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Referencia: Oposición a solicitud de patente de invención No. 10.118.493

Solicitante: Rexam Healthcare La Verpilliere

Título de la invención: Dispositivo para suministrar líquido en forma de gotas

Opositor: Productores de Envases Farmacéuticos S.A.S. Proenfar S.A.S.

**PRESENTACIÓN DE PRUEBAS ADICIONALES PARA SUSTENTAR LA OPOSICION  
DENTRO DEL TERMINO DE PRORROGA SOLICITADO BAJO EL ARTICULO 42 DE LA  
DECISION 486**

Andrea Tobos Mateus, mayor de edad y vecina de Bogotá, D.C., identificada según aparece al pie de mi firma, en mi condición de apoderada de la sociedad Productores de Envases Farmacéuticos S.A.S. Proenfar S.A.S., presento a continuación pruebas adicionales que sustentan las peticiones formuladas en la oposición que se radicó el día 13 de octubre de 2011 dentro de la solicitud de patente de la referencia.

**1. Falta de novedad de la solicitud de patente de Rexam**

En concordancia con lo establecido en la oposición radicada dentro de este expediente, confirmo que se encontraron documentos adicionales que afectan la novedad de la invención bajo análisis.

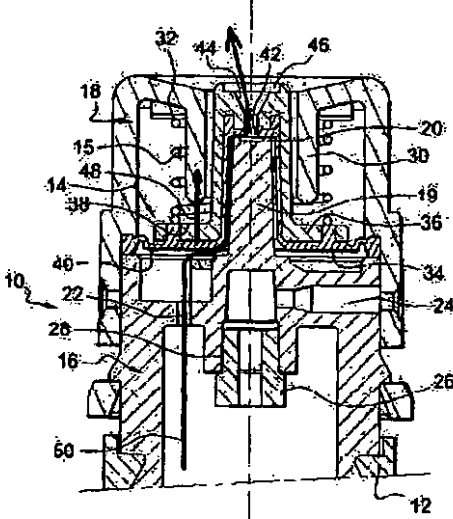
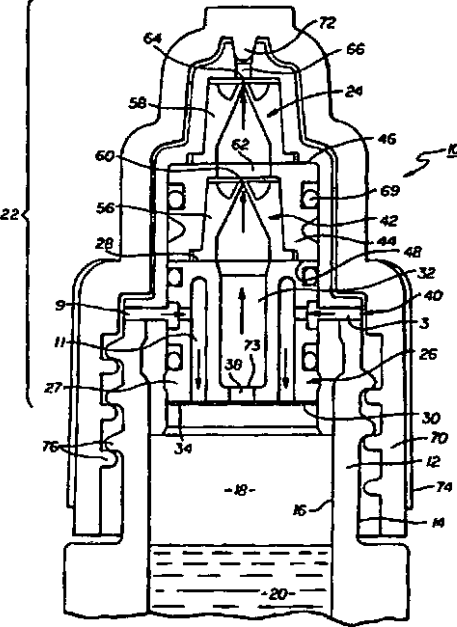
**1.1. US 5.310.094 (10 de mayo de 1994) “Preservative free sterile fluid dispensing system”. Titular: JSP Partners, L.P. (Anexo A)**

Esta publicación de patente enseña un sistema para entregar soluciones estériles libres de preservativos. El sistema comprende un juego de válvulas de auto-sellado para evitar que el fluido se devuelva a la botella o contenedor una vez ha sido entregado durante el ciclo de descompresión del contenedor.

El dispensador objeto de la patente US 5.310.094 comprende: un contenedor (12) que es deformable y que tiene un compartimiento de reserva (18) para almacenar una solución estéril (20) y un boquilla (22) adaptada para entregar la solución estéril (20); un juego de válvulas de auto-sellado (24) está unido a la superficie interna (16) del contenedor (12). Este juego de válvulas de auto-sellado (24) tienen un alojamiento para membrana (6) en donde se une el soporte de membrana hidrófoba (27), el cual sirve de soporte a la membrana (34), y que tiene una superficie superior (28) y una superficie inferior (30) y que

además, cuenta con un pasaje (40) para la entrada de aire. Este contenedor también cuenta con un canal de líquido (32).

Esta publicación presenta todas las características del dispensador de Rexam como se ve a continuación:

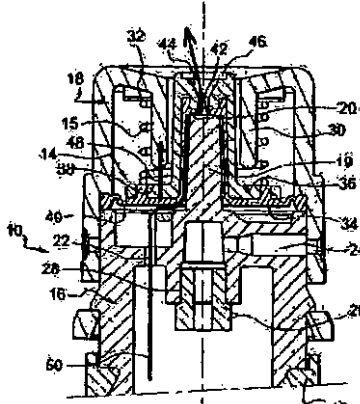
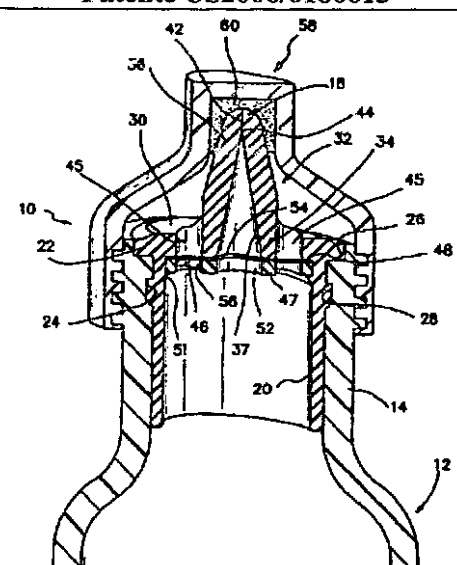
| Solicitud colombiana 10.118.493                                                                                                                                                                                                                                       | Patente US 5.310.094                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                     |  <p>FIG. 1</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Un dispositivo para suministrar cantidades de líquido medidas predeterminadas.                                                                                                                                                                                        | La presente invención se dirige a un sistema de entrega de líquido con un sistema de válvulas de auto-sellado doble para entregar multidosis de soluciones estériles en forma de gotas. (ver columna 1, líneas 12 a 15).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| (...) cuyo dispositivo incluye un miembro de sellado (14) que puede tomar una posición de liberación de líquido, que permite que fluya el líquido hacia fuera del dispositivo, y una posición de no retorno que evita que el líquido fluya de regreso al dispositivo. | El sistema utiliza válvulas de auto-sellado doble instaladas en serie dentro de un compartimiento de boquilla que se ajusta a la salida del contenedor de dosis deformable para evitar que el flujo de líquido ya entregado, se devuelva nuevamente al contenedor durante el ciclo de descompresión. (ver resumen).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Un dispositivo de acuerdo con cualquier reivindicación precedente, en donde los medios de medición (44,46) son medios para formar gotas de líquido. (reivindicación 4)                                                                                                | Después del montaje, durante el ciclo de entrega, un contenedor (12) se comprime en posición invertida con una solución estéril (20) que fluye desde el compartimiento de depósito, a través del puerto de flujo central (38), y se filtra a través de la membrana hidrófoba (73), pasa por el canal (32) en el centro del soporte de membrana hidrófoba (27), a través de la primera válvula de cierre (56) y salida (60) de la misma, a través de la entrada (62) y salida (64) de la segunda válvula de cierre (58) y finalmente, a través del sistema de salida (66) del contenedor (12). (...) Una vez que la solución se ha entregado del contenedor (12), se obtiene equilibrio en la presión durante la fase de descompresión por la entrada de aire (3) a través del puerto (9) del alojamiento (26) y canal (11) del soporte de membrana hidrófoba (27). El aire se filtra y se vuelve estéril por la membrana hidrófoba (34). (ver columna 5, líneas 40 a 58). |
|                                                                                                                                                                                                                                                                       | Otro objeto de la presente invención es proporcionar un contenedor de entrega de líquido en multidosis que puede ser utilizado para entregar soluciones medicinales, que no contienen conservantes, en forma de gotas sustancialmente uniforme. (ver columna 3, líneas 3 a 6).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

1.2. US2006/0180613 (17 de agosto de 2006) “Multi-dose liquid dispensing assembly”. Inventor: Nick J. Manesis. (Anexo B)

Esta publicación de patente divulga un dosificador nuevo y mejorado y/o conjuntos de dosificación para distribuir, por ejemplo, gota a gota sustancias estériles, sin conservantes. La invención del Sr. Manesis permite al usuario obtener gotas individuales, en lugar de flujos constantes de soluciones líquidas, por medio de apretar el contenedor de la invención. El sistema de la invención también presenta una válvula de retención resistente al reflujo, un miembro de la filtración, y una tapa con revestimiento antibacteriano, que reducen o eliminan la contaminación de la solución que se desea entregar, por lo que el uso de conservantes se hace innecesario.

De una simple comparación visual de las figuras aportadas en esta patente y las presentadas por Rexam se evidencia que los dispositivos tienen iguales características.

A continuación presentamos un cuadro comparativo para mayor ilustración:

| Solicitud colombiana 10.118.493                                                                                                                                                                                                                                                                                                                                                                                                   | Patente US2006/0180613                                                                                                                                                                                                                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <p>Fig. 2</p>                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                           |
| Un dispositivo para suministrar cantidades de líquido medidas predeterminadas cuyo dispositivo incluye un miembro de sellado (14) que puede tomar una posición de liberación de líquido y una posición de no retorno que evita que el líquido fluya de regreso al dispositivo, en donde el miembro de sellado (14) está provisto con medios de medición (44,46) para medir el líquido a ser suministrado. (ver reivindicación 1). | El contenedor de esta invención contiene una válvula que “esta estructurada para evitar el reflujo en la posición cero, así como cerca de la posición cero (...)” (ver página 2 párrafo 0014).                                                                                                                                |
| En donde la forma de campana (44) abre hacia afuera en una forma sustancialmente cilíndrica (46) (ver reivindicación 6)                                                                                                                                                                                                                                                                                                           | En una realización particularmente útil, la boquilla se configura con una forma sustancialmente gaussiana, o en forma de campana, cono truncado, y la válvula comprende una ranura normalmente cerrada que se extiende sustancialmente perpendicular a través del extremo distal de la boquilla. (ver página 2 párrafo 0016). |

Así mismo, la patente estadounidense US2006/0180613 también detalla el tamaño de la boquilla de entrega de las gotas, tal y como se muestra en la página 4, párrafo 0053: *"En cuanto a las características dimensionales de la ranura 40, la longitud de la una boquilla 32 es de 0.25-0.75 pulgadas y un diámetro final distal D en el rango de 0,05 a 0,21 pulgadas, en un rango de 0,04 a alrededor de 0,2 pulgadas. La profundidad óptima d para un corte 40 es preferiblemente en un rango de 0,01 a 0,1 pulgadas. El mínimo espesor de la pared TMIN (es decir, el espesor de la pared entre el final de la ranura 40 y la circunferencia exterior de la superficie distal 38) preferiblemente no menos de 0,01 pulgadas. El máximo espesor de la pared TMAX (...) preferiblemente no menos de 0,02 pulgadas"*.

De otra parte, la característica relacionada con el material de construcción de miembro de sellado (14) del dispositivo de Rexam, que se pretende reclamar en la reivindicación 7, no es nueva por cuanto todos los documentos estudiados prevén que sus membranas o válvulas de entrega y cierre dentro de los dispensadores pueden ser de cualquier material elastomérico y se ofrecen varios ejemplos. Así las cosas, esta reivindicación 7 contenida en la solicitud No. 10.118.493 no es nueva.

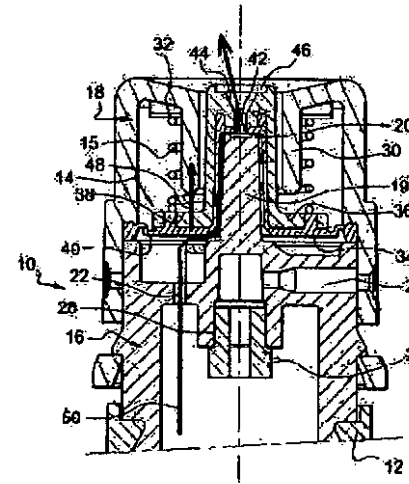
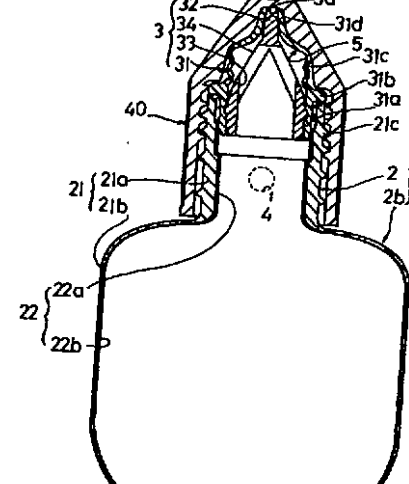
De esta manera, todas las características reclamadas por Rexam en su solicitud de patente ya fueron publicadas en las patentes mencionadas en el escrito de oposición y en estas dos patentes adicionales, dejando sin novedad el dispositivo de Rexam.

## **2. Falta de nivel inventivo de la solicitud de patente de Rexam**

Adicionalmente, a los documentos aportados como arte previo válido para desvirtuar el nivel inventivo de la solicitud de patente a nombre de Rexam, presento a continuación otros documentos que evidencian aún más la falta de nivel inventivo de la solicitud bajo estudio dado que hacen que la solución que propone Rexam sea obvia para un experto en la materia.

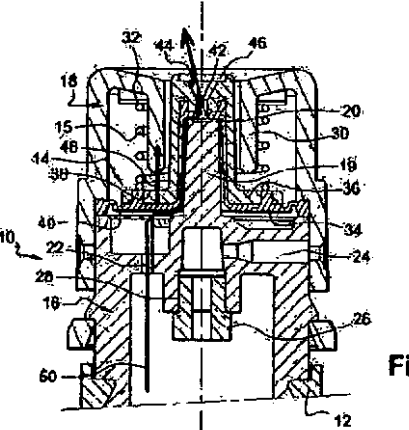
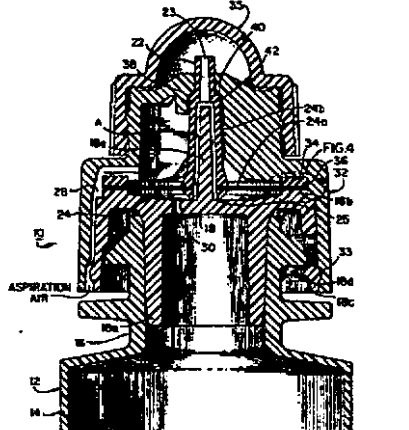
### **2.1. US2002190079 (19 de diciembre de 2002) "Dispensing container". Titular: Taisei Kako Co., Ltd. (Anexo C)**

Esta publicación de patente divulga un contenedor de entrega que comprende una botella laminada (2) con un miembro para evitar que un contenido líquido entre en contacto con aire del ambiente, sin ayuda de ningún tipo de conservantes, y que el residuo líquido localizado en la región adyacente a un orificio de salida (3a) se proteja de la contaminación. El contenedor tiene una boquilla flexible (31) y un sello (32), ambos dispuestos en la boca de la botella (2). La boquilla (31) está hecha de un material elástico y flexible, el sello (32) cuenta con un diseño tal que cierra la región de extremo distal del orificio de salida (3a). Apretando el cuerpo de la botella se aumenta la presión interna y la boquilla flexible (31) se amplía para hacer una deformación, que a su vez hace que el orificio de salida (3a) tome una posición abierta hacia el exterior.

| Solicitud colombiana 10.118.493                                                                                                                                                                                                                                                                                                                                                                                                                         | Patente US2002190079                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <p style="text-align: right;"><b>Fig. 2</b></p>                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <p>La reivindicación 1 establece:</p> <p>Un dispositivo para suministrar cantidades de líquido medidas predeterminadas, cuyo dispositivo incluye un miembro de sellado (14) que puede tomar una posición de liberación de líquido y una posición de no retorno que evita que el líquido fluya de regreso al dispositivo, en donde el miembro de sellado (14) está provisto con medios de medición (44,46) para medir el líquido a ser suministrado.</p> | <p>El tapón puede comprender una boquilla flexible que tiene un orificio de salida para distribuir el contenido líquido de la botella, y un sello capaz de cerrar el orificio de salida. El sello puede estar en la boca de la botella, y la boquilla puede ser capaz de deformación elástica alejándose de su posición normal de tal manera que el orificio de salida se desplaza hacia el exterior en relación con el sello en respuesta a un aumento de la presión en la bolsa. (Ver página , párrafo 0012)</p> |

**2.2. US5431310 (11 de julio de 1995) "Liquid dispenser nozzle assembly". Titular: Ryder International Corporation. (Anexo D)**

Esta publicación de patente estadounidense divulga un dispensador de líquidos que tiene una pared flexible y una cavidad para almacenamiento de líquidos los cuales serán entregados luego de comprimir manualmente la cavidad, lo que causa que el líquido salga a través de un conjunto de boquilla. El conjunto de boquilla que presenta la invención US 5.431.310 mantiene el líquido, como por ejemplo el líquido de limpieza de lentes de contacto y otras soluciones, estériles durante el almacenamiento y dispensación repetida del líquido contenido en la cavidad del recipiente. El conjunto de boquilla también incluye un elemento de sellado para sellar el conducto de líquido contra la fuga de líquido, dicho elemento de sellado tiene una composición que comprende politetrafluoroetileno.

| Solicitud colombiana 10.118.493                                                                                                     | Patente US5431310                                                                    |
|-------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
|  <p style="text-align: right;"><b>Fig. 2</b></p> |  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>La reivindicación 1 establece:</p> <p>Un dispositivo para suministrar cantidades de líquido medidas predeterminadas, cuyo dispositivo incluye un miembro de sellado (14) que puede tomar una posición de liberación de líquido y una posición de no retorno que evita que el líquido fluya de regreso al dispositivo, en donde el miembro de sellado (14) está provisto con medios de medición (44,46) para medir el líquido a ser suministrado.</p> | <p>El texto de la patente US5,431,310 muestra en su columna 3, líneas 56 a la 65 la siguiente característica: "El sello normal hecho por el anillo de sellado 25 bajo compresión por la porción de tapa 38, evita fugas del líquido L almacenado en el contenedor, incluso bajo la presión hidrostática cuando el recipiente se invierte durante la manipulación, y para evitar cualquier reflujo de aire no estéril o líquido del espacio A en el cuello de botella 16. También se previene el reflujo de líquido por medio de la proyección cónica en forma de pezón 18e que se proyecta hacia arriba desde la pared superior del adaptador 18. El espacio A lleva al agujero central de la porción tubular 22 y al orificio de descarga 23, y la porción 18e reduce al mínimo el volumen de líquido que queda en el espacio libre A, cuando el flujo de entrega se detiene. La pequeña cantidad de líquido que queda en lugar A, el cual puede estar expuesto a la contaminación por aire, será expulsado antes de la próxima dispensación de líquido.</p> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### 3. Pruebas adicionales en relación con el capilar 125-S desarrollado por Proenfar.

