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(54) **A CONTAINER CLOSURE SYSTEM**

(57) The present invention provides a closure system for a medicament container such as a glass vessel or the like, the closure system comprising a conventional primary closure adapted for releasably sealing the medicament container, along with a conventional secondary closure member and integrated dropper adapted for releasably sealing the medicament container, with an adapter arranged to releasably secure the secondary closure member to the primary closure member when the primary closure member is in sealing engagement with the container.

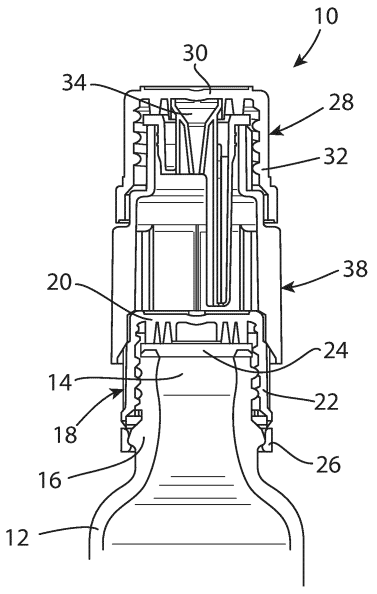

Fig 2

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Description

Field of the invention

[0001] The present invention relates to a novel container closure system, and in particular a closure system for use with a vessel or other storage container housing a solution containing an active ingredient.

Background of the invention

[0002] In the case of vegetable liquid pharmaceutical forms, especially based on volatile oils, and in particular those containing lipophilic formulation components, storage instability can occur as a result of interactions with constituents of the primary packaging that are in continuous contact with the formulation, for example a liquid formulation stored in a sealed vessel. The product contact relates to both liquid and gaseous states of a product, and both states may be present within the same vessel or other storage container, as is a particular issue with plastic component of the vessel, for example a closure or cap. This problem is reinforced by a poorer ratio between the plastic surface area and the amount of liquid product contained in the vessel. As a result smaller volumes are more affected by this issue.

[0003] Due to the phenomenon of possible migration, lipophilic drug components can migrate into the primary packing material such as the vessel body, closure, or related elements such as a dropper or similar dosing system, which often project into the vessel from an underside of the closure or cap. Many of such drug components demonstrate a special affinity for polymer based materials.

[0004] This issue particularly affects so called "droppers" made of low density polyethylene (PE-LD) plastic, which droppers can dip directly into the product or the gas head space above the product, and thus show a high contact surface area. In addition the caps or closures from which the droppers extend, which can comprise high density polyethylene (PE-HD), show this phenomenon.

[0005] Both the dropper and cap are thus capable of absorbing active ingredients in such a way that it becomes a significant loss of active ingredient. This may occur during the storage period and can therefore vary depending on the time between initial packaging of the product and the end use by the consumer.

[0006] The present invention has therefore been developed in order to avoid interactions between such liquid medicaments and their primary packaging.

Summary of the invention

[0007] According to a first aspect of the present invention there is provided a closure system for a medicament container, the closure system comprising a primary closure adapted for releasably sealing the medicament container; a secondary closure member adapted for releasably sealing the medicament container; and an adapter arranged to releasably secure the secondary closure member to the primary closure member when the primary closure member is in sealing engagement with the container.

[0008] Preferably, the secondary closure member comprises an integrated dosing element.

[0009] Preferably, the dosing element comprises a dropper.

[0010] Preferably, the adapter defines a chamber for receiving the dosing element.

[0011] Preferably, the chamber is located such as to be inaccessible when the secondary closure member is secured to the primary closure member with the adapter.

[0012] Preferably, the adapter defines a first coupling operable releasable engage the primary closure member and a second coupling operable to releasably engage the secondary closure member.

[0013] Preferably, the first coupling is defined by a first end of the adapter and is dimensioned for a press fit over the primary closure member.

