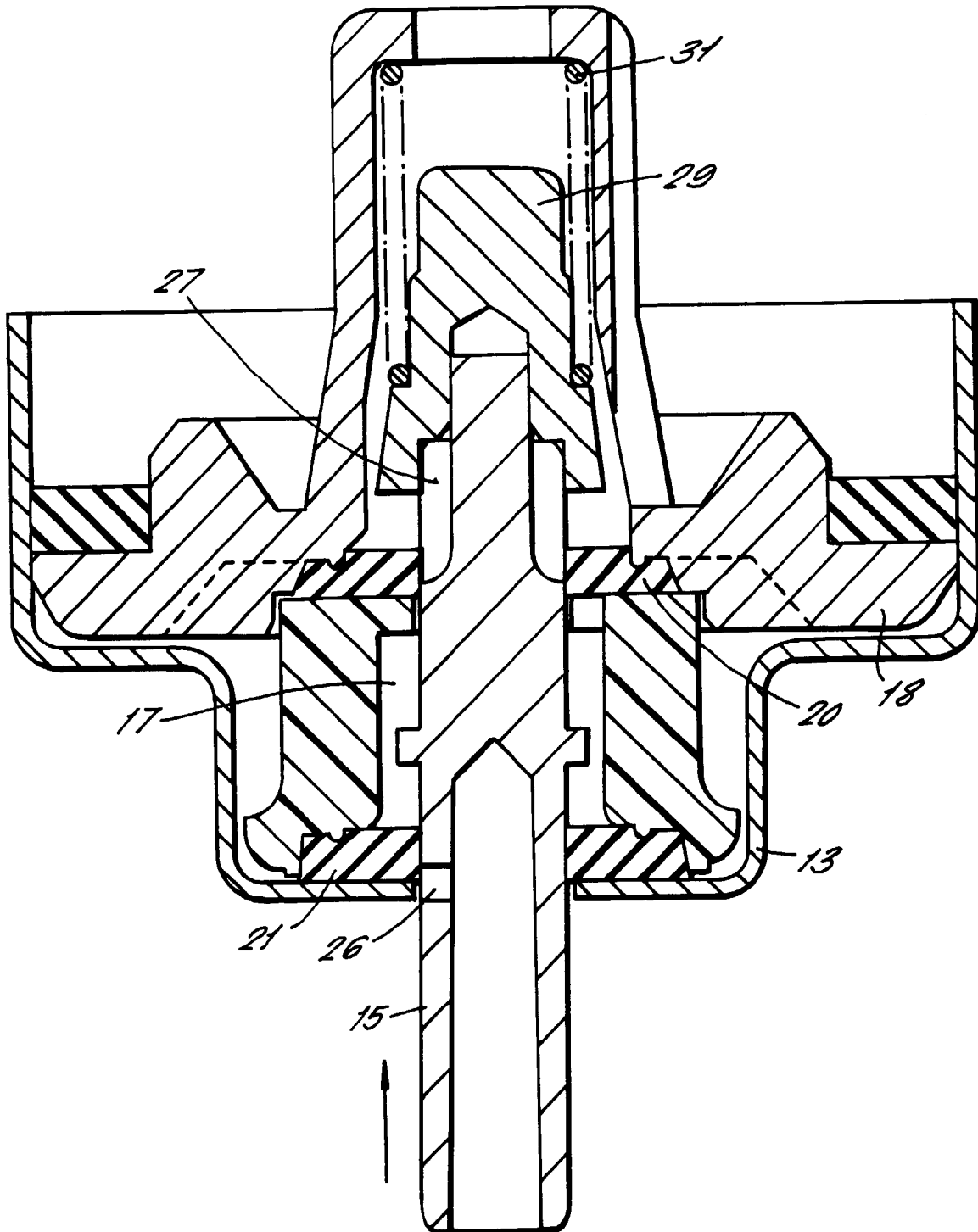


FIG. 4.