Como complemento a las observaciones que presenté en el punto 3.2.2. del escrito de oposición, presento una factura de venta del año 2006 en donde se puede constatar que el capilar que desarrolló Proenfar y que afecta la novedad de los formadores de gota (44, 46) de la invención de Rexam, se comercializa de manera exitosa desde el año 2006. La factura de venta No. ZVE-0200006158 del 26 de septiembre de 2006 (Anexo E) evidencia que en dicha fecha se vendió a la sociedad Medifarma S.A. 3,000 unidades del capilar que tiene referencia 125-S y que afecta la patentabilidad de la invención de Rexam bajo estudio.

Así mismo, se anexa una carta firmada por la gerente de logística de la sociedad Medifarma S.A. en donde dicha sociedad certifica que Proenfar S.A.S. viene suministrando a Medifarma S.A. el capilar 125-S desde septiembre del año 2006. (ver Anexo F).

De esta manera, se ha comprobado que el dispositivo de entrega de líquidos que describe Rexam en la reivindicación independiente 1 no es novedoso y por lo tanto, todas las restantes reivindicaciones 2 a 10 que dependen de la reivindicación 1, tampoco son novedosas. Así mismo, este dispositivo de Rexam no cumple con el requisito de nivel inventivo por cuanto existen publicaciones en el estado de la técnica que permitan a una persona con conocimiento en el área de los dispensadores de soluciones estériles, llegar a desarrollar el dispositivo para distribuir líquido de Rexam, simplemente con la combinación de características que eran ampliamente conocidas en el área técnica correspondiente.

### 4. Pruebas

- 4.1. ANEXO A. Copia de la publicación US 5.310.094 (10 de mayo de 1994)
- 4.2. ANEXO B. Copia de la publicación US2006/0180613 (17 de agosto de 2006)
- 4.3. ANEXO C. Copia de la publicación US2002190079 (19 de diciembre de 2002)
- 4.4. ANEXO D Copia de la publicación US5431310 (11 de julio de 1995)

4.5. ANEXO E Factura de venta No. ZVE-0200006158 del 26 de septiembre de 2006.

4.8. ANEXO F. Carta de Medifarma dirigida a la SIC indicando que Proenfar es proveedor del Capilar 125-S desde el año 2006.

## 5. Traslado

Presento con este memorial copia de este escrito con pruebas adicionales para su traslado al solicitante.

Atentamente,



ANDREA TOBOS MATEUS

C.C. 52.223.325 de Bogotá

T.P. 148648





US005310094A

United States Patent [19]

[11] Patent Number: 5,310,094

Martinez et al.

[45] Date of Patent: May 10, 1994

- [54] PRESERVATIVE FREE STERILE FLUID DISPENSING SYSTEM.
- [75] Inventors: F. Jesus Martinez, Mission Viejo; Steven R. Bystrom, El Toro; Peter W. Chan, Northridge, all of Calif.
- [73] Assignee: JSP Partners, L.P., Northridge, Calif.
- [21] Appl. No.: 792,989
- [22] Filed: Nov. 15, 1991
- [51] Int. Cl.<sup>5</sup> ..... B65D 37/00
- [52] U.S. Cl. .... 222/212; 137/512; 137/846; 222/476; 222/494
- [58] Field of Search ..... 222/189, 212, 215, 476, 222/494; 137/512, 846, 849
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Primary Examiner—Andres Kashnikow

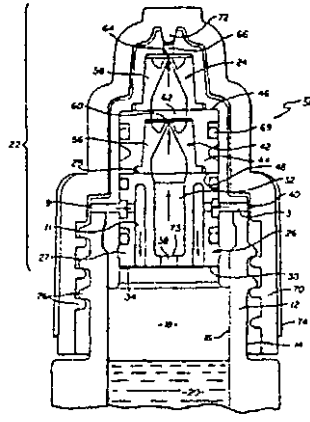
Assistant Examiner—J. A. Kaufman

Attorney, Agent, or Firm—Robbins, Berliner & Carson [57]

ABSTRACT

A fluid dispensing system for delivering sterile preservative free solution is disclosed. The system uses double self-sealing valves mounted in series inside a tip compartment which fits on the outlet of a multiple dosage squeeze container to prevent undesirable retrograde flow of the dispensed liquid back into the bottle during the decompression cycle. The valves used are positive acting, normally closed duckbill valves which open to express solution from the container when squeezing pressure is applied to the bottle and which automatically close when the pressure is released. A hydrophobic filter is provided to sterilize the replacement air which enters the container upon release of the squeezing pressure.

19 Claims, 1 Drawing Sheet



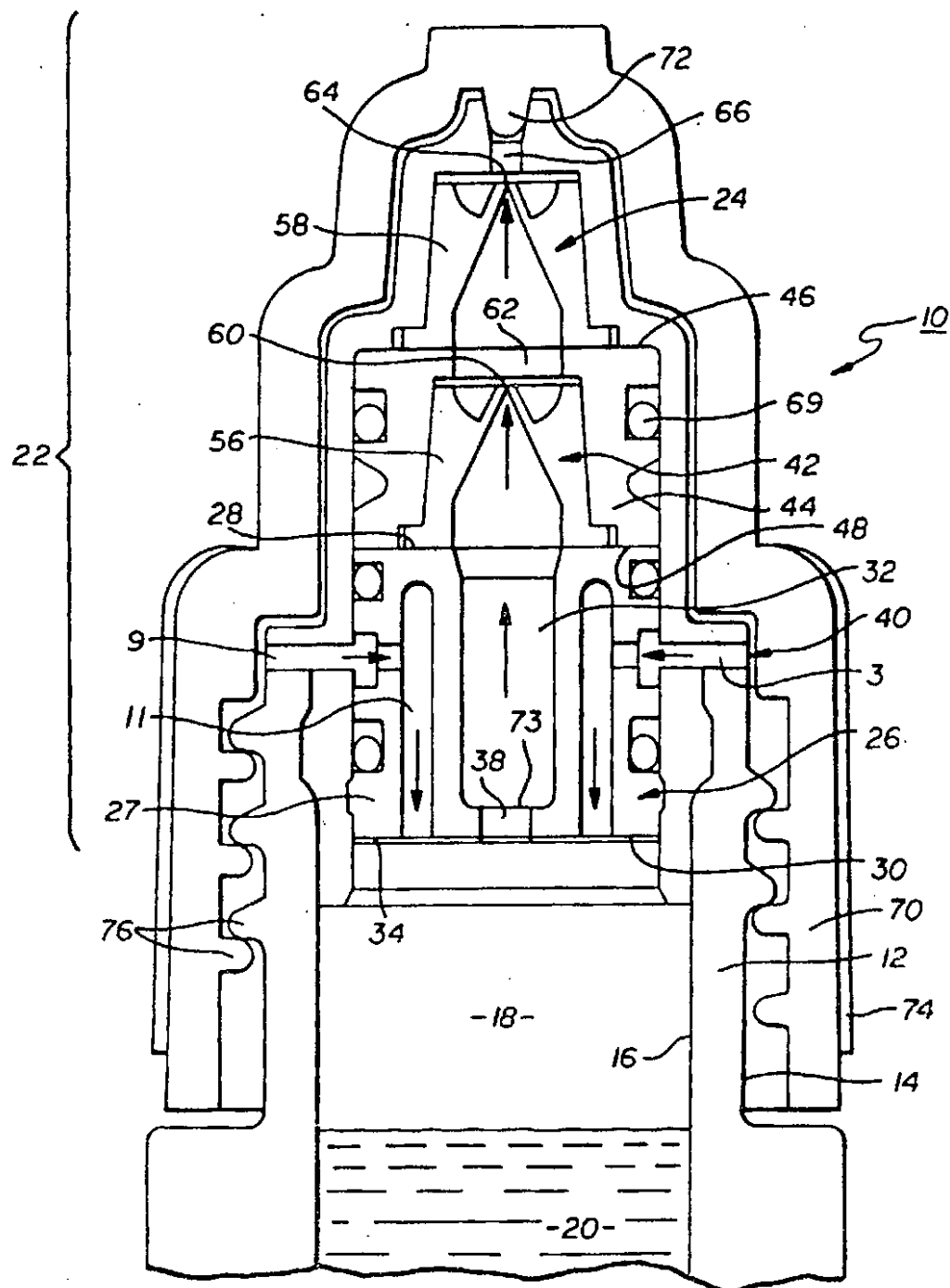


FIG. 1

**PRESERVATIVE FREE STERILE FLUID DISPENSING SYSTEM**

**BACKGROUND OF THE INVENTION**

**1. Field of the Invention**

The present invention relates to a fluid dispensing system specifically designed to deliver multidose sterile, or homogenized and pasteurized, chemical preservative, antibacterial or antimicrobial additive free (hereinafter known collectively as "preservative free") solutions. More, specifically, the present invention is directed to a fluid dispensing system with a dual self-sealing valve system to dispense multidose sterile solutions in a dropwise form. The dual self-sealing valve system and hydrophobic air filter protects the solutions from contamination after multidose dispensing without the use of preservatives.

**2. Description of the Prior Art**

Large number of solutions including those that are sold and administered as over-the-counter ("OTC") and/or prescription preparations, such as ophthalmic pharmaceutical, contact lens solutions, drop-administered medicines for the ear or nose, and some consumer health care liquid solutions, such as creams, gels and lotions, must be kept sterile to prevent contamination from bacteria or other microbes. The conventional means of preventing such contamination is to add a preservative or other antibacterial agent to the solution during packaging. Commonly used preservatives include benzalkonium chloride, methyl parabens, propyl parabens, thimerosal and chlorobutanol. Commonly used antibacterial agents include saline formulations. While these preservatives keep the enclosed solution sterile, the bottle itself may harbor external bacterial or microbial growth which is carried along with the outflow of fluids. In addition, the preservatives themselves are often toxic, not just to bacteria or microbes, but also to the cells which are being treated by the bottled solution. For example, the preservatives used in most eye drops can disrupt the corneal epithelium, irritate conjunctival tissues and cause allergic reactions. Because of this toxicity level, continued use can cause more long-term problems than the solutions solve.

Furthermore, squeezable dispensing bottles containing saline formulations in the dispensing liquids may be provided with nozzles including filter membranes which are permeable to the dispensed liquid as well as being permeable to the air which must be aspirated through the nozzle to replace the dispensed liquid and reinflate or re-expand the container. However, the filter membrane must be impermeable to bacteria in order to prevent the aspirated air from carrying bacteria into contact with the stored solution, and contaminating the solution due to repeated dispensing. Yet, filter membrane materials which are sufficiently hydrophilic to permit permeation of the saline solution often permit retention of the saline solution on the filter so that the retained solution increases the resistance of the filter to passage of the aspirating air. The partially obstructed flow of aspirating air not only retards the re-expansion of the squeezed bottle wall, but also impedes repeated squeezing of the bottle when large quantities of the solution must be dispensed. When portions of the filter are treated to repel the solution and improve air passage, the solution can sometimes leach the treating composition from the filter.

In addition, consumer food products, such as milk and dairy products, must be kept refrigerated to reduce the contamination and/or action of bacteria or other microbes.

Container contamination can also be the result of particulate matter being drawn back into the container with the liquid in the dropper tip that has not been delivered as a drop. Over several drop deliveries, for example, in dusty conditions, a significant accumulation of dust in the container is possible.

Despite these and other problems with filter bottles, and the use of preservatives in dispensing liquids, various designs for liquid dispenser for sterile solutions have been reported.

U.S. Pat. No. 4,938,389 describes a dispenser including a filter assembly having a hydrophobic filter and a hydrophilic filter in tandem with the hydrophobic filter located near the dispensing tip.

U.S. Pat. No. 3,760,987 describes a snap assembled dispensing package and cover made up of a container which has a tapered shank on its discharge end and a piercing device, snappably connected to the container, which also serves as a conduit for dispensing the medicament. The dispensing package further contains an air filter and a solution filter.

U.S. Pat. Nos. 4,917,271 and 3,149,758, and WO 90/15015 all teach dispensing devices with single filtering membranes or composite membranes where a portion of the membrane is hydrophobic and another portion of the membrane hydrophilic.

U.S. Pat. No. 4,463,880 describes a medicine drop dispenser with a single hydrophobic and microporous antibacterial filter that provide a barrier to the ingress of bacteria and for permitting the egress of sterile liquid.

U.S. Pat. No. 4,533,068 describes sterile solution delivery and venting devices including a positive acting, normally closed check valve which opens to express solution from the package when squeezing pressure is applied and which automatically closes when the pressure is released. A hydrophobic filter is included to sterilize the replacement air which enters the package upon release of the squeezing pressure.

U.S. Pat. No. 2,684,789 describes seal cap and dispensing nozzle for tubes or bottles having a self-closing dispensing valve.

U.S. Pat. No. 3,176,883 describes a fluid dispenser of the squeeze bottle type having an air vent post extending to the side of the dropper tip and directly above the lip of the container.

U.S. Pat. Nos. 4,739,906, 4,234,103 and 4,773,551 all describe bottles with caps containing a protuberance for closing the hole in the dropper tip.

It would be desirable to provide a convenient, economical and safe fluid dispensing system for the delivery of sterile preservative free solutions.

Accordingly, it is an object of the present invention to provide an improved sterile solution delivery and fluid dispensing system of the type set forth.

It is another object of the present invention to provide a multidose fluid dispensing system which can protect the solutions from contamination under prolonged and repeated use without the use of preservatives.

It is another object of the present invention to provide a multidose fluid dispensing bottle for dispensing ophthalmic pharmaceutical, contact lens solutions, consumer health care liquid solutions and consumer food product solutions which provide good flow properties

and protection against bacterial or microbial contamination.

Another object of the present invention is to provide a multidose fluid dispensing bottle which can be used to dispense medicine solutions, which do not contain preservatives, in substantially uniform drops.

It is another object of the present invention to provide a novel fluid dispensing system which incorporates positive acting, normally closed, valve means in combination with a hydrophobic membrane air sterilizing filter means.

It is another object of the present invention to provide a novel fluid dispensing system which incorporates two positive acting, normally closed, valve means in series and in combination with a hydrophobic membrane air sterilizing filter means.

It is another object of the present invention to provide a novel fluid dispensing system having a container with a system outlet and an air passageway, positive acting, normally closed, valve means positioned between the system fluid outlet and a hydrophobic filter positioned at the end of the air inlet passageway, the valves means being openable upon the application of pressure built up within the container and being automatically sealed upon release of the pressure.

Other objects and advantages of the invention will become apparent from the following detailed disclosure.

### SUMMARY OF THE INVENTION

In accordance with the present invention, a preservative free sterile solution dispensing system is provided to eliminate the need of using preservatives in ophthalmic, pharmaceutical, contact lens solutions, consumer health care liquids and consumer food product solutions. The fluid dispensing system for dispensing sterile preservative free solution comprises a container having an outer and an inner surface. The container further has a reservoir compartment for storing sterile solution and a tip compartment adapted to dispense the sterile solutions. A dual self-sealing valve dispensing assembly is sealed by an adhesive, mechanical compression, ultrasonic sealing, gasket, encapsulation or other commonly known methods, to the inside surface of the tip compartment and comprises a hydrophobic membrane assembly having a membrane housing. The membrane housing is constructed of a thermoplastic material, such as polyethylene, polypropylene, polystyrene, ethylene-vinyl acetate or a combination thereof. A hydrophobic membrane support is connected to the membrane housing. The hydrophobic membrane support has a top surface and a bottom surface. The hydrophobic membrane support further has a central fluid channel to allow the solution to pass through. The hydrophobic membrane support is also generally constructed of a thermoplastic material such as polyethylene, polypropylene, polystyrene, ethylene-vinyl acetate or a combination thereof. A hydrophobic membrane is hermetically sealed to the bottom surface of the hydrophobic membrane support separating the reservoir compartment from the tip compartment. The membrane further connects to a central solution flow port which in turn is in communication with the fluid channel in the hydrophobic membrane support to allow the solution to pass through. The hydrophobic membrane is constructed of a hydrophobic polymer, such as polyfluoroethylene, including TEFLON®, polyolefins or a combination thereof. A passageway for ingress of air from outside

the container through the membrane is provided in the hydrophobic membrane support. The dual self-sealing valve dispensing assembly further comprises a valve assembly, which in turn, comprises a valve housing support with a top and a bottom surface. The bottom surface of the valve housing support further connects to the top surface of the hydrophobic membrane support; a first self-sealing valve is hermetically sealed to the bottom surface of the housing support; a second self-sealing valve is hermetically sealed to the top surface of the valve housing support and in series with the first self-sealing valve wherein an outlet of the first valve opens to an inlet of the second valve to allow the solution to pass through; and a system outlet from which solution from an outlet of the second valve passes through.