[0014] Preferably, the second coupling is defined by a second end of the adapted and is dimensioned for a press fit into the secondary closure member.

[0015] Preferably, the adapted defines a lumen extending between the first end and the second end.

[0016] Preferably, the secondary closure member at least partially comprises a material have an affinity for a product to be stored within the medicament container.

[0017] Preferably, the primary closure member comprises an occlusion element arranged to overlie a mouth of the medicament container.

[0018] Preferably, the occlusion element comprises at least a product contacting face having a low affinity for a product to be stored within the medicament container.

[0019] Preferably, the occlusion element comprises a sealing disc have an aluminium or polyethylene layer defining the product contacting face.

[0020] Preferably, the adapted is a contrasting colour to the primary closure member and the secondary closure member.

[0021] According to a second aspect of the present invention there is provided a medicament container comprising a vessel for retaining a quantity of a liquid medicament, the vessel comprising a mount from which the medicament may be withdrawn; and a closure system according to the first aspect of the invention.

[0022] According to a third aspect of the present invention there is provided an adapter for a container closure system for a medicament container, the adapter being arranged to releasably secure a secondary closure member of the container to a primary closure member of the container when the primary closure member is in sealing engagement with the container.

[0023] Preferably, the adapter defines a chamber for receiving a dosing element of the secondary closure member.

[0024] Preferably, the chamber is located such as to

be inaccessible when the secondary closure member is secured to the primary closure member with the adapter.

[0025] Preferably, defines a first coupling operable releasable engage the primary closure member and a second coupling operable to releasably engage the secondary closure member.

[0026] Preferably, the first coupling is defined by a first end of the adapter and is dimensioned for a press fit over the primary closure member.

[0027] Preferably, the second coupling is defined by a second end of the adapted and is dimensioned for a press fit into the secondary closure member.

[0028] Preferably, the adapter defines a lumen extending between the first end and the second end.

[0029] As used herein, the term "product" is intended to mean a substance, composition or active ingredient contained therein, for use as a medicament.

Brief description of the drawings

[0030] The present invention will now be described with reference to the accompanying drawings, in which:

Figure 1 illustrates a side elevation of a closure system for a medicament container and secured in place on the medicament container;

Figure 2 illustrates a sectioned side elevation of the closure system illustrated in Figure 1 ;

Figure 3 illustrates a sectioned side elevation of a primary closure member forming part of the closure system, and secured in place on the medicament container;

Figure 4 illustrates a sectioned side elevation of a secondary closure member forming part of the closure system, in isolation from the remainder of the closure system;

Figure 5 illustrates a sectioned side elevation of the secondary closure member secured to the medicament vessel;

Figure 6 illustrates the side elevation of an adaptor forming part of the closure system; and

Figure 7 illustrates a sectioned side elevation of the adaptor illustrated in Figure 6.

Detailed description of the drawings

[0031] Referring now to the accompanying drawings there is illustrated a container closure system, generally indicated as 10, for use in sealing a vessel 12 which contains, in use, a medicament or other liquid composition, for example a vegetable liquid pharmaceutical composition, in particular based on volatile oils, for example containing lipophilic components which are prone to storage instability as detailed above. It will however be appreciated that the closure system 10 of the present invention may be used to fill any number of alternative vessels or containers (not shown), containing various other liquids or liquid compositions, and need not be limited to use with liquid medicaments.

[0032] In the particular embodiment illustrated the vessel 12 comprises a glass bottle having a mouth 14 formed at the free end of a threaded neck 16 of the vessel 12, via which the mouth 14 the liquid composition contained within the vessel 12 may be accessed or dispensed. The use of glass for the vessel 12 avoids the absorption of the liquid composition or active ingredient into the material forming the vessel 12, and it will therefore be appreciated that any other suitable material or form may be chosen for the vessel 12. It will of course also be understood that the threaded neck 16, providing a mechanism by which the vessel 12 may be sealed via the closure system 10, may be replaced with any other suitable functional alternative which allows the closure system 10 to be releasably secured to the vessel 12 as hereinafter described.