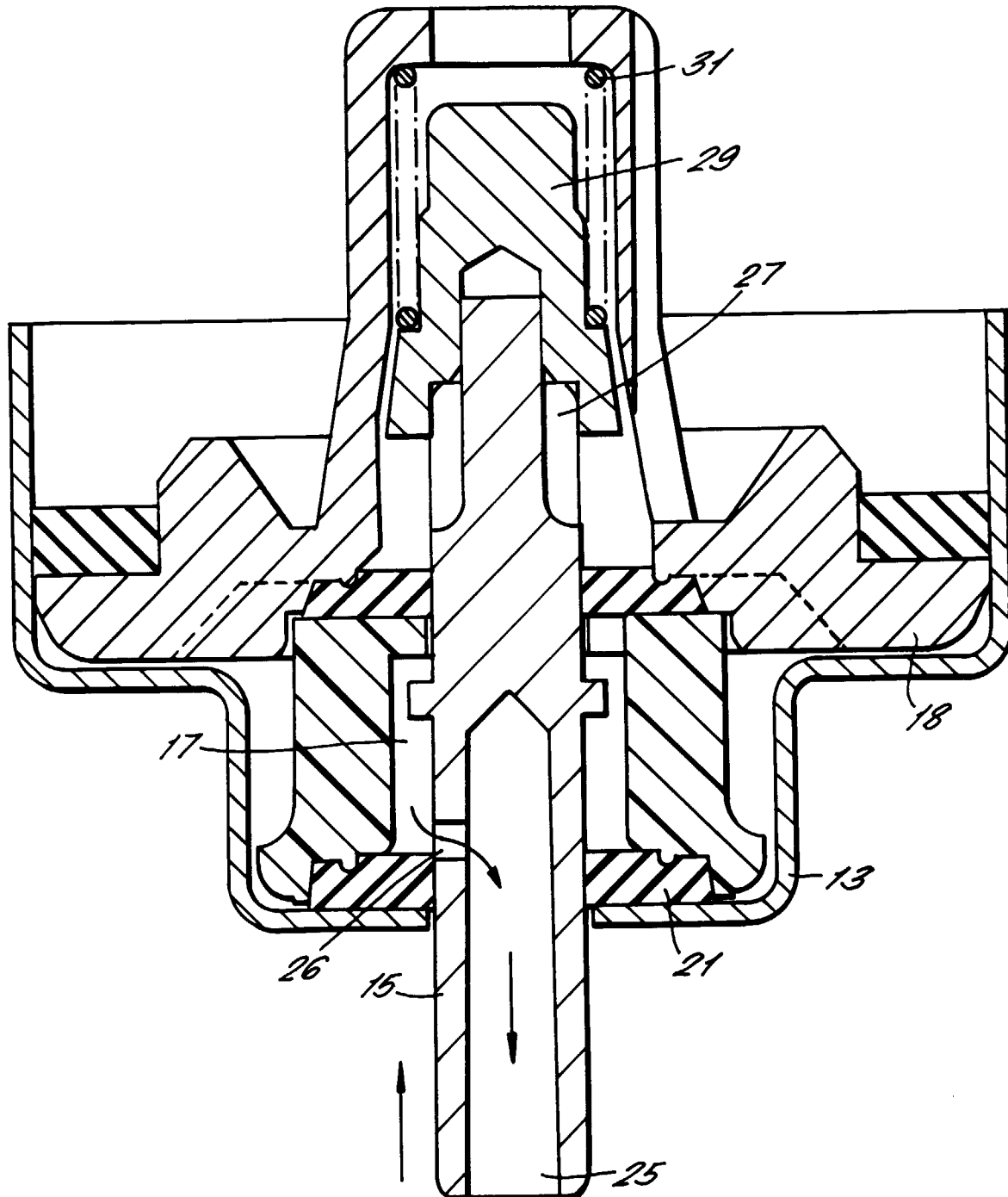




FIG. 5.