### BRIEF DESCRIPTION OF THE DRAWING

The novel features which are believed to be characteristic of the invention are set forth with particularity in the appended claims. The invention itself, however, both as to its organization and method of construction and operation, may best be understood by reference to the following description, taken in connection with the accompanying drawing in which:

FIG. 1 is a perspective cross-sectional view of a preservative free sterile fluid dispensing system of the present invention.

### DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to FIG. 1, the preservative free fluid dispensing system 10 is provided with a container 12 having an outer surface 14 and an inner surface 16. The container 12 is provided with means to temporarily reduce its volume, typically by providing that at least part of the container is elastically deformable. Thus, pressure on a deformable portion of the container will force the fluid contained therein out of the container when it is appropriately oriented. The container 12 can be a standard dispensing bottles with removable tip, e.g., low density polypropylene such as those made by Wheaton Plastics, Melville, N.J.

The container 12 further has a reservoir compartment 18 for storing sterile solution 20 and a tip compartment 22 adapted to dispense the sterile solution 20. A dual self-sealing valve dispensing assembly 24 is sealed to the inside surface 16 of the container 12. The dual self-sealing valve dispensing assembly 24 has a membrane housing 26 to which hydrophobic membrane support 27 with a top surface 28 and a bottom surface 30 is attached. The hydrophobic membrane support 27 further has a central fluid channel 32 for the solution 20 to pass through. A hydrophobic membrane 34 is hermetically sealed to the bottom surface 30 of the hydrophobic membrane support 27, separating the reservoir compartment 18 from the tip compartment 22 except at a central solution flow port 38 which is in communication with the fluid channel 32 of the hydrophobic membrane support to allow the solution 20 to pass through. The hydrophobic membrane support 27 also has a passageway 40 (comprising an inflow 3, side port 9 and channel 11 discussed below) for ingress of air from outside the container 12 through the membrane 34. The hydrophobic membrane 34 has pore openings from 0.01 to 1 micron, and preferably about 0.2 to 0.24 micron, in flat sheet configuration. Such hydrophobic membranes are readily available commercially and can be fabricated

from any suitable hydrophobic polymer, such as tetrafluoroethylene, polyolefins, including polyethylene and polypropylene or a mixture thereof. In the preferred example, the hydrophobic membrane is a laminated tetrafluoroethylene (e.g. TEFLON®), a trademark of E. I. du Pont de Nemours Co.) membrane obtained from W. L. Gore, Inc. and has a pore size of about 0.2 to about 0.24 microns and preferably about 0.22 microns. Since the hydrophobic membrane is used to separate the reservoir compartment 18 from the tip compartment 22, it has a surface area of about 0.1 to about 0.2 cm<sup>2</sup> and preferably about 0.13 cm<sup>2</sup>. The dual self-sealing valve dispensing assembly 24 further has a valve assembly 42 comprising a valve housing 44 with a top surface 46 and a bottom surface 48 and sealed by gasket to the top surface 28 of the hydrophobic membrane support 27. A first self-sealing valve 56 is hermetically sealed to the bottom surface 48 of the valve support 44. A second self-sealing valve 58 is similarly hermetically sealed to the top surface 46 of the valve housing support 44 and in series with the first self-sealing valve 5 wherein the outlet 60 of the first valve opens to an inlet 62 of the second valve to allow solution to pass through. Solution 20, after passing through the outlet 64 of the second self-sealing valve 58, then dispenses to the outside of the container 12 via system outlet 66. The first and second self-sealing valves used are generally of the duckbill type and are normally closed during storage. The self-sealing valves used in the preferred embodiment are of the duckbill type, model X60Z9 and can be obtained from Vernay Laboratories, Inc. The outlet 64 from the second self-sealing valve opens to a system outlet 66 from which the solution 20 is dispensed. In a preferred embodiment, elements 26 (system housing), 35 hydrophobic membrane support 27, valve housing support 44, second self-sealing valve 56 and gasket 69 (in the form of O-rings), all coact to form a hermetically tight assembly with container 12.

After assembly, during a dispensing cycle, bottle 12 is squeezed in an inverted position with sterile solution 20 flowing from the reservoir compartment, through the central solution flow port 38, and percolate through hydrophobic membrane 73, channel 32 in the center of hydrophobic membrane support 27, through the first self-sealing valve 56 and outlet 60 of same, through inlet 62 and outlet 64 of second self-sealing valve 58 and finally out through system outlet 66 of container 12. To minimize contamination by reducing exposure to outside aerial bacteria or microbes, the system outlet 66 is of a dimension of only about 0.050 to about 0.127 cm. Once the solution is discharged from container 12, pressure equilibrium during the decompression stage is obtained by the inflow of room air 3 through side port 9 of housing 26 and channel 11 of hydrophobic membrane support 27. The air is then filtered and rendered sterile by hydrophobic membrane 34.

Protection of the external surface 14 of the container tip compartment 22 is achieved by means of a cap 70 with bayonet extension 72 which hermetically seals the outlet of the fluid dispensing system upon closure. The cap further is provided with antislip knurls 74 which are threaded together by means of threads 76. In addition, the cap 70 can be rendered bactericidal and bacteriostatic by further impregnating the plastic material with an antibacterial agent such as salts of common heavy metal oxides, including oxides of silver, gold or copper.

## EXAMPLES

The performance of the dual self-sealing valve dispensing assembly was tested under the following conditions:

### Example 1. Dye Diffusion Tests

A 5% aqueous solution of food grade blue dye was prepared from a stock concentrate. Fifteen double duckbill self-sealing valve dispensing assemblies in their normally closed position were connected in parallel on a tubing set testing fixture. The entire tubing set was primed with the dye solution and the dual double duckbill self-sealing valve assemblies connected to each of the parallel tubing arms. A calibrated pressure gauge connected to the tubing assembly was used to monitor the hydraulic pressure continuously for 24 hours. After 24 hours exposure to a pressure of 20 mm Hg, no retrograde migration of dye was detected past the first or second duckbill valve by direct observation and by colorimetric determination. When samples of the self-sealing double duckbill assembly were subjected to 24 hours exposure under 160 mm Hg external pressure (about 10 times greater than normally expected during the bottle decompression cycle), no retrograde dye migration was observed past the first or second self-sealing duckbill valves. When samples with the duckbill valve closer to the dispensing tip outlet were purposely damaged and tested under the same conditions as above, the second self-sealing duckbill valve prevented retrograde migration of dye past the normally closed seal surface.

### Example 2. Double Duckbill Back Flow Air Pressure Integrity Tests

Fifteen double duckbill self-sealing valve dispensing assemblies were inserted into the outlet of standard Wheaton squeeze bottles containing 15 ml of water. To each unit, a "T" tubing assembly containing a pre-calibrated pressure gauge and a compressed air source was connected to the dispensing tip outlets. The self-sealing double duckbill valve assemblies were subjected to an air pressure of 160 mm Hg for 90 seconds and isolated from the air pressure source by cross clamping the tubing. With the squeeze bottle inverted, no air bubbles were detected entering the water contained within the bottle while the pressure gauge reading remained constant.

### Example 3. Hydrophobic Membrane Air Venting Tests

Fifteen Wheaton bottles containing 15 ml of water were each equipped with double duckbill self-sealing valve dispensing assemblies and integrity tested for leaks. The valve assemblies were provided with a freshly mounted hydrophobic membrane disc measuring 8 mm in diameter and hermetically sealed to a holder on two separate, but concentric sealing surfaces. The hydrophobic disc contained a functional surface area of 0.13 cm<sup>2</sup> and 0.2 micron pore size. The hydrophobic membrane discs had not been exposed to water before the tests. During the tests, the squeeze bottles were inverted and hand squeezed until 5 drops to 3-4 ml of water were expelled through the double duckbill valves and tip assembly. Upon release of the squeezing external pressure on the sides of the bottles, the differential negative pressure created within the bottles was sufficient to allow air in the form of bubbles to filter through the hydrophobic membrane into the inverted

bottle. Depending on the amount of water expelled from the bottle, pressure equalization required from 2 seconds to 10 seconds. The same results were obtained when the bottle was set in the upright position.

#### Example 4. Hydrophobic Membrane Air Venting Tests

The same conditions as in Example 3 except that the hydrophobic membrane discs in all fifteen double duckbill valve assemblies were immersed in water at room temperature for 24 hours. The ability of the hydrophobic membrane discs to filter air entering the bottle was similar to the results obtained with the hydrophobic membrane never exposed to water.

#### Example 5. Bottle Cap Bayonet Seal Integrity Tests

Fifteen Wheaton squeeze bottles completely filled with water and equipped with double duckbill valve assemblies were each hermetically sealed by intrusion of the bayonet of the bottle cap into the dropper tip opening and hand tightening the cap on the bottle with the usual twisting force. With each bottle in an inverted position, the bayonet seal was challenged with two to three times the positive liquid pressure than is normally expected for a total of 90 seconds. After the integrity pressure test, each bottle was set in an upright position and the cap removed and examined for the presence of water inside the cap well. In each of the assemblies no water was found. The bayonet in the screw-on bottle cap coacting with the mating surface on the dispensing tip hermetically sealed the outlet channel on the dispensing tip assembly.

#### Example 6. Sterility Test

After the sterile fluid dispensing system 10 with a hydrophobic membrane air filter 34 and dual self-sealing valve dispensing assembly 24 in the preferred embodiments of the present invention was tested with *Pseudomonas Diminuta* to a population of 10 million per milliliter (HIMA challenge), the bacterial retentivity of the membranes and the double self-sealing valving system met a sterility grade barrier.

Those skilled in the art will fully appreciate that the present embodiment shown and desirable to illustrate the present invention is exemplary only and that the same principles may be employed in providing other preservative free sterile fluid dispensing systems. It will be further appreciated that various other minor modifications or changes, particularly with respect to details of component construction, might be made without departing from the gist and essence of the invention. Accordingly, it should be interpreted as encompassing all component constructions fairly regardable as functional equivalents of the subject matter to which claims are directed.

Having described our invention, what we claim and desire to secure by letter patent is:

1. A fluid dispensing system for dispensing sterile preservative free solution comprising:
  - a container having an outer surface and an inner surface;
  - said container further having a reservoir compartment for storing a sterile solution and a tip compartment adapted to dispense the sterile solution;
  - said container further having at least part of it elastically deformable;
  - a dual self-sealing valve dispensing assembly sealed to the inside surface of said tip compartment;

wherein said dual self-sealing valve dispensing assembly further comprises:

- a membrane assembly having a membrane housing;
  - a hydrophobic membrane support connected to said membrane housing;
  - said hydrophobic membrane support further having a top surface, a bottom surface and a central fluid channel to allow the sterile solution to pass through;
  - a hydrophobic membrane hermetically sealed to said bottom surface of said hydrophobic membrane support separating said reservoir compartment from said tip compartment, said membrane further connected to a central solution flow port which in turn communicates with said fluid channel of said hydrophobic membrane support to allow the solution to pass through;
  - a passageway located in said hydrophobic membrane support for ingress of air from outside said container through said hydrophobic membrane;
  - a valve assembly comprising a valve housing support with a top surface and a bottom surface;
  - said bottom surface of said valve housing support further connected to said top surface of said hydrophobic membrane support;
  - a first self-sealing valve hermetically sealed to said bottom surface of said housing support;
  - a second self-sealing valve hermetically sealed to said top surface of said valve housing support and in series with said first self-sealing valve wherein an outlet of said first valve opened to an inlet of said second valve to allow the solution to pass through; and
  - a system outlet from which the solution from an outlet of said second valve passes through.
2. A fluid dispensing system of claim 1, wherein said membrane housing is constructed of a thermoplastic material.
  3. A fluid dispensing system of claim 2, wherein said thermoplastic material is selected from the group consisting of polyethylene, polypropylene, polystyrene, ethylene-vinyl acetate and combinations thereof.
  4. A fluid dispensing system of claim 2, wherein said hydrophobic support is constructed of a thermoplastic material.
  5. A fluid dispensing system of claim 4, wherein said thermoplastic material is selected from the group consisting of polyethylene, polypropylene, polystyrene, ethylene-vinyl acetate and combinations thereof.
  6. A fluid dispensing system of claim 4, wherein said hydrophobic membrane is constructed of a hydrophobic polymer.
  7. A fluid dispensing system of claim 6, wherein said hydrophobic polymer is selected from the group consisting of polyfluoroolefins, polyolefins and combinations thereof.
  8. A fluid dispensing system of claim 7, wherein said hydrophobic membrane further has a pore size of about 0.01 to about 1 micron.
  9. A fluid dispensing system of claim 8, wherein said hydrophobic membrane further has a pore size of about 0.2 to about 0.24 micron.
  10. A fluid dispensing system of claim 9, wherein said hydrophobic membrane is suitable for resisting the passage of bacterial and microbial contamination and has a surface area of about 0.1 to about 0.2 cm<sup>2</sup>.
  11. A fluid dispensing system of claim 10, wherein said hydrophobic membrane is suitable for resisting the

9

passage of bacterial and microbial contamination and has a surface area of about 0.13 cm<sup>2</sup>.

12. A fluid dispensing system of claim 9, wherein said housing support is constructed of polyolefins and combinations thereof.

13. A fluid dispensing means of claim 12, wherein said first-sealing valve is a normally closed deformable duckbill valve.

14. A fluid dispensing system of claim 13, wherein said second sealing valve is a normally closed deformable duckbill valve.

15. A fluid dispensing system of claim 14, wherein said system outlet is further provided with a cap having bayonet extension means which displaces residual fluid and hermetically seals said outlet upon closure.

16. A fluid dispensing system of claim 15, wherein said cap is further provided with antislip knurls and threads for sealing to said outlet.

17. A fluid dispensing system of claim 15, wherein said cap is further rendered bactericidal and bacteriostatic with an agent selected from the group consisting of silver oxide, gold oxide and copper oxide.

18. A fluid dispensing system of claim 14, wherein said system outlet is of a dimension of about 0.050 to about 0.127 cm.

19. A fluid dispensing system for dispensing sterile, preservative-free solutions comprising:

a container having at least part of it elastically deformable;

said container further having an outer surface and an inner surface;

said container further having a reservoir compartment for storing a sterile solution and a tip compartment adapted to dispense the sterile solution;

a dual self-sealing valve dispensing assembly sealed to the inside surface of said tip compartment;

said dual self-sealing valve dispensing assembly further comprising:

a membrane assembly having a polyethylene membrane housing;

a polyethylene hydrophobic membrane support connected to said polyethylene membrane housing;

10

said polyethylene hydrophobic membrane support further having a top surface, a bottom surface and a central fluid channel to allow the sterile solution to pass through;

a tetrafluoroethylene polymer hydrophobic membrane hermetically sealed to said bottom surface of said polyethylene hydrophobic membrane support separating said reservoir compartment from said tip compartment;

said tetrafluoroethylene polymer hydrophobic membrane further being connected to a central solution flow port which in turn communicates with said fluid channel of said hydrophobic membrane support to allow the solution to pass through;

said tetrafluoroethylene polymer hydrophobic membrane further having a pore size of about 0.22 micron and a surface area of about 0.13 cm<sup>2</sup>;

a passageway located in said hydrophobic membrane support for ingress of air from outside said container through said tetrafluoroethylene polymer hydrophobic membrane;

a valve assembly comprising a valve housing support with a top surface and a bottom surface;

said bottom surface of said valve housing support further connecting to said top surface of said hydrophobic membrane support;

a first normally closed deformable self-sealing duckbill valve hermetically sealed to said bottom surface of said housing support;

a second normally closed deformable self-sealing duckbill valve hermetically sealed to said top surface of said valve housing support and in series with said first normally closed deformable self-sealing duckbill valve wherein an outlet of said first normally closed deformable self-sealing duckbill valve opens to an outlet of said second normally closed deformable self-sealing duckbill valve to allow the solution to pass through; and

a system outlet of a dimension of about 0.050 to about 0.127 cm from which the solution from an outlet of said second normally closed deformable self-sealing duckbill valve passes through.

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## ANEXO B

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US 2006/0180613A1

(19) **United States**

(12) **Patent Application Publication**  
Manesis

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(54) **MULTI-DOSE LIQUID DISPENSING ASSEMBLY**

Publication Classification

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(57)

ABSTRACT

A dispensing assembly to be coupled to a resilient-walled vessel includes a tip defining an unobstructed bore positioned to be in direct communication with the vessel when coupled to the vessel. The tip includes a valve structured to allow drop-wise liquid dispensing when sufficient pressure is applied to the resilient wall of the vessel, and to prevent liquid back flow at zero as well as near zero pressure differentials across the valve. The assembly also includes at least one vent opening structured to allow air into and out of the vessel, and at least one filtration element extending across the vent opening. A cap having an antibacterial liner is also provided. The combination of the filtration element, the antibacterial liner in the cap, and the ability of the valve to prevent back flow enables the solution in the vessel to remain sterile, with no need for preservatives.