[0033] The closure system 10 comprises a primary closure member 18 which in the embodiment illustrated is in the form of a conventional threaded cap comprising a top 20 which in use overlies the mouth 14 when the primary closure member 18 is engaged about the threaded neck 18, and a cylindrical sidewall 22 depending from the top 20. An internal surface of the sidewall 22 is threaded to engage with the threaded neck 16 in order to releasably secure the primary closure member 18 to the vessel 12 in conventional fashion. The primary closure member 18 additionally incorporates a sealing disc 24 on the underside of the top 20, the ceiling disc 24 being provided with a laminated aluminium layer on the product facing side in order to minimise or eliminate absorption of the product and/or active ingredient into the material forming the primary closure member 18 while the primary closure member 18 is secured to the vessel 12, for example during storage and before the user has opened the vessel 12 and begun using the medicament or other liquid solution contained therein. As an alternative it will be appreciated that the primary closure member 18 itself, or at least the product facing surface of the top 20, is formed from a material which does not absorb the medicament or active ingredient therein.

[0034] The primary closure member 18 additionally comprises, in the embodiment illustrated, a tamper evident ring 26 frangibly secured to the lower circumferential edge of the sidewall 22 and which, in conventional fashion, is separated from the sidewall 22 during the act of the first removal of the primary closure member 18 from the vessel 12. It will be appreciated that any other tamper evident seal may be employed, or indeed may be omitted as required.

[0035] In the preferred embodiment illustrated the primary closure member 18, in particular the top 20 and

sidewall 22, are formed from a low density polyethylene, but any other suitable material or combination of materials may be employed.

[0036] The closure system 10 additionally comprises a secondary closure member 28 which is arranged to be releasably engaged with the vessel 12 about the threaded neck 16 in a similar manner to the primary closure member 18. The secondary closure member 28 comprises a top 30 depending from which is a cylindrical sidewall 32, an internal surface of which is threaded to engage with the threaded neck 16. Integrated with the primary closure member 28 is a dosing element in the form of a dropper 34 which is of conventional design and operation known in the art, and as a result no further description of the configuration and operation thereof is considered necessary.

[0037] The dropper 34 may be released from within the secondary closure member 28 in order to be used in extracting a dose of the medicament or other liquid composition from within the vessel 12, to be administered or otherwise dispensed from the dropper 34, again in conventional fashion. The dropper includes a stem 36 which, when the dropper 34 is secured within the secondary closure member 28, projects downwardly beyond the free end of the cylindrical sidewall 32. As a result the dimensions of the stem 36 prevent the use of a sealing disc similar to the sealing disc 24, were the secondary closure member 28 and integrated dropper 34 fitted directly to the vessel 12 at the point of filling the vessel 12 with the medicament or other liquid composition. The dropper 34 and the interior surface of the secondary closure member 28 would be in contact with the medicament or other liquid composition, whether directly or with a gaseous phase off the composition in the head space existing within the sealed vessel 12, thereby resulting in absorption of the medicament or active ingredient into the material forming the dropper 34 and/or secondary closure member 28 during storage of the filled vessel 12 prior to use.

[0038] In order to overcome this problem the closure system 10 of the invention additionally comprises an adaptor 38 which is arranged to releasably secure the secondary closure member 28 to the primary closure member 18 while the primary closure member is in sealing engagement with the vessel 12. The adapter 28 thus permits the use of the sealing disc 24 with the primary closure member 18, while maintaining the dropper 34 out of contact with the liquid composition within the vessel 12. The adaptor 38 comprises a substantially cylindrical sidewall 40 defining a first or lower end 42 and a second or upper end 44, each of which are shaped and dimensioned to provide a complimentary and engaging fit with the primary closure member 18 and secondary closure member 28 respectively and as hereinafter described. The adaptor 38 is hollow thereby defining a lumen or chamber 46 therein which is dimensioned to entirely contain the stem 36 of the dropper while the secondary closure member 28 is secured to the primary closure member 18 via the adaptor 38.