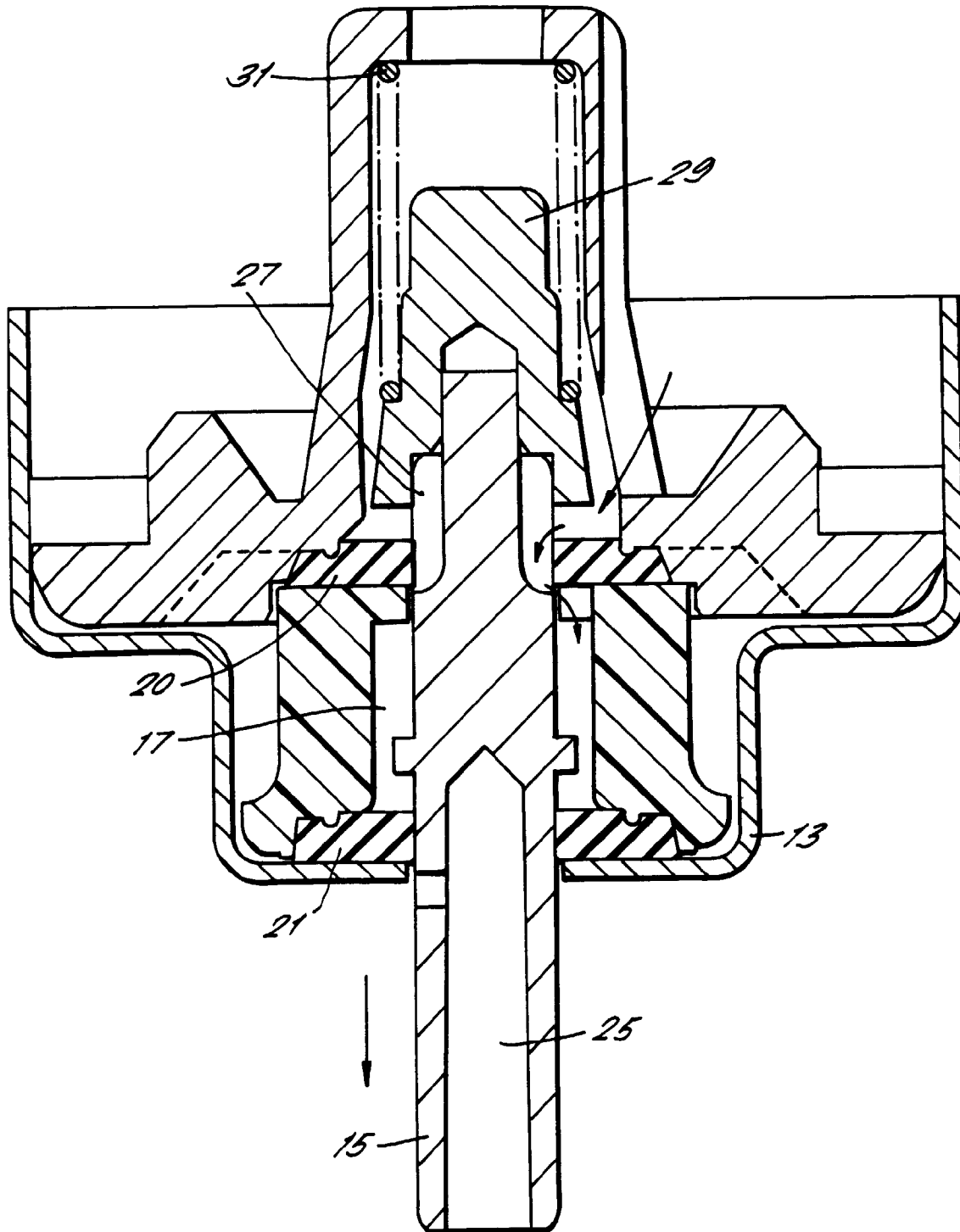


FIG. 6.