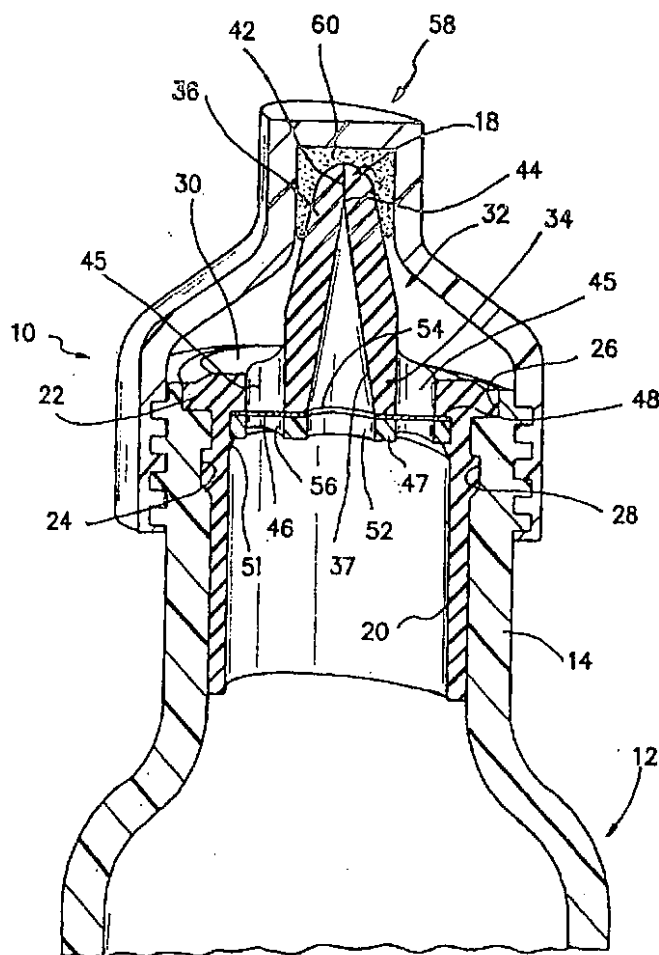
(21) Appl. No.: 10/551,753

(22) PCT Filed: Mar. 31, 2004

(86) PCT No.: PCT/US04/09746

Related U.S. Application Data

(60) Provisional application No. 60/458,686, filed on Mar. 31, 2003.



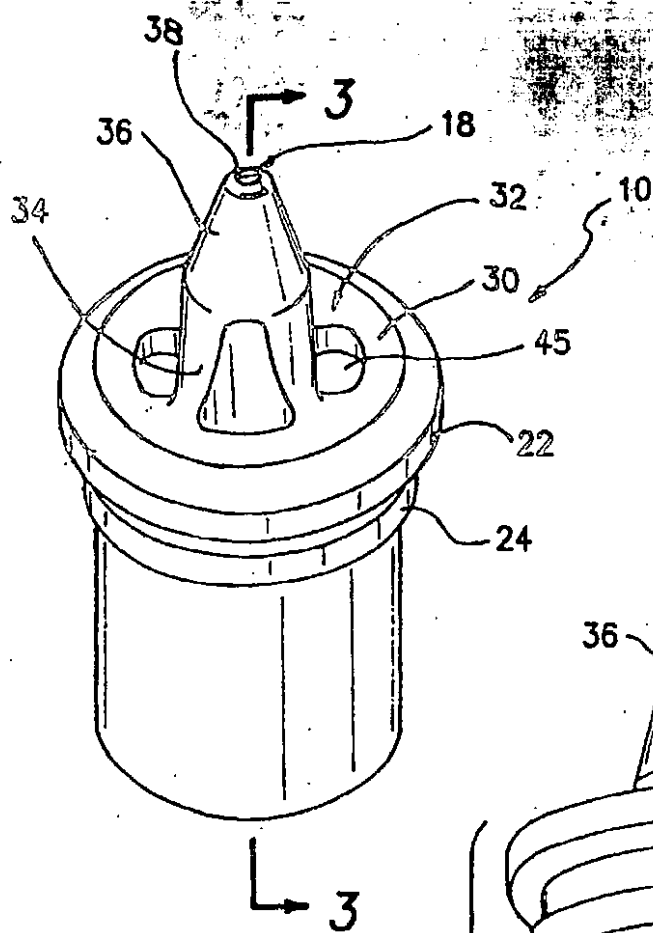


FIG. 1

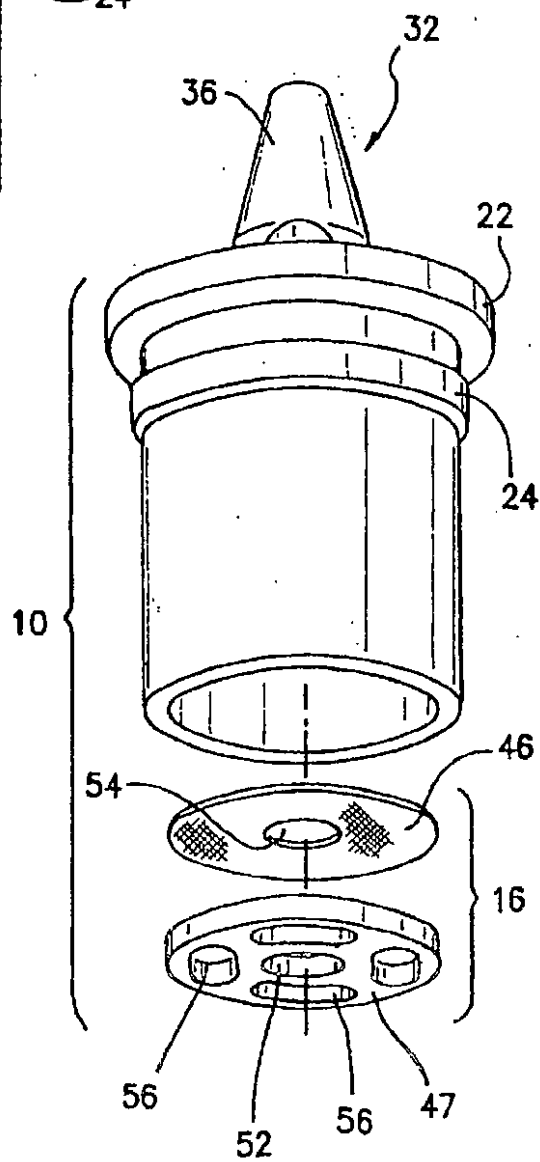


FIG. 2

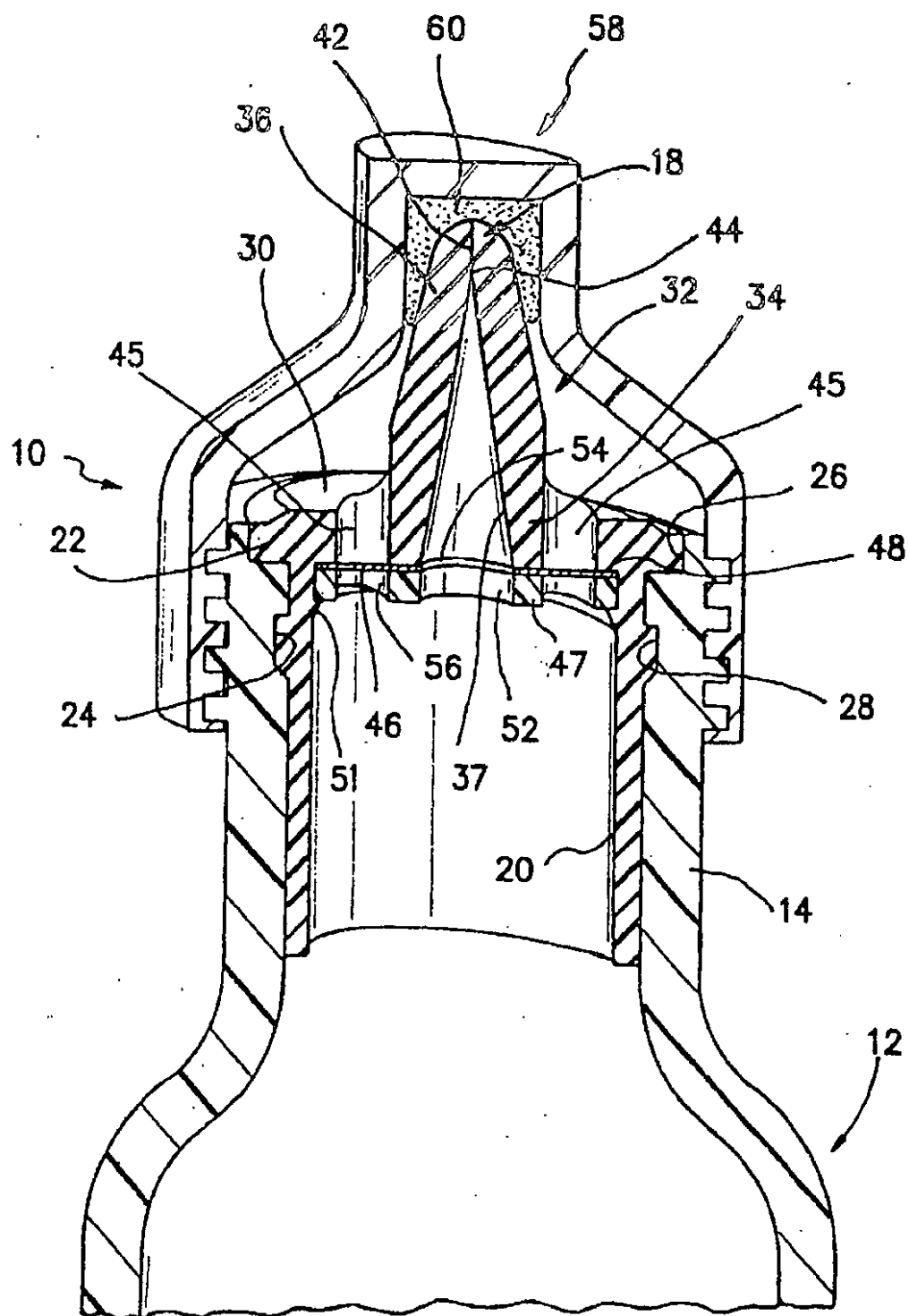


FIG. 3

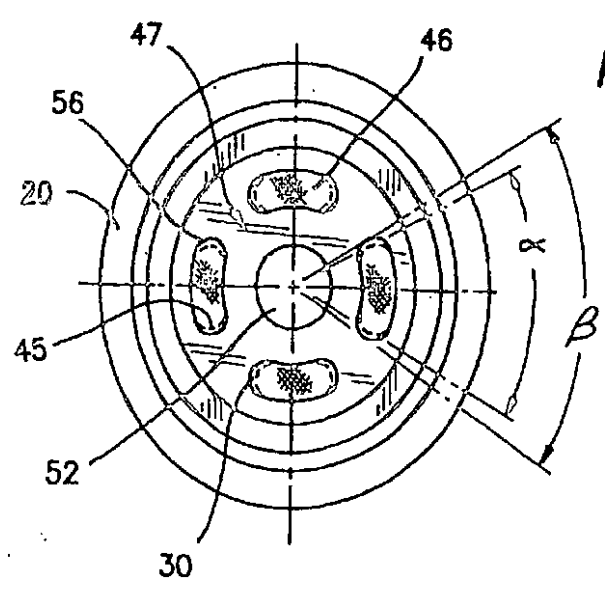


FIG. 3A

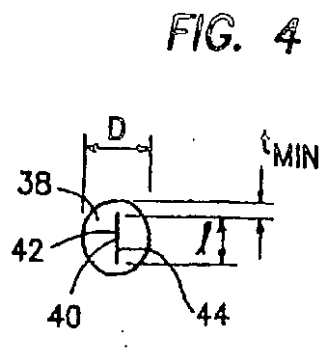


FIG. 4

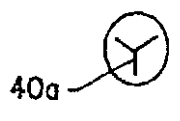


FIG. 4A



FIG. 4B

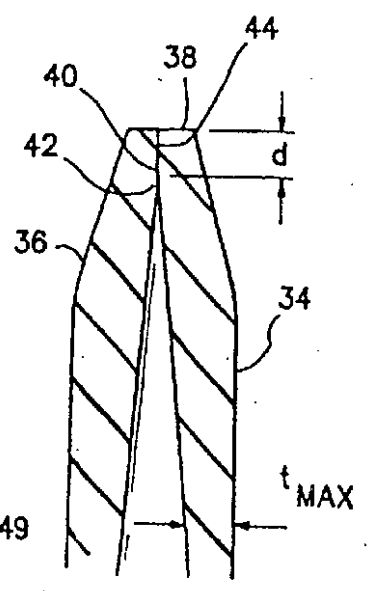


FIG. 4C

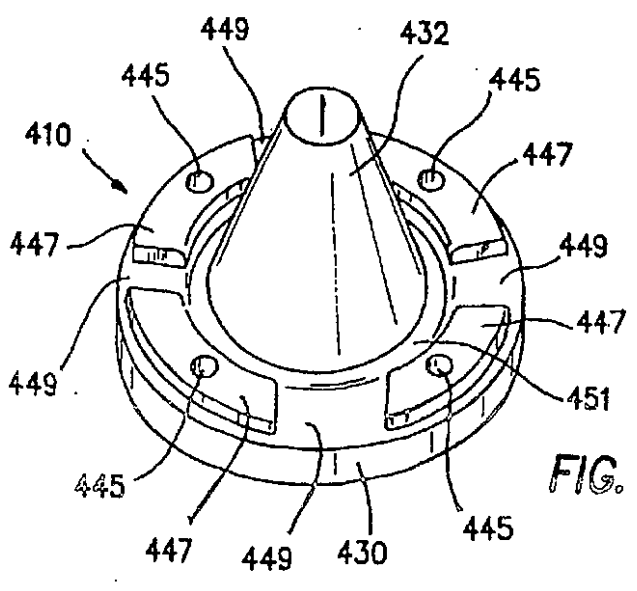


FIG. 11

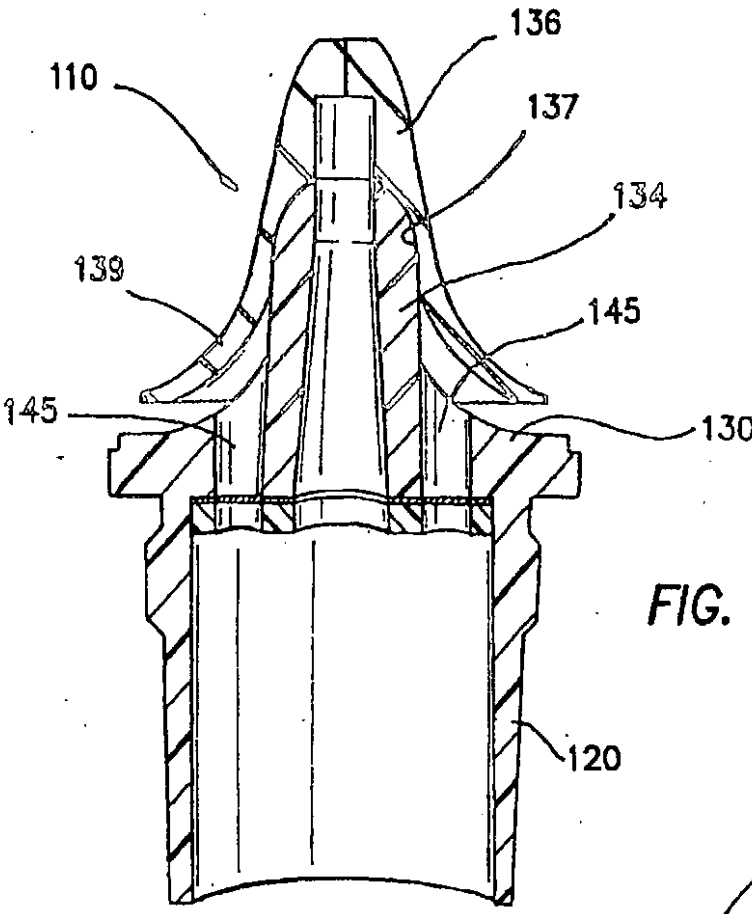


FIG. 5

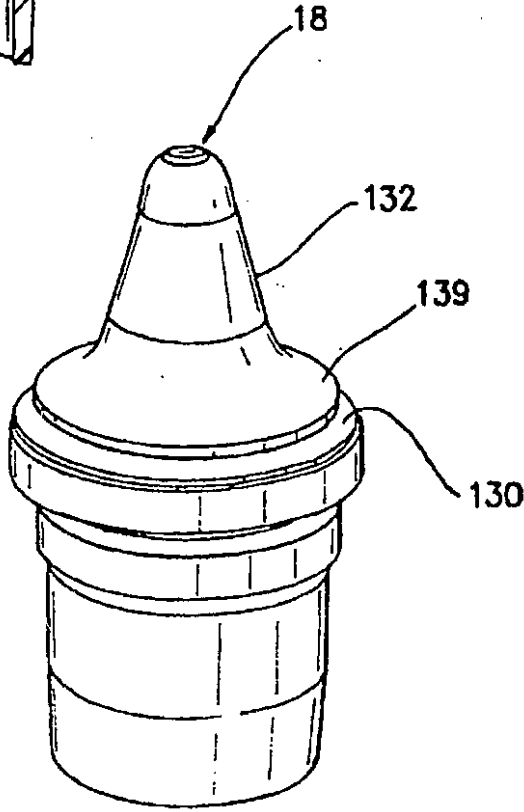
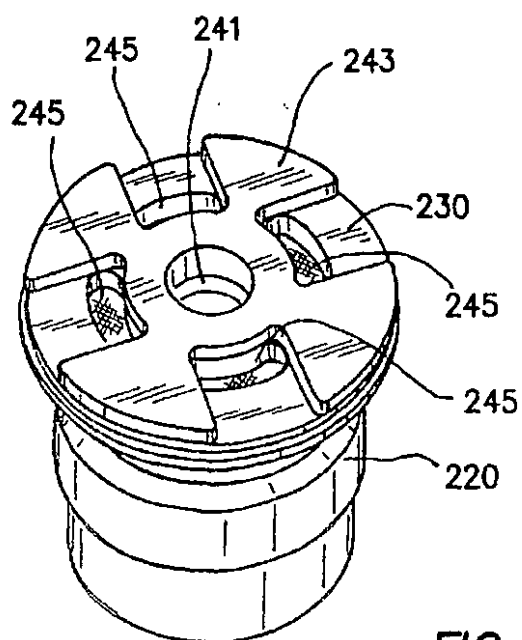
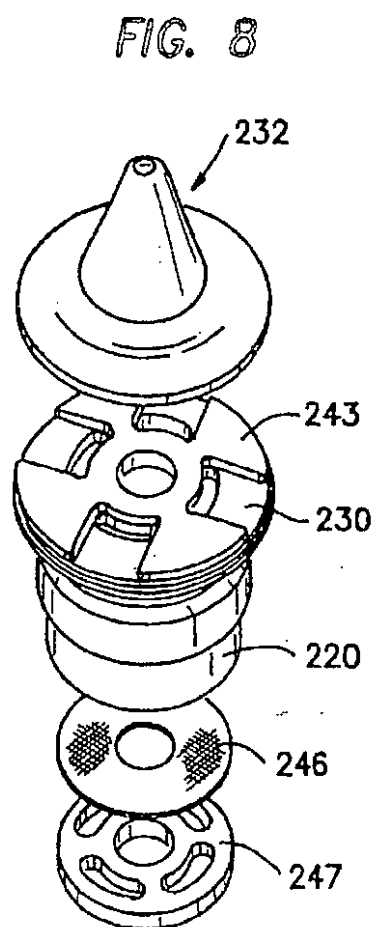
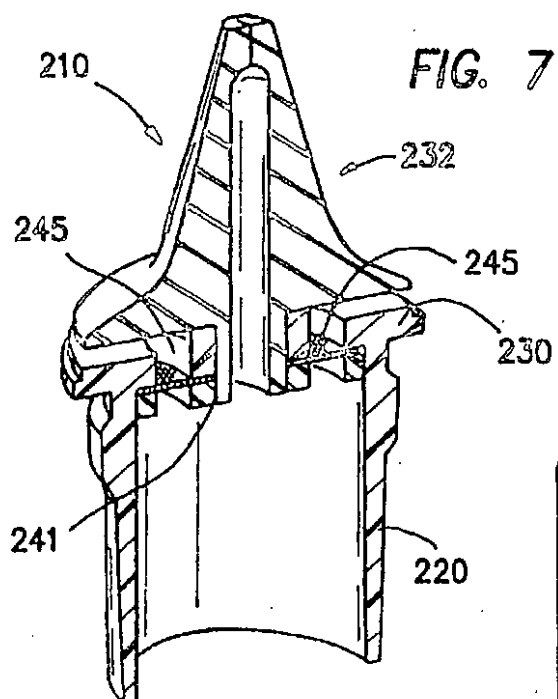