[0039] In the preferred embodiment illustrated the first end 42 has an internal diameter approximately equal to the external diameter of the upper end of the primary closure member 18 such that a press fit between the first end 42 of the adaptor 38 and the primary closure member 18 may be achieved, thereby allowing the adaptor 38 to be releasably engaged above the primary closure member 18 as illustrated in Figures 1 and 2. The second end 44 of the adaptor 38 is stepped inwardly with respect to the sidewall 40 such as to define an external diameter substantially equal to the internal diameter of the open end of the sidewall 32 of the secondary closure member 28. In this way the second end 44 of the adaptor can achieve a press fit internally of the secondary closure member 28, as clearly visible in Figure 2, the sidewall 40 of the adaptor 38 being of sufficient height to fully accommodate the stem 36 within the lumen 46 when the adaptor 38 is secured to both the primary closure member 18 and the secondary closure member 28. In this way the stem 36 and indeed entire dropper 34 are sealed within the internal lumen or chamber 46 and are therefore inaccessible and so protected from contact and/or damage during storage of the vessel 12.

[0040] It will be appreciated that any other suitable functional alternative to the press fit arrangements hereinbefore described may be provided between the ends of the adaptor 38 and the primary closure member 18 and secondary closure member 28. For example a threaded engagement may be provided therebetween.

[0041] Thus in use the vessel 12 is filled with a liquid composition, whether an medicament or otherwise containing an active ingredient, and the primary closure member 18 releasably secured to the neck 16, with or without the sealing disc 24 as hereinbefore described, in order to occlude the mouth 14 and thus contain the contents within the vessel 12 such as to prevent or minimise absorption of the product or active ingredient into the material forming the primary closure number 18.

[0042] The adaptor 38 is then pressed onto the primary closure member 18 and the secondary closure member 28 then pressed onto the adaptor 38 such that the dropper 34 is contained within the lumen 46. The combined closure system 10 and vessel 12 may then be located within any other suitable external packaging (not shown) or the like for transport and/or storage prior to use by the consumer or other end user. The end user will then remove the secondary closure member 28 from the adaptor 38, and also remove the adaptor 38 from the primary closure member 18. The primary closure member 18 may then be unscrewed from the vessel 12 and discarded, along with the adaptor 38, the secondary closure member 28 then being screwed onto the vessel 12 to act as the combined closure and dropper. In this way the secondary closure member 28 and dropper 34 can be formed from conventional materials such as low density polyethylene, while avoiding the potential for product absorption during the storage phase of the medicament or other liquid composition.

[0043] The closure system 10 of the present invention therefore provides a relatively simply yet effective means of allowing the use of a conventional closure member and integrated dropper while avoiding product absorption.

Claims

1. A closure system for a medicament container, the closure system comprising a primary closure adapter for releasably sealing the medicament container; a secondary closure member adapter for releasably sealing the medicament container; and an adapter arranged to releasably secure the secondary closure member to the primary closure member when the primary closure member is in sealing engagement with the container.

2. A closure system according to claim 1, in which the secondary closure member comprises an integrated dosing element, optionally in which the dosing element comprises a dropper.

3. A closure system according to claim 2, in which the adapter defines a chamber for receiving the dosing element, in particular wherein the chamber is located such as to be inaccessible when the secondary closure member is secured to the primary closure member with the adapter.

4. A closure system according to any of the preceding claims, in which the adapter defines a first coupling operable releasable engage the primary closure member and a second coupling operable to releasably engage the secondary closure member,
optionally wherein the first coupling is defined by a first end of the adapter and is dimensioned for a press fit over the primary closure member, and/orin which the second coupling is defined by a second end of the adapter and is dimensioned for a press fit into the secondary closure member, in particular wherein the adapter defines a lumen extending between the first end and the second end.