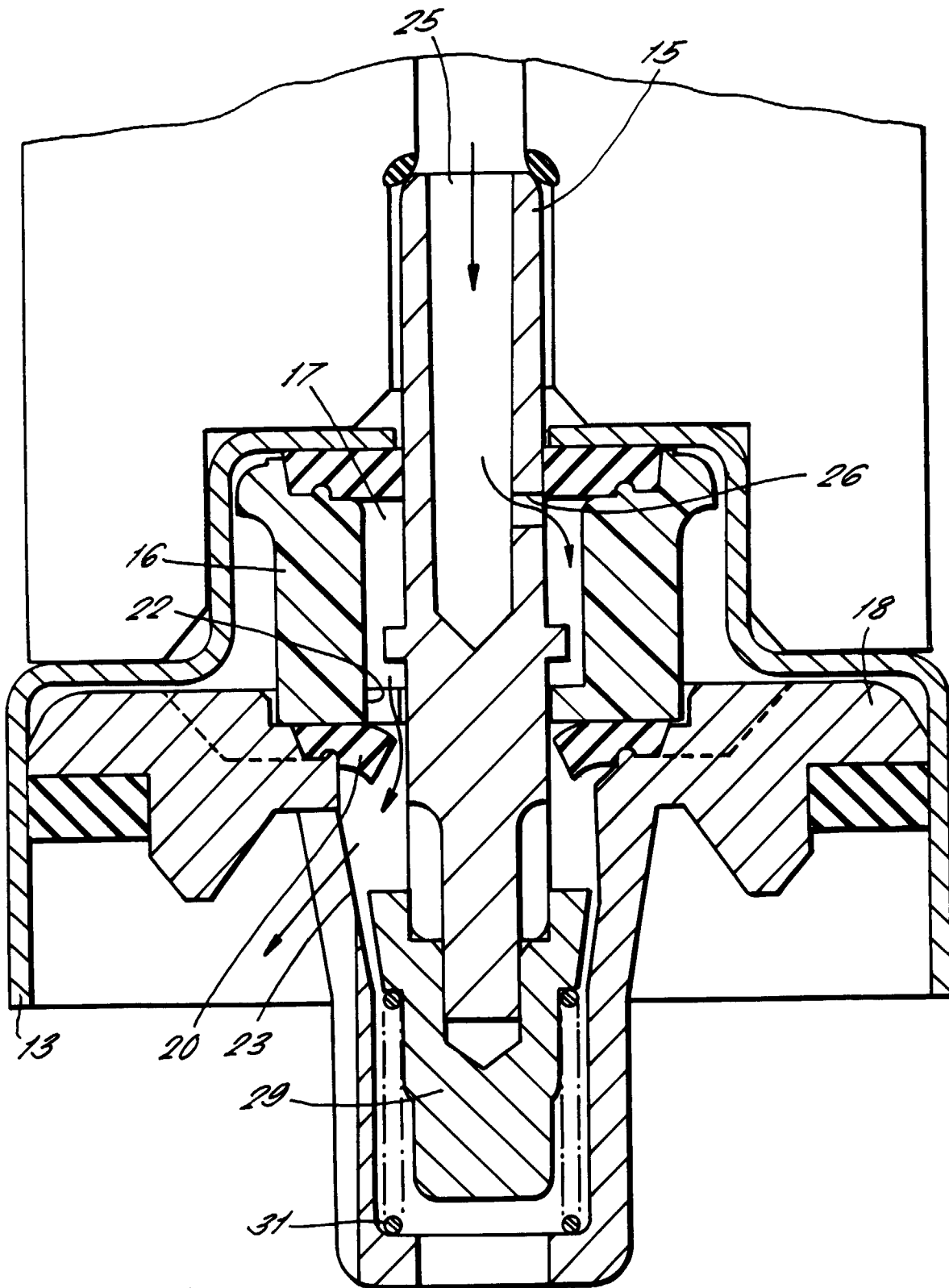


FIG. 7.