FIG. 6



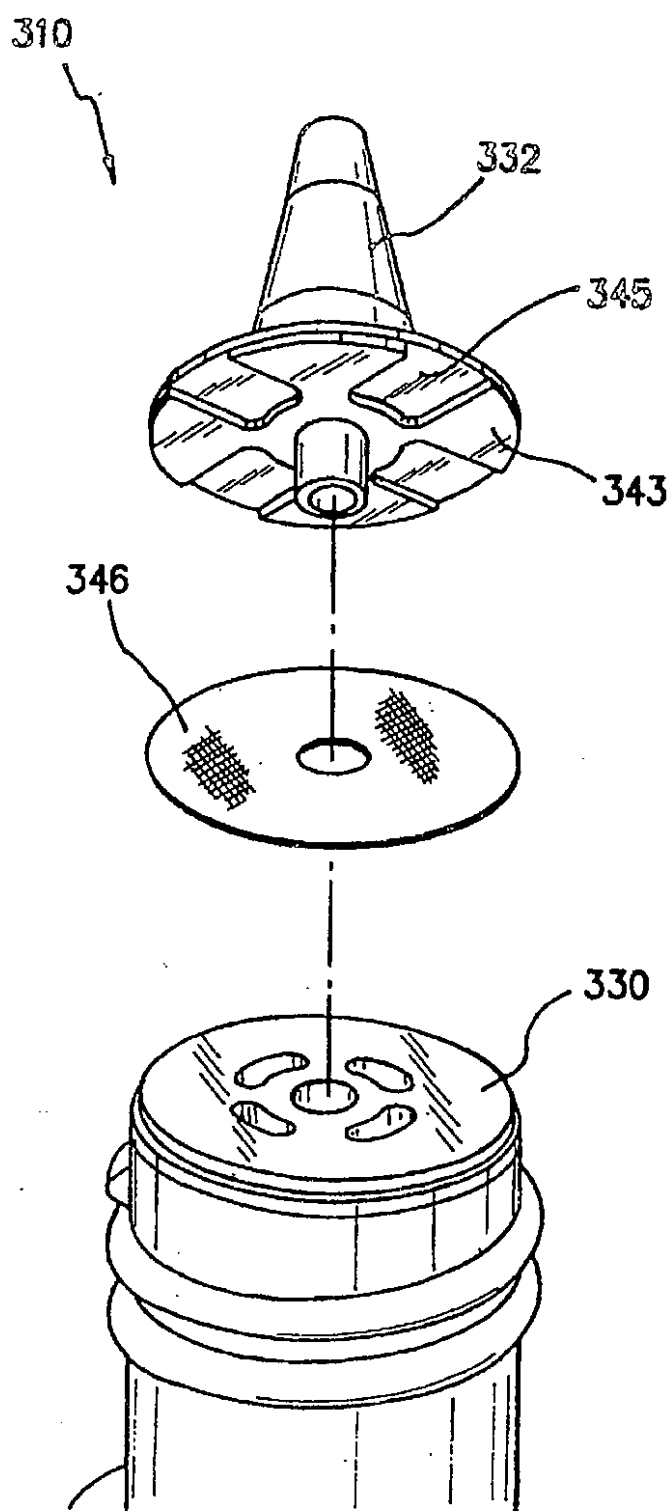


FIG. 10

### MULTI-DOSE LIQUID DISPENSING ASSEMBLY

[0001] This application claims the benefit of provisional application Ser. No. 60/458,686, filed Mar. 31, 2003, the disclosure of this provisional application is incorporated in its entirety herein by reference.

### BACKGROUND OF THE INVENTION

[0002] The present invention relates to containers and dispensers of liquids, especially of sterile liquids such as medications and medicaments. More particularly, the invention relates to a dispensing tip for placement in or over an opening in a resilient-walled vessel, the tip including a valve structured to allow drop-wise dispensing from the vessel when sufficient manual pressure is applied to the resilient wall of the vessel, and to prevent back flow at zero as well as near zero pressure differentials across the valve.

[0003] Various liquid solutions, particularly ophthalmic pharmaceutical and OTC solutions such as anti-glaucoma, anti-allergy and dry eye solutions, must be kept sterile in order to prevent contamination from bacteria and other microbes. Typically, sterility is maintained by adding a preservative such as, for instance, benzalkonium chloride, methyl parabens, propyl parabens, thimerosal and chlorbutanol, or another antibacterial agent such as a biguanide to a saline based formulation.

[0004] Unfortunately, such preservatives and/or antibacterial agents often have unwanted side effects such as allergic reactions and/or irritation of the tissue, for instance conjunctival or corneal tissue, in the patients being treated by the solution. In order to avoid the problems associated with preservatives and/or antibacterial agents, some manufacturers have developed single service containers which remain sealed until use, eliminating the need for the preservatives and/or antibacterial agents. Such single service containers are considerably more expensive, on a per treatment basis, than containers capable of dispensing multiple doses.

[0005] Accordingly, numerous attempts have been made to develop dispensing systems allowing multiple-dose dispensing of preservative-free liquid solutions. Some of these attempts are described in Ranalletta et al. U.S. Pat. Nos. 5,025,957, 5,183,184, 5,255,826, and 5,320,254. Other attempts are described in Ryder et al. U.S. Pat. No. 5,154,325 and Kanner et al. U.S. Pat. No. 5,431,310. Still other attempts are described in Meierhoefer et al. U.S. Pat. No. 4,533,068 and Martinez et al. U.S. Pat. No. 5,310,094. The disclosures of each of the aforementioned patents is incorporated in its entirety herein by reference.

[0006] Each of the aforementioned Ranalletta et al. patents discloses a liquid dispensing nozzle assembly including an adapter for placement in a resilient-walled liquid container. The adapter includes a complex, elastomeric diaphragm defining a frustoconical nozzle that extends upwardly from a tubular elastomeric valve portion. The valve portion, which fits loosely around a nipple formation that extends upwardly from the adapter wall, terminates in a tapered sealing ring that normally seals against the adapter wall at its surface surrounding the nipple to prevent leakage of the stored liquid when the container is inverted. When the container is squeezed, the liquid in the container flows through a set of passageway bores formed in the adapter wall and exerts hydraulic pressure on the elastomeric diaphragm,

thus compressing the valve portion and deflecting the sealing ring from the adapter wall to allow liquid to be discharged through the nozzle. The assembly also includes an air aspiration conduit for aspirating air into the container to replace the dispensed liquid, and an air filter, integrally formed with the valve, for filtering the air as it enters the container.

[0007] The liquid solution in the container of Ranalletta et al. must follow a rather tortuous and narrow flow path before it is dispensed through the nozzle. Initially, the solution flows in an axial direction through the passageway bores in the adapter wall. Next, the flow is diverted in a radial direction toward the inlet of the nozzle, where it is redirected in the axial direction by the nipple. One advantage of this tortuous flow path is that it slows the flow of the solution, possibly allowing drop-wise dispensing. A disadvantage, however, is that rather complicated manufacturing processes are required to provide the necessary flow restriction structures, thus increasing the overall cost of manufacture.

[0008] The Kanner et al. patent discloses a number of nozzle assemblies which, like the Ranalletta et al. nozzle assemblies, include flow restriction structures possibly enabling drop-wise dispensing. One embodiment without flow restriction structures is also disclosed. In this embodiment, the dispensing nozzle terminates in a conventional duckbill valve. The duckbill embodiment of Kanner et al. does not appear to be capable of drop-wise dispensing. Also, to the best of our knowledge, all commercially available duckbill valves allow at least some back flow at zero differential pressure across the valve. Accordingly, the duckbill nozzle assembly disclosed by Kanner et al. may not fully close after dispensing, thus allowing small amounts of contaminated liquid solution to reenter the bottle after use.

[0009] Ryder et al. shows a number of other nozzle assemblies having flow restriction structures. In one embodiment of particular interest, the nozzle includes a terminal valve portion comprising a generally circular prism portion having a normally closed slit which resiliently opens with the hydraulic pressure of the dispensed fluid, and then closes to prevent entry of the potentially contaminating air.

[0010] The patents to Martinez et al. and Meierhoefer both show nozzle assemblies having distally disposed duckbill valves, specifically duckbill valves manufactured by Vernay Laboratories, Inc. However, graphs found on the Vernay web page (<http://www.vernay.com>) show that all their stock products allow some back flow at zero as well as near zero pressure differentials. Accordingly, the nozzle assemblies of Martinez et al. and Meierhoefer may not effectively prevent contaminated liquid from reentering the container after dispensing.

[0011] Accordingly, there exists a need for dispensing systems allowing sterile, multiple-dose, drop-wise dispensing of preservative-free liquid solutions. In particular, a need exists for simple and economical multiple-dose, drop-wise dispensing assemblies which are substantially free of flow restriction structures and which allow substantially no back flow at zero as well as near zero pressure differentials.

### SUMMARY OF THE INVENTION

[0012] The present invention provides new and enhanced dispensing tips and/or dispensing assemblies for dispensing,

for example, sterile, multiple-dose, drop-wise dispensing of preservative-free liquid solutions. Methods of dispensing using such dispensing tips and/or assemblies are also provided.

[0013] The dispensing assemblies of the present invention enable a user to dispense individual drops, rather than streams, of a liquid solution, by squeezing a resilient-walled vessel with a force that is comfortable for consumers, yet greater than the force required by dispensers having conventional duckbill valves. Furthermore, the dispensing assemblies are capable of drop-wise dispensing over a broad force range, without the need for flow restrictors or other obstructions. The dispensing assemblies of the present invention also include features, such as a back flow-resistant check valve, a filtration member, and an antibacterial cap liner, which reduce or eliminate contamination of the solution being dispensed, making the use of preservatives unnecessary. Moreover, the dispensing assemblies of the present invention are straightforward in construction, and are simple and economical to manufacture.

[0014] In accordance with one aspect of the invention, dispensing tips to be coupled to a resilient-walled vessel comprise a tip defining a bore structured to communicate directly with the opening in a resilient-walled vessel when coupled to the vessel; and a valve that is structured to allow drop-wise dispensing from the vessel when the tip is coupled to the vessel and sufficient manual pressure is applied to the resilient wall of the vessel. The valve is further structured to prevent back flow at zero as well as near zero pressure differentials across the valve. Such dispensing tips also include at least one vent opening structured to allow air into and out of the vessel when the dispensing tip is coupled to the vessel. Advantageously, the present dispensing tips include at least one filtration element extending across the at least one vent opening and structured to allow gaseous fluid to pass through the vent opening while blocking liquid fluids and contaminants.

[0015] In a useful embodiment of the invention, the valve is a check valve having a cracking pressure equal to at least about 0.1 psi, preferably at least about 0.5 psi, and more preferably still, at least about 1.0 to 4.5 psi.

[0016] In a particularly useful embodiment, the tip is configured as a substantially gaussian, or bell-shaped, truncated cone, and the valve comprises a normally closed slit extending substantially perpendicularly through the distal end of the tip. The distal end of the tip is preferably substantially planar. The dimensions of the slit relative to the diameter of the tip, as well as the wall thickness, material properties of the tip and method of formation of the slit, are selected to ensure that the mutually facing edges extending along opposite sides of the slit exert sufficient force on one another to prevent microbe-sized particles from passing through the slit when the valve is closed. More preferably, these properties are selected such that the mutually facing surfaces exert sufficient force on one another to prevent particles larger than one micron in diameter from passing through the slit when the valve is closed. Even more preferably, the force is sufficient to prevent particles larger than 0.22 microns in diameter from passing through the slit when the valve is closed.

[0017] In one advantageous embodiment, the present dispensing tips include a retaining member structured to main-

tain the at least one filtration member in a fixed position relative to the at least one vent opening in the tip. Preferably, the retaining member includes at least one aperture alignable with the at least one vent opening, wherein the aperture and the vent opening are sized and placed to allow air flow through both the aperture and the vent opening regardless of the coaxial orientation of the retaining member.

[0018] In another advantageous embodiment, the present dispensing tips have a two-piece structure having a base portion formed of a first, relatively rigid material, and an end portion, including the valve, that is formed of a second, more flexible material. Preferably, the first material is selected from the group consisting of polyethylene, polypropylene, polystyrene, polycarbonate, acrylonitrile butadiene styrene, and mixtures thereof, and the second material is selected from the group consisting of silicone polymer, polyisoprene, plasticized polyvinyl chloride, polyurethane, ethylene-butylene copolymers, styrenics, and mixtures thereof.

[0019] In other advantageous embodiments, the dispensing tips include at least one deflector element structured to deflect liquid from the at least one vent opening. For instance, in one embodiment, the deflector element includes an apron structure extending radially outwardly from a central axis of the tip. In another embodiment, the at least one vent opening is located in a plateau formed on a base portion of the tip, and the deflector element comprises at least one channel provided adjacent the plateau for directing liquid away from the vent opening.

[0020] Another useful embodiment of the invention provides a cap for covering the dispensing tip when the assembly is not in dispensing use, and an anti-microbial liner located in the cap and effective in reducing or preventing contamination of the external surface of the tip about the slit. Advantageously, the anti-microbial liner comprises a resilient component adapted to sealingly engage the tip when the cap is positioned thereon, and an antimicrobial component. The antimicrobial component may comprise an anti-microbial coating on the resilient component, or may be dispersed throughout the resilient component. Alternatively, the liner may be eliminated and an antimicrobial component incorporated directly into the cap material or applied as a coating on the inner surface of the cap.

[0021] In accordance with another aspect of the invention, dispensing assemblies are provided comprising a tip defining a bore positioned to be in direct communication with the vessel when coupled to the vessel, the tip including a distal end, and a valve provided at the distal end of the tip. The valve, which extends substantially coaxially with the bore, is structured to allow drop-wise liquid dispensing from the vessel when sufficient manual pressure is applied to the resilient wall of the vessel and to prevent liquid back flow at zero as well as near zero pressure differentials across the valve. Vent openings, at least one filtration element, a retaining member, and a cap having an anti-microbial liner, as described above, may also be provided with the assembly.

[0022] In accordance with still another aspect of the invention, dispensing assemblies to be coupled to a resilient-walled vessel are provided and comprise a tip defining an unobstructed bore structured to communicate directly with the opening in the vessel when the assembly is coupled to the vessel. The tip includes a distal end, and a valve provided at the distal end of the tip. The valve extends substantially

coaxially with the bore and comprises a planar surface defining at least one slit. A plurality of mutually facing surfaces extend along opposite sides of the at least one slit, the mutually facing surfaces being structured to exert sufficient force on one another when the valve is closed to prevent microbe-sized particles from passing through the at least one slit when the valve is closed. As in the previous aspects, vent openings, at least one filtration element, a retaining member, and a cap having an anti-microbial liner, as described above, may also be provided.

[0023] In accordance with yet another aspect of the invention a dispensing assembly to be coupled to a vessel containing a sterile liquid comprises a tip structured to dispense liquid from the vessel, a cap structured to cover the tip when the assembly is not in use, and an anti-microbial liner in the cap for preventing contamination of the tip. The anti-microbial liner is preferably in the form of a resilient component and an anti-microbial component, wherein the anti-microbial component may either be dispersed throughout the resilient component or provided in the form of a surface coating thereon.