5. A closure system according to claim 1, in which the secondary closure member at least partially comprises a material have an affinity for a product to be stored within the medicament container.

6. A closure system according to claim 1, in which the primary closure member comprises an occlusion element arranged to overlie a mouth of the medicament container.

7. A closure system according to claim 2, in which the dosing element comprises the dropper and in which the occlusion element comprises at least a product contacting face having a low affinity for a product to be stored within the medicament container.

8. A closure system according to claim 3, in which the occlusion element comprises a sealing disc have an aluminium or polyethylene layer defining the product contacting face.

9. A closure system according to any of the preceding claims, in which the adapter is a contrasting colour to the primary closure member and the secondary closure member.

10. A medicament container comprising a vessel for retaining a quantity of a liquid medicament, the vessel comprising a mount from which the medicament may be withdrawn; and a closure system according to any of claims 1 to 9.

11. An adapter for a container closure system for a medicament container, the adapter being arranged to releasably secure a secondary closure member of the container to a primary closure member of the container when the primary closure member is in sealing engagement with the container.

12. An adapter according to claim 11 which defines a chamber for receiving a dosing element of the secondary closure member,
optionally wherein the chamber is located such as to be inaccessible when the secondary closure member is secured to the primary closure member with the adapter.

13. An adapter according to any of claims 11 to 12 which defines a first coupling operable releasable engage the primary closure member and a second coupling operable to releasably engage the secondary closure member, in particular wherein the first coupling is defined by a first end of the adapter and is dimensioned for a press fit over the primary closure member.

14. An adapter according to claim 13 in which the second coupling is defined by a second end of the adapter and is dimensioned for a press fit into the secondary closure member.