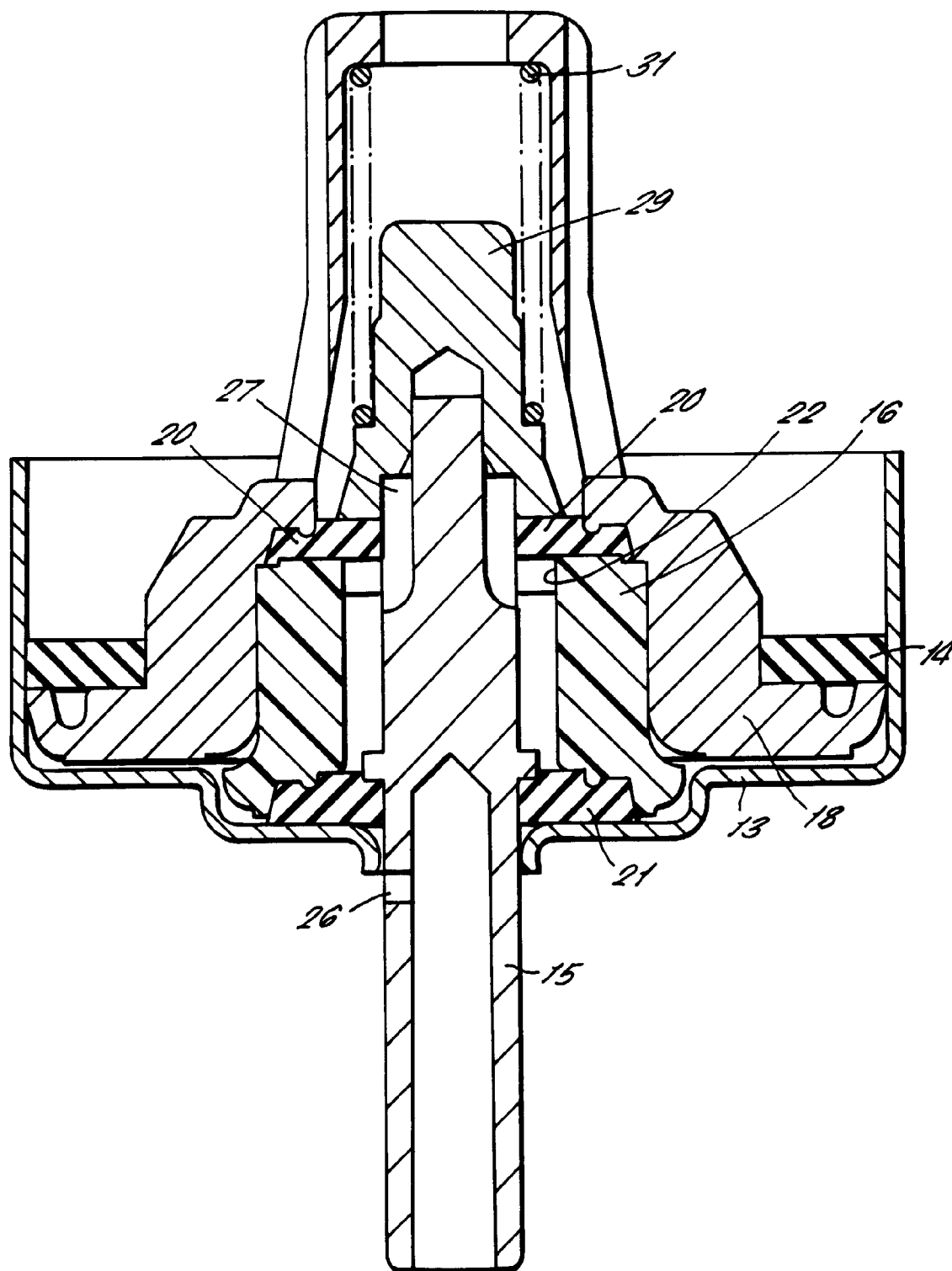


FIG. 8.