[0024] In accordance with a further aspect of the invention, dispensing assemblies to be coupled to a vessel containing a liquid are provided and comprises a dispensing tip including a normally closed valve structured to allow dispensing from the vessel when the dispensing tip is coupled to the vessel and the valve is open, at least one vent opening structured to allow air into and out of the vessel when the dispensing tip is coupled to the vessel, at least one filtration member extending across the at least one vent opening and structured to allow gaseous fluids to pass through the vent opening while blocking liquid fluid and contaminants, and a retaining member structured to maintain the at least one filtration element in a fixed position when juxtaposed therewith. The retaining member defines at least one aperture configured to communicate with the vent opening when the retaining member is juxtaposed with the filtration member, regardless of the coaxial orientation of the retaining member.

[0025] In a useful embodiment, the at least one vent opening comprises a plurality of vent openings symmetrically arranged about the valve (or the base of the nozzle), and the at least one aperture comprises a plurality of apertures sized and placed to allow communication between the apertures and the vent openings regardless of the angular orientation of the retaining member relative the dispensing tip.

[0026] Methods of dispensing preservative-free liquid solutions are provided in accordance with an additional aspect of the present invention. In general, these methods involve using the dispensing tips and dispensing assemblies in accordance with the present invention, as described elsewhere herein. For example, such methods comprise the steps of 1) providing a liquid solution, such as a preservative-free liquid solution, in a resilient-walled vessel having a dispensing tip including a normally closed valve structured to open when sufficient pressure, for instance manual pressure, is applied to the resilient wall and to prevent back flow at zero as well as near zero pressure differentials across the valve; and 2) applying sufficient pressure to the resilient wall to cause the valve to open. Preferably, the step of applying sufficient pressure comprises manually squeezing the container long enough to dispense one or more drops, prefer-

ably, only a single drop, of the solution. Substantially immediately after the desired amount of liquid has been dispensed, the pressure on the resilient wall of the vessel is released and the valve closes.

[0027] Each and every feature described herein, and each and every combination of two or more of such features, is included within the scope of the present invention provided that the features included in such a combination are not mutually inconsistent.

[0028] Additional aspects and advantages of the present invention are set forth in the following description and claims, particularly when considered in conjunction with the accompanying drawings in which like parts bear like reference numerals.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0029] FIG. 1 is a perspective view showing a dispensing assembly according to the present invention;

[0030] FIG. 2 shows elements of the dispensing assembly of FIG. 1 in exploded relationship to one another;

[0031] FIG. 3 is a sectional view taken through line 3-3 of FIG. 1;

[0032] FIG. 3A is a bottom view of FIG. 1;

[0033] FIG. 4 is a plan view of a dispensing tip according to the present invention;

[0034] FIGS. 4A and 4B are plan views of dispensing tips having alternate slit arrangements;

[0035] FIG. 4C is a longitudinal sectional view of the tip shown in FIG. 4;

[0036] FIG. 5 is a longitudinal sectional view of a dispensing tip according to an alternate embodiment of the invention;

[0037] FIG. 6 is a perspective view of the tip shown in FIG. 5;

[0038] FIG. 7 is a view, similar to FIG. 5, of a dispensing tip according to another embodiment of the invention;

[0039] FIG. 8 is a perspective view showing the elements of the tip of FIG. 7 in exploded relationship to one another;

[0040] FIG. 9 is a perspective view showing the base portion of the tip of FIG. 7;

[0041] FIG. 10 is an exploded perspective view of a dispensing tip according to still another embodiment of the invention; and

[0042] FIG. 11 is a perspective view showing a dispensing tip according to yet another embodiment of the invention.

#### DETAILED DESCRIPTION OF THE DRAWINGS

[0043] Referring now to FIGS. 1-3, a dispensing assembly or tip 10 in accordance with the present invention is provided for coupling to a resilient-walled vessel 12 such as a squeeze bottle having an open neck 14. The assembly 10 may be used to dispense liquids of virtually any kind, but is particularly useful for dispensing medicaments and other liquid pharmaceutical or ophthalmic solutions, such as anti-glaucoma, anti-allergy and dry eye solutions, that advantageously are to be kept sterile. Such solutions may be

preservative-free, for example, so as to be useful to a broad range of patients, including those that are sensitive to preservatives and those that prefer no preservatives.

[0044] In conventional dispensers, such solutions would require preservatives and/or antibacterial agents. However, the combination of a microbe-impermeable filter assembly 16 and a back flow-resistant check valve 18, as described herein, make the use of preservatives and/or antibacterial agents unnecessary in solutions dispensed using the assembly 10 of the present invention.

[0045] With particular reference to FIG. 3, the dispensing assembly 10 according to the present invention preferably includes a cylindrical neck 20 configured to be inserted into the open neck 14 of the vessel 12. The neck 20 of the assembly 10 preferably includes a pair of longitudinally spaced apart annular flanges or ribs 22, 24 configured to snap or otherwise fit into corresponding grooves or recesses 26, 28 in the neck 14 of the vessel 12, thus tightly securing the assembly 10 within the vessel 12 and providing a fluid-tight seal therebetween.

[0046] A base portion 30 extends transversely across a distal end of the neck 20 of the dispensing assembly, and a nozzle 32 extends distally from a central portion of the nozzle base portion 30. The nozzle 32 includes a generally cylindrical proximal portion 34 and a distal portion 36 having a substantially gaussian, or bell-shaped, truncated conical configuration. The nozzle defines a conical bore 37 communicating at its distal end with the back flow-resistant check valve 18 carried in the planar distal surface 38 of the distal portion 36 and at its proximal end with the interior of the resilient-walled vessel 12. The bore 37 may have any suitable cross-section, such as, without limitation, a circular or an oval cross section.

[0047] The back flow-resistant check valve 18, shown in greater detail in FIGS. 4 and 4C, comprises at least one normally closed slit 40 extending substantially perpendicularly through the distal surface 38. Although shown here as a single slit, plural slits such as, for instance, slits arranged in "Y" or "X" configuration could also be provided, as shown in FIGS. 4A and B, respectively. A plurality of mutually elastically contacting edges 42, 44, which may also be described as lips or mutually facing surfaces, extend along opposite sides of the slit or slits 40.

[0048] The geometry, material and method of forming of the distal portion 36 of the nozzle 32, as well as the dimensions of the slit 40 and the thickness of the material surrounding the slit 40 are selected such that the edges or surfaces 42, 44 exert sufficient force on one another when the valve is closed to prevent microbe-sized particles from passing through the at least one slit when the valve is closed. More specifically, these properties are selected such that the force exerted by the edges 42, 44 on one another when the valve is closed is sufficient to prevent particles larger than one micron in diameter from passing through the at least one slit 40 when the valve 18 is closed. Preferably, the properties are selected such that the force is sufficient to prevent particles larger than 0.22 microns in diameter from passing through the slit when the valve is closed.

[0049] The dimensions and material properties of the check valve 18 should also be selected such that the cracking pressure of the valve is greater than about 0.1 psi. More

preferably, the cracking pressure of the valve should be above about 0.5 psi, and more preferably still, in the range of 1-4.5 psi, since cracking pressures in this range have been found to be comfortable for consumers, while at the same time allowing drop-wise dispensing without the need for flow restrictors in the vessel 12 or dispensing assembly 10. This is in direct contrast to conventional check valves, where manual pressure above 0.1 psi would cause liquid to exit in a stream, rather than individual drops, unless a flow restrictor or other obstruction were provided.

[0050] Both the cracking pressure and the ability of the check valve 18 to resist back flow are determined by a number of factors, including the resiliency of the elastomer in the distal end 38 of the nozzle 32, the dimensional features of the slit 40 and surrounding structure, the bulk of material surrounding the slit 40, the annular geometry of the material surrounding the slit 40 and the precision and method with which the slit 40 is formed.

[0051] Specifically, it has been found that the material used to form the distal portion 36 of the nozzle 32 should be a highly resilient material having an elongation greater than or equal to about 150% or greater than or equal to about 200%, a tear strength greater than or equal to about 150 ppi or greater than or equal to about 200 ppi, a compression set less than or equal to about 40%, and a Shore A durometer of about 30 to about 70 or about 80. Useful materials having some or all of these properties include silicone polymers, polyisoprene, plasticized polyvinyl chloride, polyurethane, ethylene-butylene copolymers, styrenics, and mixtures thereof.

[0052] Any of the above materials may optionally also include an anti-microbial agent that has been added into the resin during manufacture. Alternately, an anti-microbial agent may optionally be applied to the tip in the form of a coating. Suitable antimicrobial agents may include salts of common heavy metal oxides, including oxides of silver, gold or copper, or may be substantially metal-free. Particularly useful antimicrobial components that are known to be substantially non-leachable and to be compatible with injection-moldable resins may be selected from the group consisting of antimicrobial quaternary ammonium containing groups, antimicrobial amine-containing groups, antimicrobial peptide-containing groups, antimicrobial phosphazene-containing groups and mixtures thereof. Such antimicrobial components are more fully described in Dziabo et al. U.S. Pat. No. 5,515,117, which is incorporated in its entirety by reference herein.

[0053] Regarding the dimensional features of the slit 40, the preferred slit length  $l$  for a nozzle 32 having a length of 0.25-0.75 inches and a distal end diameter  $D$  in the range of about 0.05 to 0.21 inches is in a range of about 0.04 to about 0.2 inches. The optimum depth  $d$  for such a slit 40 is preferably in a range of about 0.01 to about 0.1 inches. The minimum wall thickness  $t_{MIN}$  (i.e. the thickness of the wall between an end of the slit 40 and the outer circumference of the distal surface 38) preferably is no less than about 0.01 inches. The maximum wall thickness  $t_{MAX}$  (i.e. the thickness of the wall between the bore 37 and the outer surface of the nozzle 32 at the junction between the cylindrical proximal portion 34 and the substantially gaussian truncated conical distal portion 36) preferably is no less than about 0.02 inches.

[0054] In relative terms, the length  $l$  of the slit 40 preferably is no greater than about  $0.96D$ , where  $D$  is the diameter of the planar distal surface 38 of the nozzle 32. The depth  $d$  of the slit 40 preferably is no less than about  $0.04D$ . The maximum wall thickness  $t_{MAX}$  preferably is no less than about  $1.5d$ .

[0055] In accordance with the present invention, the process of forming the slit 40 in the planar surface 38 preferably is carefully controlled in order both to obtain the proper cracking pressures and to ensure that no back flow occurs at zero as well as near zero pressure differentials.

[0056] Accordingly, a new procedure for introducing the slit into the surface in a clean, precise, and reproducible manner has been discovered. This process comprises inserting the nozzle 32 distal end down in a female cavity in a blocking fixture. The cavity has an inner geometry substantially matching, for example substantially exactly matching, the outer geometry of the nozzle 32, and includes an opening having a diameter substantially equal to, for example substantially exactly equal to, the outer diameter of the distal surface 38 of the nozzle 32. Very slight compression of the nozzle end 36 occurs when the nozzle 32 is placed in the fixture.

[0057] Once the nozzle 32 has been placed in the blocking fixture such that the axis of the nozzle is substantially perpendicular to the plane of the fixture and the distal end 38 is aligned with the matching opening, a slitting blade is positioned coaxially over the tip and actuated downwardly through the distal end of the nozzle. The slitting blade, preferably made of hardened stainless steel or ceramic, is sharpened at one end to resemble a double edged chisel, wherein the taper of the cutting edge is longer than, for example about 0.05 inches longer than, the wall thickness of the distal end 38. Thus, the blade is able to consistently penetrate the surface 38 and create a clean, complete slit having a width equal to the edge-to-edge distance (i.e. the width) of the blade.

[0058] A hard rubber pad, for example having a Shore A durometer of about 70 to about 100, is placed under the surface 38 during the slitting operation to substantially prevent, minimize, or at least reduce flexing thereof. The blade moves downwardly until it encounters a mechanical stop, which ensures that exactly the desired length of slit is obtained, at which point the blade is retracted and the nozzle 32 removed from the blocking fixture.

[0059] Various other methods of forming the slit will readily occur to the skilled practitioner, and are included within the scope of the present invention.

[0060] In addition to the check valve 18, the dispensing assembly 10 includes a plurality of vent openings 45 allowing gaseous fluids such as air to flow into and out of the bottle. In the illustrated embodiment, four generally triangular openings 45 are provided at intervals of approximately  $90^\circ$ . The base of each triangular opening 45 extends circumferentially along the base portion 30 of the dispensing assembly 10, subtending an angle of approximately  $45^\circ$ . The apex of each triangular opening 45 extends axially, terminating near the proximal end of the distal end portion 36 of the nozzle. However, this arrangement of openings is merely exemplary. Various arrangements involving other shapes, sizes and numbers of vent openings 45 will also be apparent to the skilled practitioner, and are included within the scope of the present invention.

[0061] At least one filtration element 46, such as a membrane or the like, is juxtaposed with the vent openings 45 to prevent liquid and airborne contaminants from entering the vessel 12. Preferably, the filtration element 46 is in the form of an annular disk having its underside communicating with the interior of the vessel 12 and its upper surface abutting the base portion 30 of the dispensing assembly. Any commercially available hydrophobic, air permeable filter having a sufficiently small pore size to exclude bacteria may be suitable for use in this assembly. The filtration element 46 may optionally also be made from or treated with one or more antibacterial materials, such as oxides of silver, gold or copper, or any of the substantially non-metal, non-leachable antibacterial components described in the aforementioned Dziabo et al. patent.

[0062] In the illustrated embodiment, a retainer member 47 is positioned against the filtration element 46 for securing the filtration element 46 in place against the annular underside 48 of the base member 30, preventing air from moving around it. The retaining member 47 is shown here as a rigid ring secured within the cylindrical neck 20 of the dispensing assembly 10. Preferably the neck 20 includes a chamfered lip 51 that urges the retaining member or ring 47 tightly against the annular underside 48.

[0063] Alternately, the entire filtration element retainer member assembly 16 may be inserted as stated above but with the filtration element 46 on the opposite side of the retainer member 47.

[0064] Other methods of securing the filtration element 46 to the retaining member or ring 47 may also be used. For instance, the filtration element 46 may be adhesively bonded or heat sealed to the retaining member 47, or molded with the retaining member 47 as an integral assembly. Alternatively, the retaining member could be dispensed with altogether, and the filtration element 46 could be press fit directly into the cylindrical neck 20, molded in place at the time of fabrication, or sealed against the annular underside 48 of the base member 30, for instance by heat sealing, adhesive bonding, welding or the like.

[0065] The retaining member or ring 47 includes a central bore or aperture 52 that is alignable with the central bore or aperture 54 of the filtration element, thus allowing liquid to flow unimpeded from the vessel 12 to the dispensing nozzle 32. In addition, the retaining member 47 includes a number of vent apertures 56 that are alignable with the vent openings 45 in the base portion 30 of the dispensing assembly 10. Preferably, the size and position of the vent apertures 56 is selected to allow air flow through both the vent apertures 56 and the vent openings 45 regardless of the coaxial orientation of the retaining member relative the vent apertures 56. In other words, the vent apertures 56 are configured to ensure that at least a portion of at least one of the vent apertures 56 communicates with at least a portion of at least one of the vent openings even if either the retaining member 47 or the base member 30 is unintentionally moved along or rotated about their common axis. This ensures that air flow will not be blocked if the retaining member 47 is misaligned during the assembly process.

[0066] In the illustrated embodiment, since the base portion 30 includes four vent openings 45 arranged  $90^\circ$  apart, each vent opening subtending an angle  $\alpha$ , the retaining member 46 includes four vent apertures 56, each subtending

an angle  $\beta > \alpha$ , as seen in FIG. 3A. Alternatively, the retaining member 46 could have a single vent aperture subtending an angle greater than  $270^\circ$ , two vent apertures, each subtending an angle greater than  $135^\circ$ , and so forth. The skilled practitioner will recognize numerous variations that can be made in the number, size and spacing of the vent apertures 56 that will allow continuous air flow through the vent openings 45, even in the event of misalignment of the retaining member 47. All such variations are included within the scope of the present invention.

[0067] The dispensing assembly 10 preferably includes a protective cap 58, as shown in FIG. 3. The cap 58 preferably defines an inner cavity having a shape that generally conforms to the shape of at least the distal end 36 of the dispensing nozzle 32. An anti-microbial liner 60 in the cap prevents contamination of the nozzle 32. The liner 60 is preferably made of a resilient material such as silicone polymer, rubber, sponge, or the like. An anti-microbial agent may either be dispersed throughout or applied as a coating to the resilient material.

[0068] The protective cap 58 preferably is internally threaded, allowing it to be screwed on over external threads provided on the neck 14 of the vessel 12. However, other ways of securing the cap 58 to the vessel are also included within the scope of the invention.

[0069] In the illustrated embodiment, the liner 60 is configured to be in intimate contact with the distal end 36 of the nozzle 32 when the cap 58 is in a closed position over the assembly. Alternately, the liner 60 may be configured to allow a small gap between the liner 60 and the distal end 36, thus allowing any residual liquid on the end 36 to be wicked onto the liner, while avoiding contact between the distal end 36 and the antimicrobial component.

[0070] A two-piece dispensing assembly 110 illustrating the principles of the present invention is shown in FIGS. 5 and 6. The neck 120, the base 130, and the proximal portion 134 of the nozzle 132 of this assembly 110 are integrally formed, for instance molded, from a first, relatively rigid material, preferably selected from the group consisting of polyethylene, polypropylene, polystyrene, polycarbonate, and acrylonitrile-butadiene-styrene, and mixtures thereof, while the distal portion 136 of the nozzle 132 is made from a more resilient material, preferably from the group consisting of silicone polymer, polyisoprene, plasticized polyvinyl chloride, polyurethane, ethylene-butylene copolymers, styrenics, and mixtures thereof.