15. An adapter according to claim 14 which defines a lumen extending between the first end and the second end.

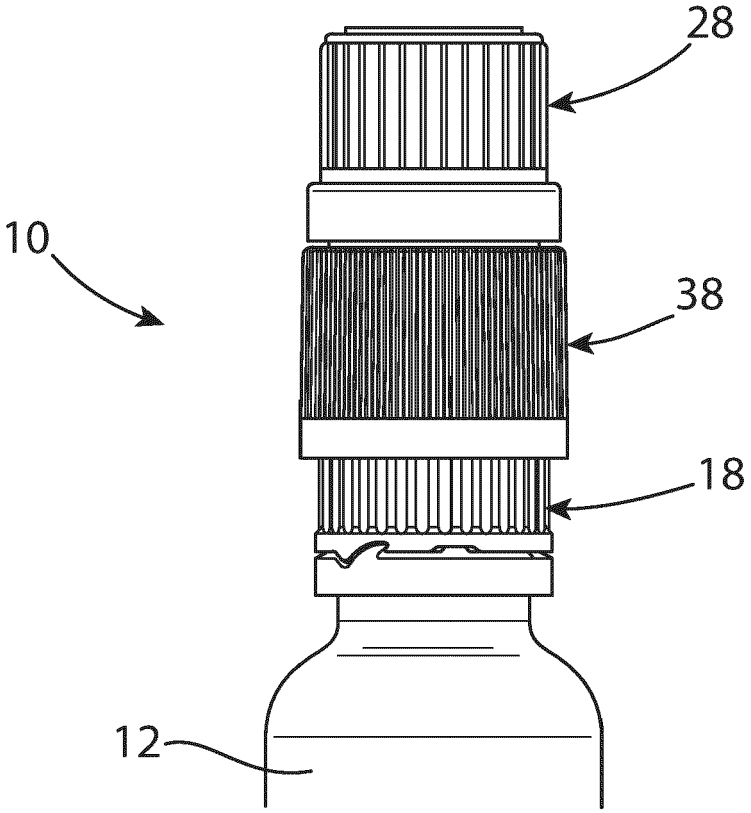

Fig 1

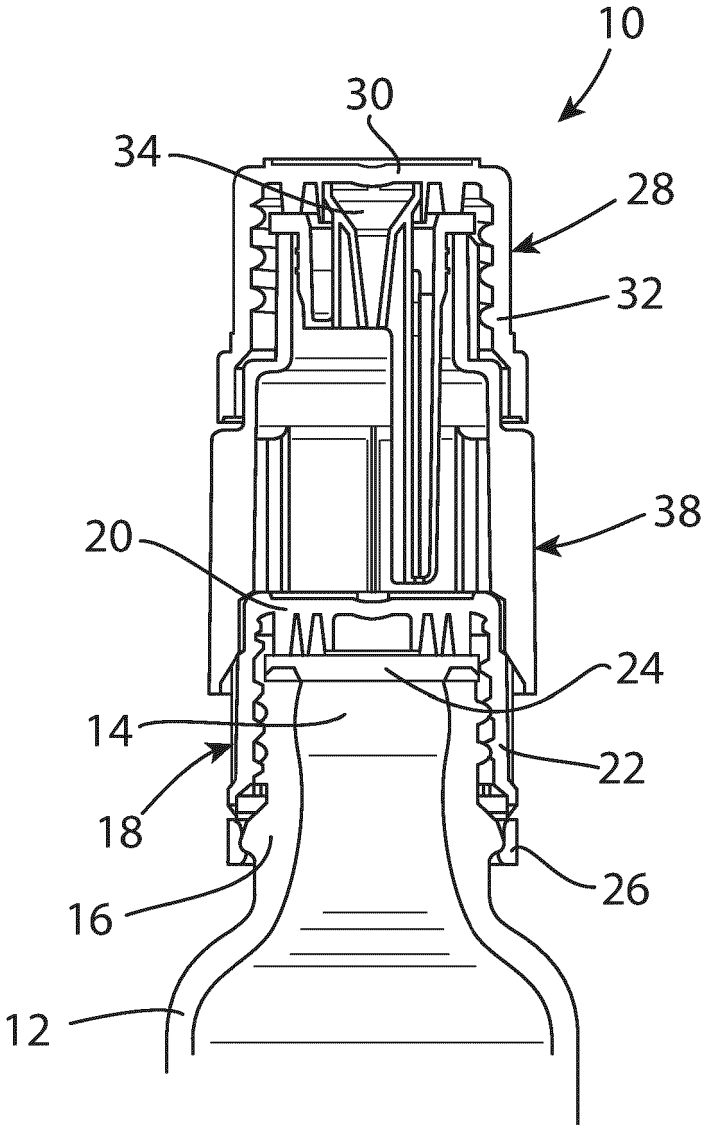

Fig 2