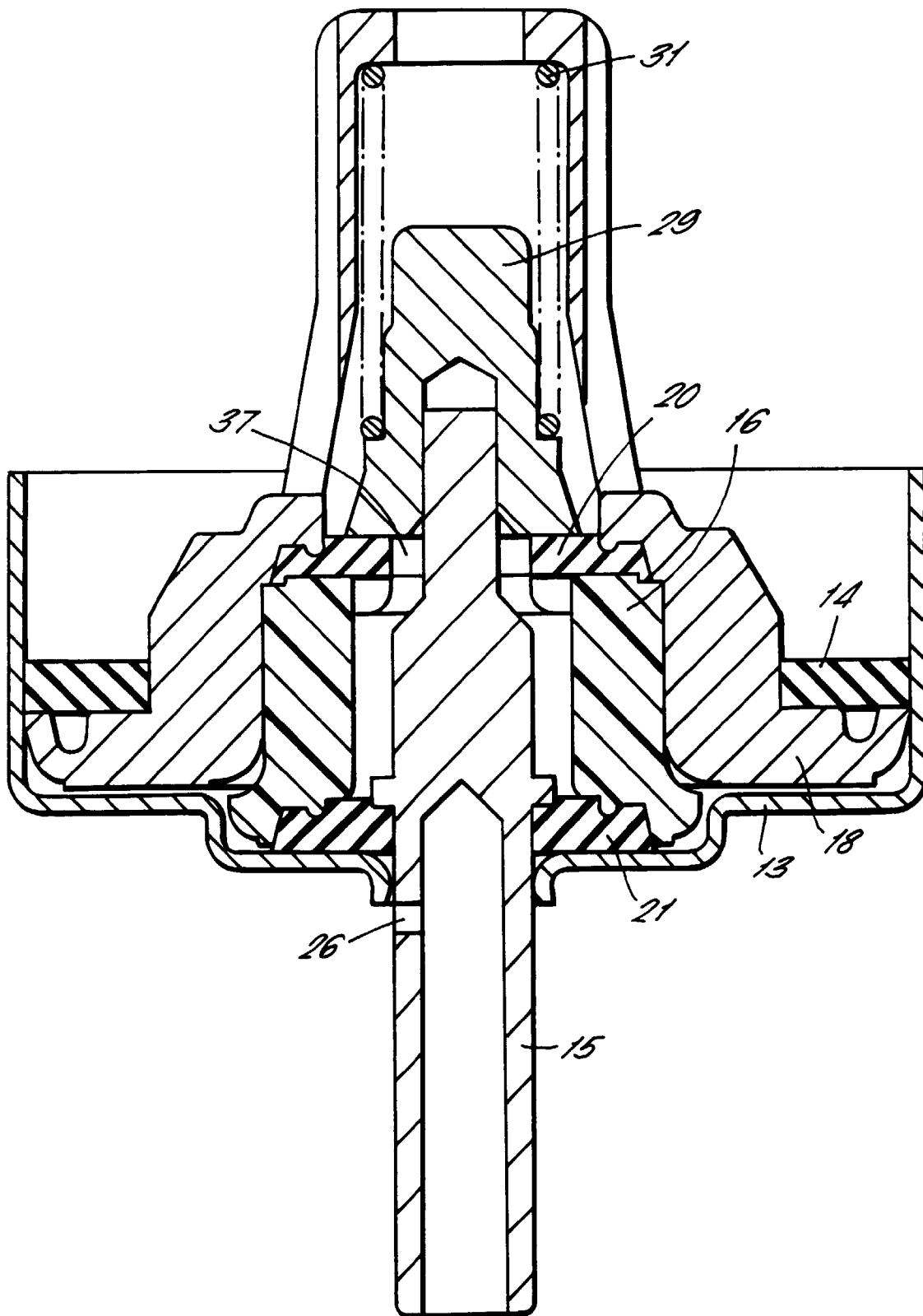
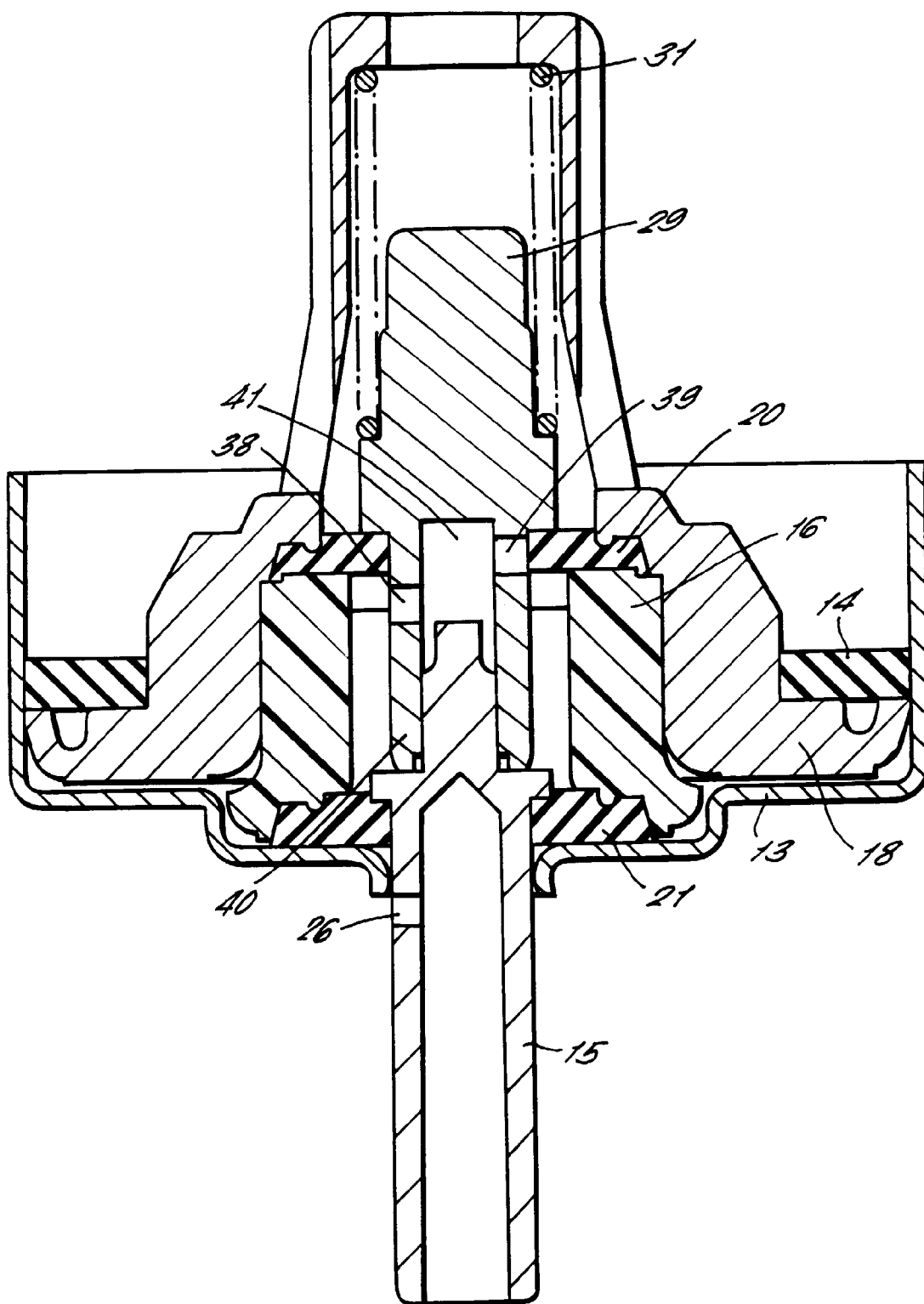