[0071] The distal portion 136 of the nozzle 132, which includes a normally closed check valve 18 as described above, is configured as a female element having a generally cylindrical cavity 137 for receiving the generally cylindrical proximal portion 134 of the nozzle 132. The proximal portion 134 may simply be press-fit or snapped into the cavity 137, or it may be bonded in place by means of over-molding, adhesives, heat sealing, welding, or the like.

[0072] The distal portion 136 further includes a skirt or apron portion 139 that circumscribes the cylindrical cavity 137 and slopes radially outwardly in the proximal direction to form a roof or shield over the vent openings 145 in the base 130. This prevents any residual liquid, or runoff, from flowing into and blocking the vent openings 145. The proximal end of the apron portion 139 is spaced from the

base 130 and extends substantially perpendicularly to the axis of each vent opening 145, thus forming an angle in the path followed by ventilation air.

[0073] FIGS. 7-9 show a dispensing assembly 210 that is generally similar to the previous assembly 110, except that the entire nozzle 232 is formed of relatively resilient material and is configured as a male element configured to be received in a central bore 241 of the base portion 230. The base portion 230, which is formed of more rigid material, includes a raised cloverleaf structure 243 which serves as a seat for supporting the proximal surface of the nozzle 232, as well as spacing means for maintaining the nozzle 232 a sufficient distance from the vent openings 242 to ensure a substantially unimpeded flow of ventilation air.

[0074] In an alternate dispensing assembly 310 shown in FIG. 10, a cloverleaf structure 343 is integrally formed on the proximal surface 345 of the nozzle 332, rather than on the base portion 330 of the assembly 310. In addition, the filtration element 346 is sandwiched between the base 330 and the proximal end 343 of the nozzle, eliminating the need for a retaining ring.

[0075] FIG. 11 shows an alternative arrangement for deflecting runoff liquid from the vent openings 445 in the base portion 430 of a dispensing assembly 410. Each of the vent openings 445 is formed in a raised plateau 447. Each plateau 447 is separated from an adjacent plateau 447 by a gutter 449 that extends radially outwardly from an internal annular gutter 451 surrounding the nozzle 432. Other arrangements for deflecting runoff liquid will be apparent to the skilled practitioner. For instance, an annular wall or chimney could be provided around each vent opening 445. All such arrangements are included within the scope of the present invention.

[0076] A method of dispensing a preservative-free solution using a dispensing assembly of the present invention comprises the steps of: providing the preservative-free solution in a resilient-walled vessel having a tip defining an unobstructed bore directly communicating with the vessel and a check valve provided at the distal end of the tip, the valve being structured to allow drop-wise liquid dispensing from the vessel when sufficient manual pressure is applied to the resilient wall of the vessel, and to prevent liquid backflow at zero as well as near zero pressure differentials across the valve; applying sufficient manual pressure to the resilient wall of the vessel to dispense a single drop of the solution; and immediately removing the manual pressure to close the valve and prevent further dispensing and/or backflow. Preferably, the amount of manual pressure applied is greater than about 0.1 psi, and more preferably is greater than about 0.5 psi. Most preferably, the amount of manual pressure applied is in the range of about 1 to about 4.5 psi.

[0077] While this invention has been described with respect to various specific examples and embodiments, it is to be understood that the invention is not limited thereto and that it can be variously practiced within the scope of the following claims.

1-105. (canceled)

106. A dispensing assembly to be coupled to a resilient-walled vessel containing a liquid, comprising:

a neck portion including a sidewall structured to engage the interior of a neck of a resilient walled-vessel;

- a tip distally extending from the neck portion and defining a bore positioned to be in direct communication with the vessel when coupled to the vessel to provide a substantially linear fluid flow path from the vessel to the tip, the tip including a distal end; and
  - a valve provided at the distal end of the tip, the valve extending substantially coaxially with the bore;
- wherein the valve is structured to allow drop-wise liquid dispensing from the vessel when the assembly is coupled to the vessel and sufficient manual pressure is applied to the resilient wall of the vessel, and to prevent liquid back flow at zero as well as near zero pressure differentials across the valve.
107. The dispensing assembly of claim 106, further comprising:
- at least one vent opening structured to allow air into and out of the vessel when the dispensing assembly is coupled to the vessel; and
  - at least one filtration element extending across the at least one vent opening and structured to allow gaseous fluids to pass through the vent opening while blocking liquid fluids and contaminants.
108. The dispensing assembly of claim 107, wherein the at least one vent opening is oriented at a substantially perpendicular angle to the bore of the tip.
109. The dispensing assembly of claim 107, wherein the at least one vent opening is oriented coaxially with the bore of the tip.
110. The dispensing assembly of claim 107, further comprising a retaining member structured and positioned to maintain the at least one filtration element in a fixed position.
111. The dispensing assembly of claim 106, wherein the valve comprises a distal surface, at least one slit extending through the distal surface and a plurality of mutually facing surfaces extending along opposing sides of the at least one slit, the plurality of mutually facing surfaces being structured to exert sufficient force on one another when the valve is closed to prevent microbe-sized particles from passing through the at least one slit when the valve is closed.
112. The dispensing assembly of claim 111, wherein the plurality of mutually facing surfaces are structured to exert sufficient force on one another to prevent particles larger than 0.22 microns in diameter from passing through the at least one slit when the valve is closed.
113. The dispensing assembly of claim 106, further comprising a cap structured to cover the tip when the assembly is not in dispensing use.
114. The dispensing assembly of claim 113, further comprising an anti-microbial liner in the cap.
115. The dispensing assembly of claim 106, wherein the tip is an over-molded elastomeric nozzle coupled to the neck portion, and the assembly further comprises at least one vent opening located in the neck portion structured to allow air into and out of the vessel when the dispensing tip is coupled to the vessel, and at least one co-molded filtration member extending across the at least one vent opening and structured to allow gaseous fluids to pass through the vent opening while blocking liquid fluid and contaminants.
116. The dispensing assembly of claim 106, wherein the neck portion is formed of a first material, and the tip is formed of a second material more flexible than the first material.
117. The dispensing assembly of claim 114, wherein the first material is selected from the group consisting of polyethylene, polypropylene, polystyrene, polycarbonate, and acrylonitrile-butadiene-styrene polymers, and mixtures thereof, and the second material is selected from the group consisting of silicone, polyisoprene, plasticized polyvinyl chloride, polyurethane, ethylene-butylene copolymers, and mixtures thereof.
118. The dispensing assembly of claim 106, further comprising a filtration member, wherein the neck portion, the tip, and the filtration member are coupled together as a unitary structure to be coupled to resilient walled vessel.
119. The dispensing assembly of claim 106, wherein the bore of the tip provides an unobstructed fluid flow path from the vessel to the tip.
120. The dispensing assembly of claim 106, wherein the valve is a check valve having a cracking pressure greater than 0.1 psi.
121. The dispensing assembly of claim 106, wherein the distal end of the tip has a diameter, and the valve comprises a slit formed in the distal end, the slit having a length less than the diameter of the distal end of the tip.
122. The dispensing assembly of claim 106, further comprising at least one deflector element structured to deflect liquid away from the at least one vent opening.
123. The dispensing assembly of claim 106 coupled to a resilient-walled vessel containing a liquid.
124. A method of dispensing a preservative-free solution, comprising:
- providing a preservative-free solution in a resilient-walled vessel comprising the dispensing assembly of claim 106;
  - applying sufficient manual pressure to the resilient wall of the vessel to dispense a single drop of the solution; and
  - immediately thereafter removing the manual pressure to close the valve.

\* \* \* \* \*

## ANEXO C





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(54) **DISPENSING CONTAINER**

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(57) **ABSTRACT**

A dispensing container comprises a delaminating bottle (2) as a member for shutting off a liquid content from ambient air so that, without aid of any preservatives, a liquid residue is protected from contamination at a region adjacent to an outlet hole (3a). The container has a flexible nozzle (31) and a rod-shaped closer (32), both disposed in the mouth of bottle (2). The nozzle (31) is made of a pliable and elastic material, with the closer (32) being shaped to close a distal end region of the outlet hole (3a). By squeezing the barrel of bottle to increase its internal pressure, the flexible nozzle (31) expands to make a deformation, which in turn causes the outlet hole (3a) to take an outward open position.

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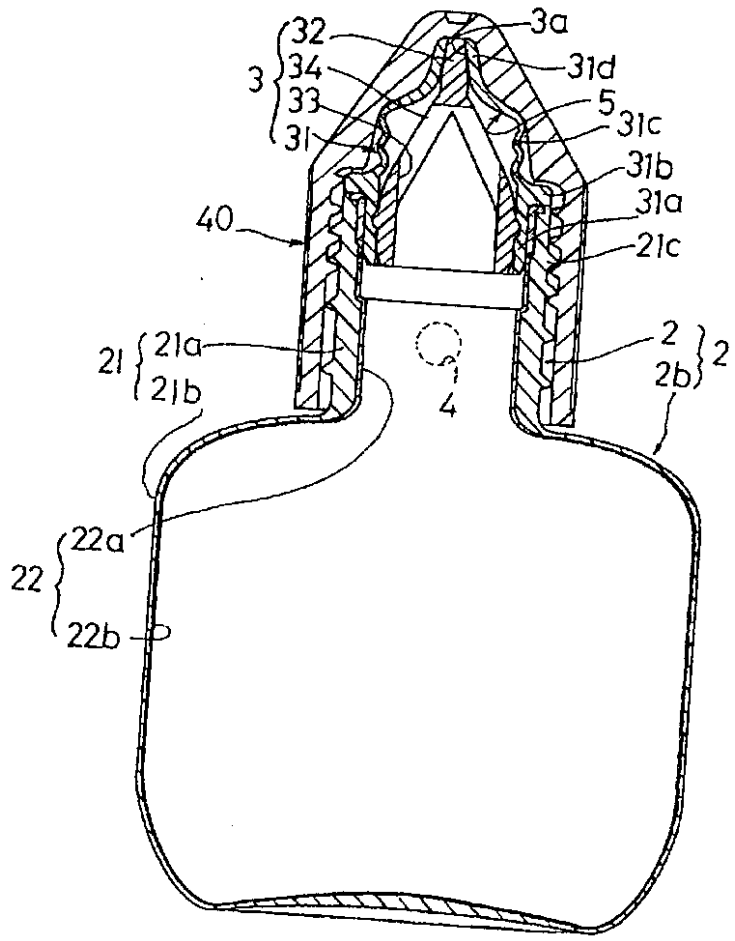


Fig.1 (a)

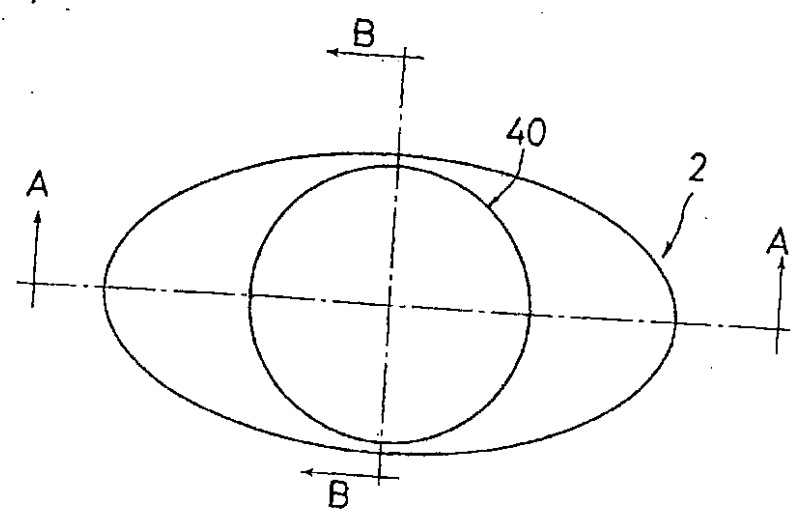


Fig.1 (b)

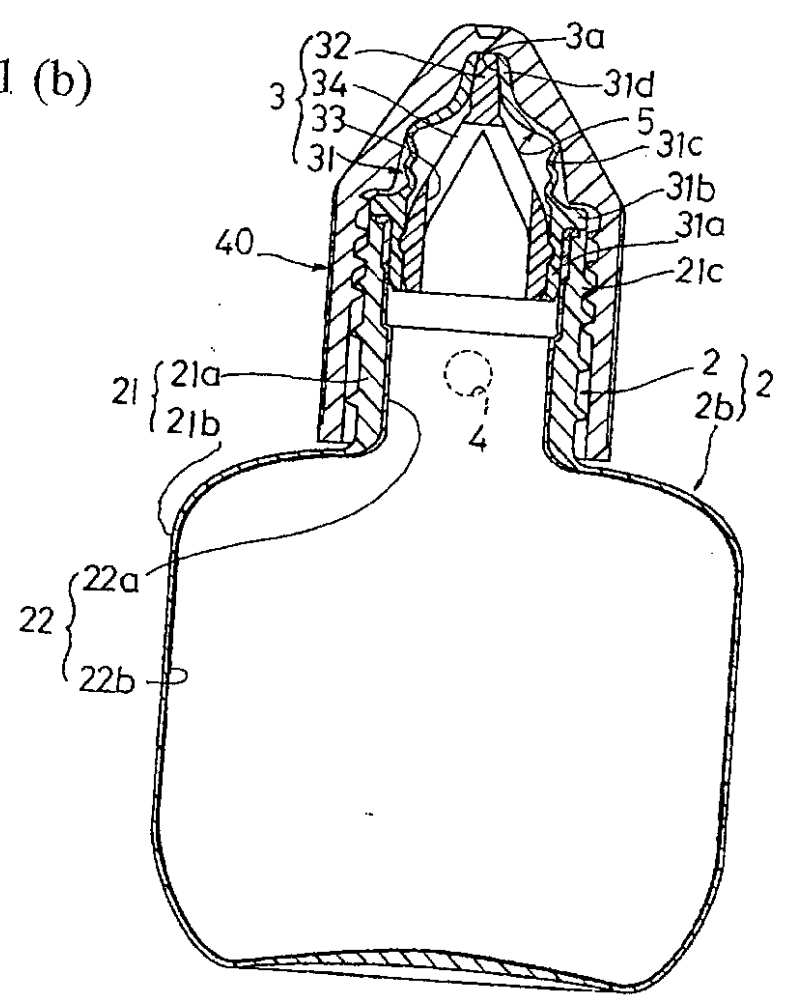


Fig.2

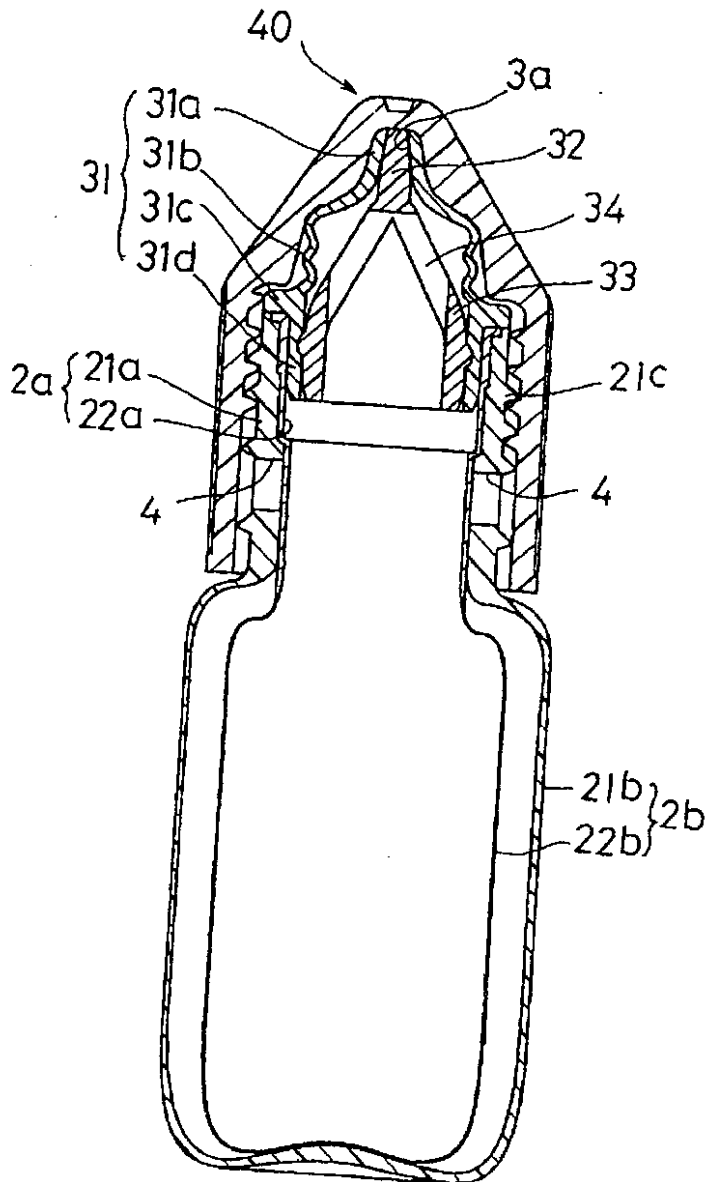


Fig.3 (a)

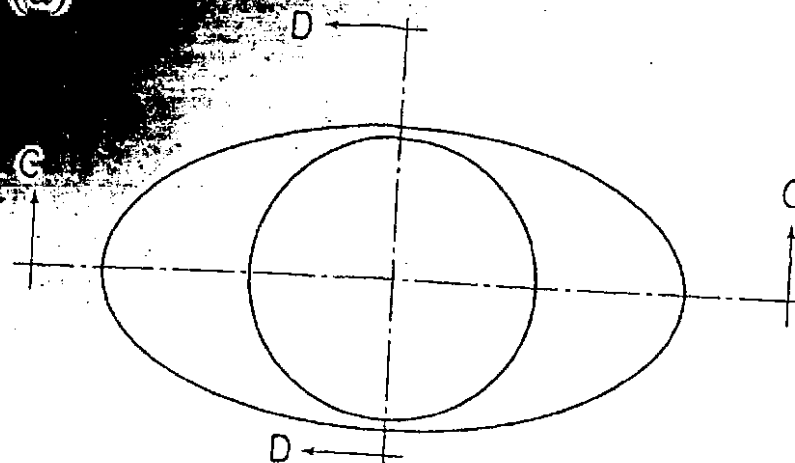


Fig.3 (b)