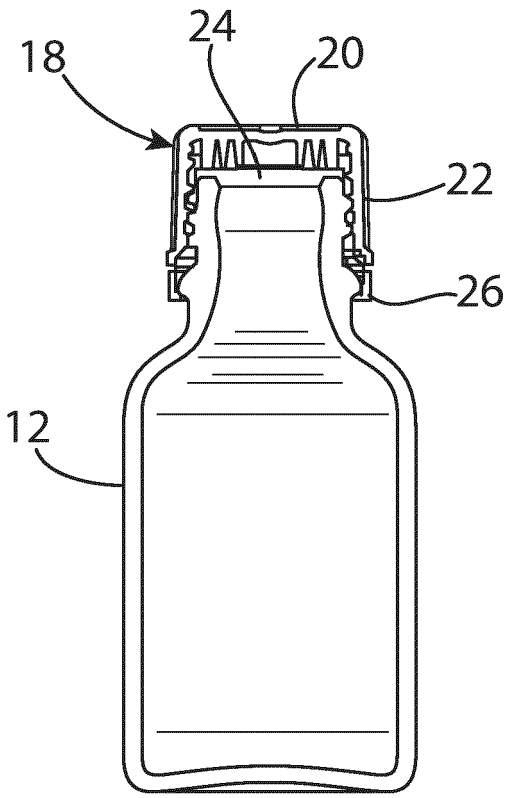

Fig 3

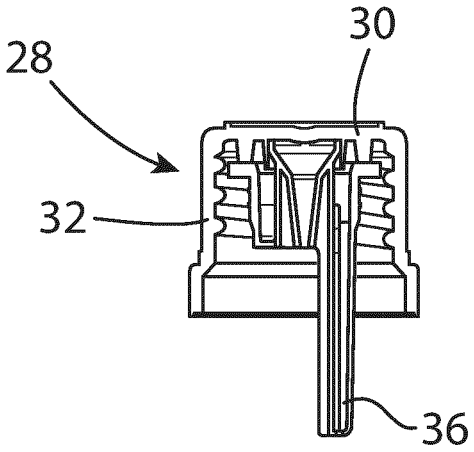

Fig 4

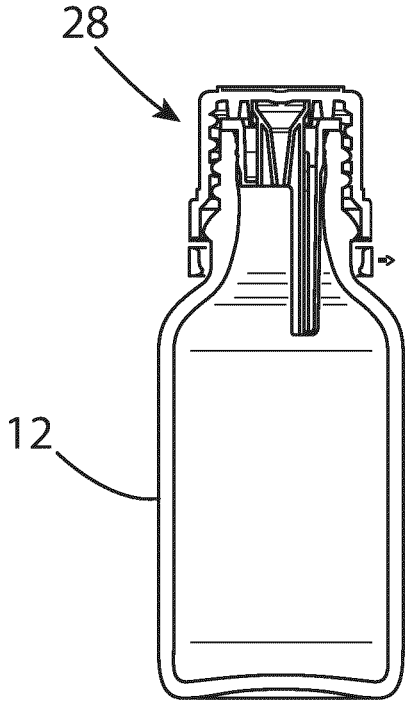

Fig 5

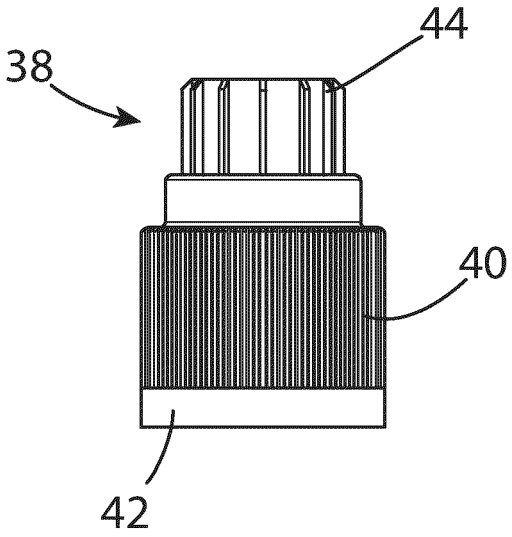

Fig 6

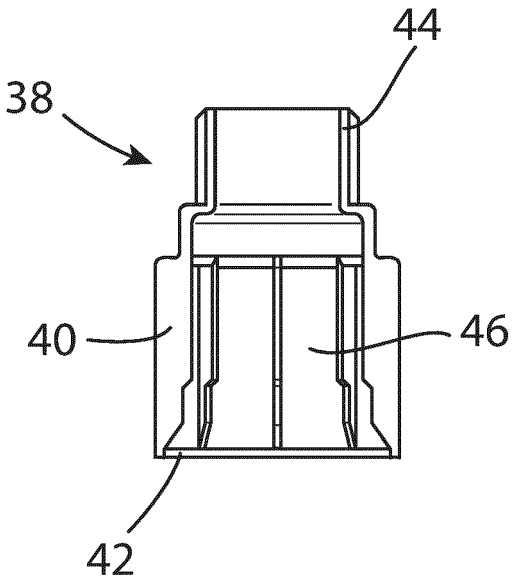

Fig 7