FIG. 9.





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# EUROPEAN SEARCH REPORT

Application Number  
EP 97 30 2729

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.6)
X	DE 19 34 397 A (GREEN) * page 6, line 6 - page 11, line 10; figures 2-5 *	1,2,4-6	B65D83/54
X	EP 0 350 376 A (VALOIS S.A.) * column 3, line 4 - column 4, line 2; figures 1A-4 *	1,4-6	
X	US 3 499 584 A (WARREN) * column 1, line 66 - column 2, line 49; figures 1,2 *	1,3,5,6	
X	EP 0 101 036 A (F.HOFFMAN-LA ROCHE) * page 6, line 27 - page 7, line 1; figures 1-7 *	1-4,6	
X	FR 1 400 855 A (BLANC) * page 1, left-hand column, line 15 - page 2, left-hand column, line 9 *	1,4,6	
X	EP 0 692 434 A (V.A.R.I. ) * figures 1-5 *	1-3,5,6	TECHNICAL FIELDS SEARCHED (Int.Cl.6)
X	GB 1 201 919 A (BESPAK INDUSTRIES) * page 1, line 54 - line 67; figure 1 *	1,4-6	B65D
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 29 July 1997	Examiner Berrington, N
<b>CATEGORY OF CITED DOCUMENTS</b> 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	

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