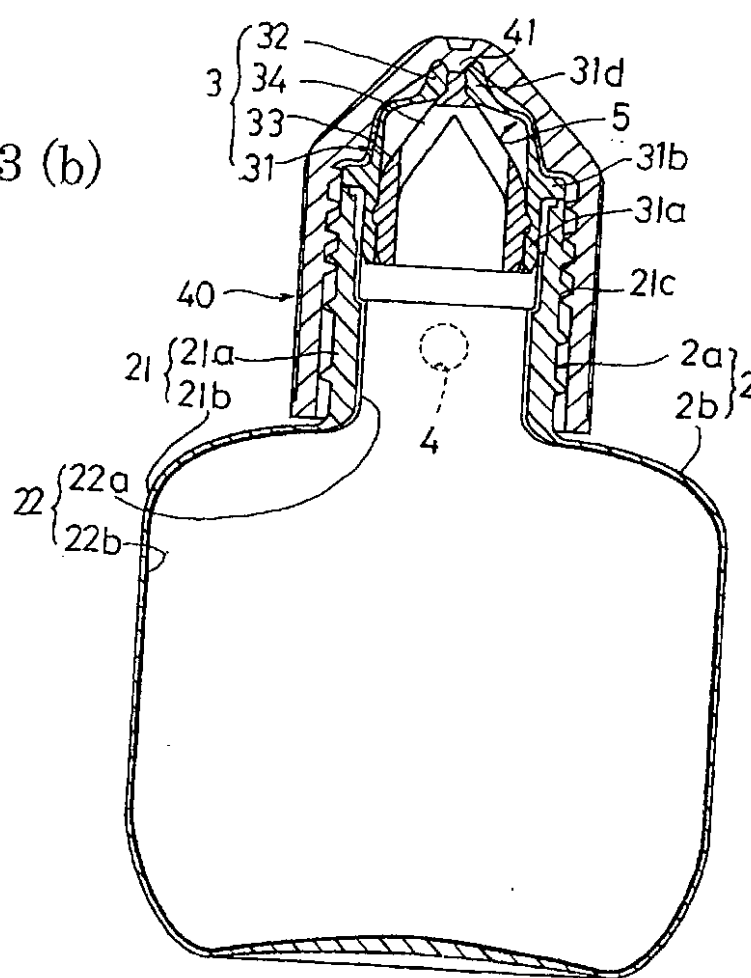


Fig. 4

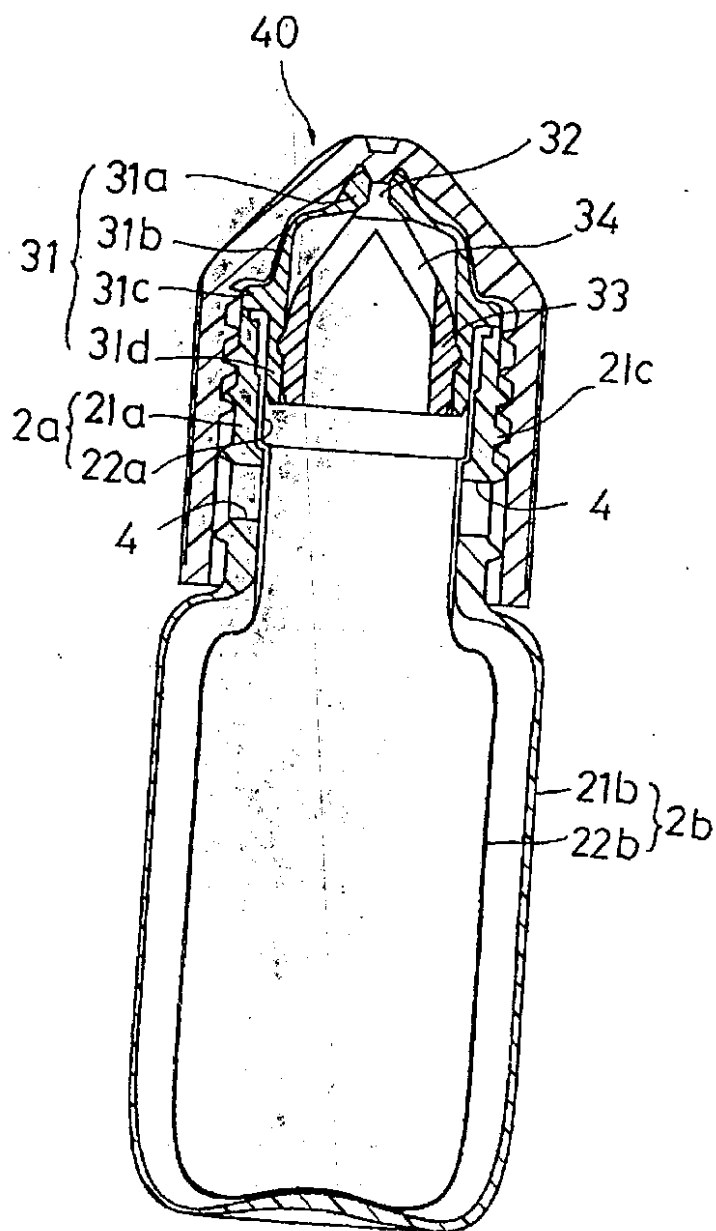


Fig.5 (a)

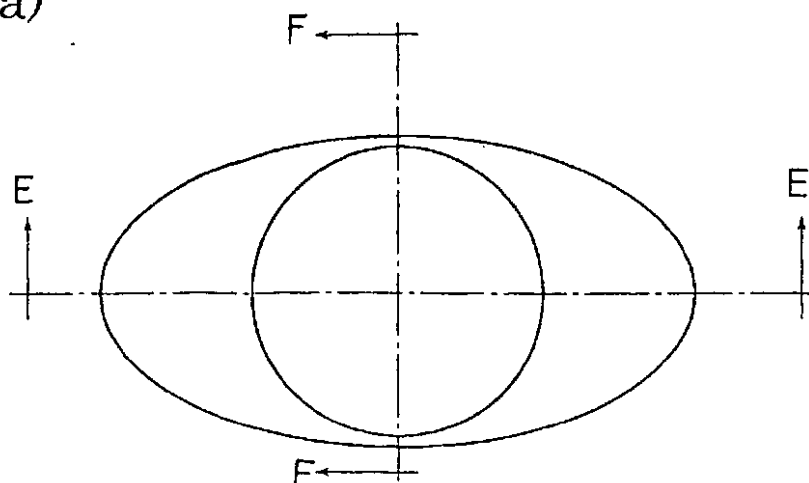


Fig.5 (b)

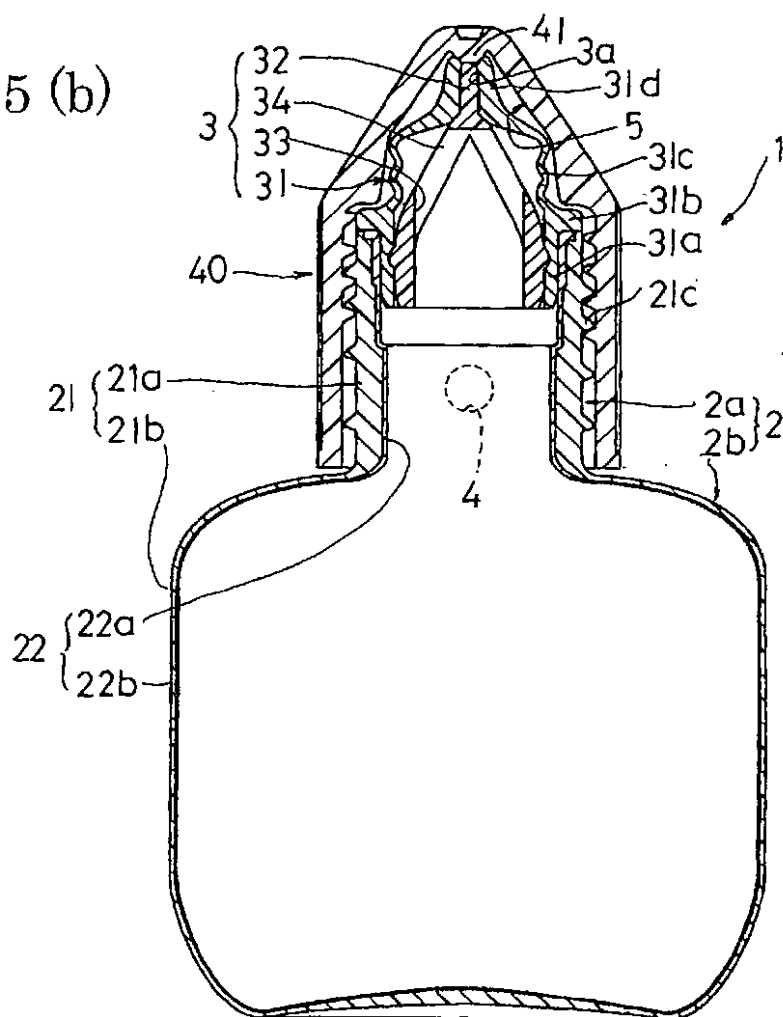


Fig.6

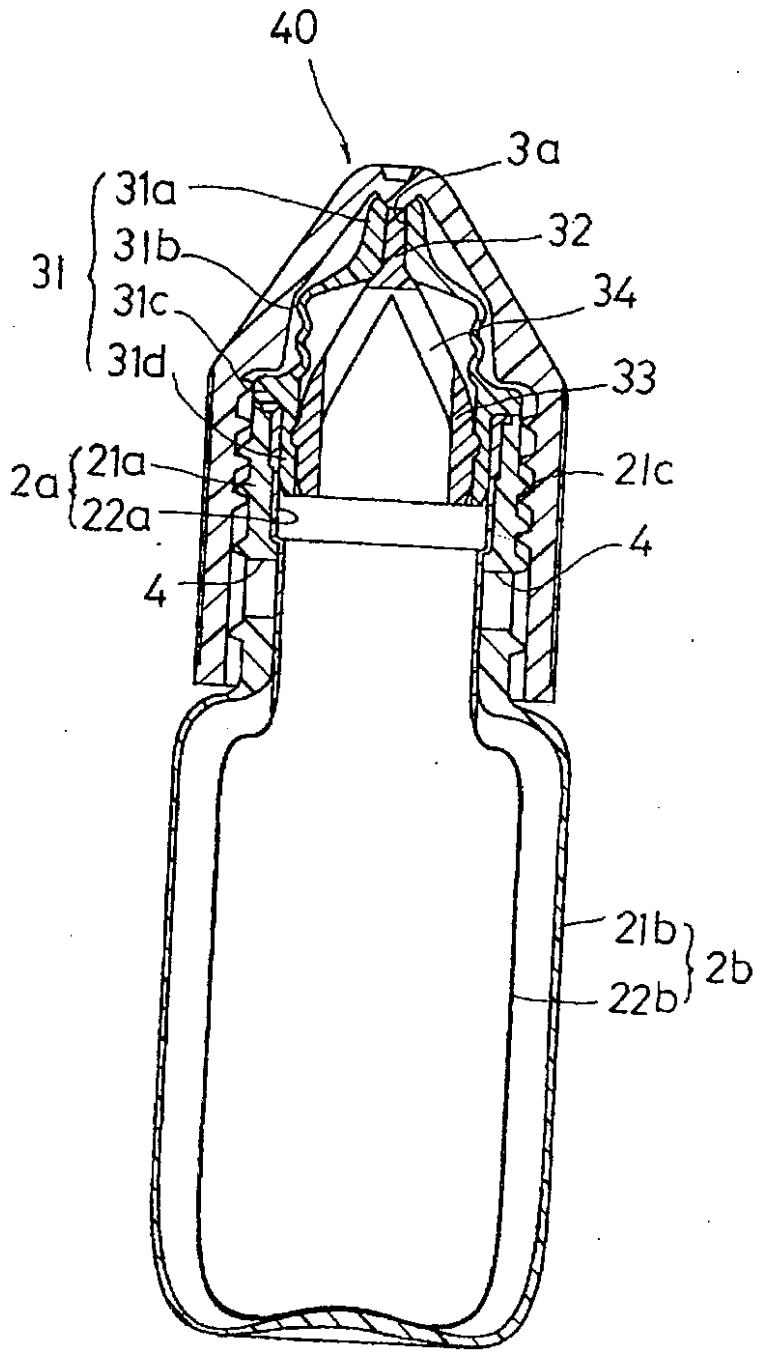
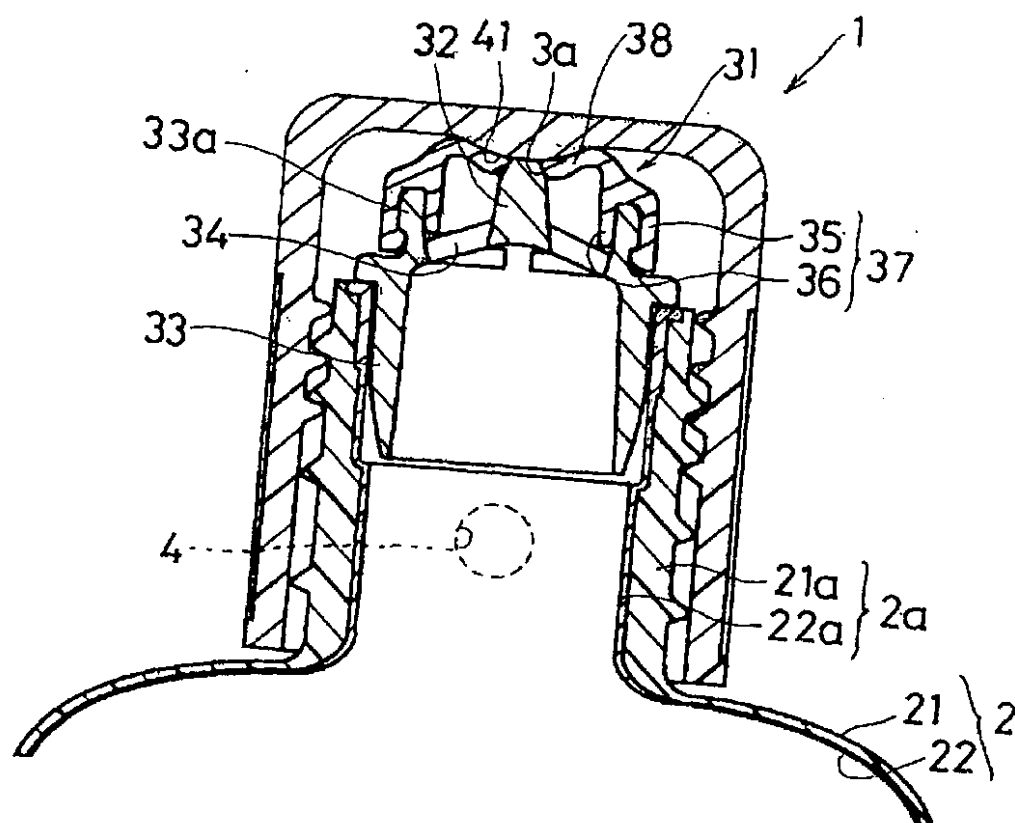


Fig. 7



## DISPENSING CONTAINER

## FIELD OF THE INVENTION

[0001] The present invention relates to a dispensing container adapted for packaging eye drops in aseptic condition, packaging some cosmetic liquids free of any preservatives, bactericides, antiseptics or the like pasteurizing agents, or packaging any other similar liquid products.

## BACKGROUND OF THE INVENTION

[0002] There are known some types of plug assemblies to be attached to the mouths of containers filled with any liquids. The known plug assemblies comprise each a dispensing valve that will remain closed so long as the internal pressure in the container is balanced with atmospheric pressure. Examples of such plug assemblies are disclosed in some Japanese Patent Laying-Open Gazettes No. 8-282704, No. 8-282703, or in the U.S. Pat. No. 5,213,236, No. 5,339,995 and No. 5,439,143.

[0003] Such conventional plug assemblies may preferably be used in certain dispensing containers for eye drops, liquid detergents or foods. Contents of these containers will surely be protected from leakage and allowed to smoothly exude when necessary.

[0004] Internal pressure will decrease as the content is discharged through the plug assembly, and will become lower than atmospheric pressure after every dosage. A dispensing valve incorporated in said plug assembly will thus open inwards to suck an amount of ambient air to cancel such a negative pressure. Since a variety of pathogenic microbes such as true fungi and viruses are present in the ambient air, certain preservatives have been added to those liquid contents so as to assure safe usage thereof.

[0005] However, as widely known in the art, preservatives have produced harmful side effects. It has been reported that eye drops with preservatives would cause inflammation or the like damage of the eyes, if used repeatedly. Contact lens-wearers sometimes suffer from allergic reactions even against some kinds of preservatives of a considerably low concentration. Hair detergents also contain such a preservative as causing inflammation of head skin and/or loss of hair. Further, many of recent consumers have in general a dislike to addition of preservatives to any products whatever.

[0006] Therefore, certain proposals were made to selectively remove only preservatives and other additives of no medical effects, from a liquid content flowing out of a bottle. According to one of those proposals, a filter for removing preservatives is disposed in a flow channel formed through an eyedropper, as disclosed in the Japanese Laying-Open Gazette No. 4-297264 or No. 6-14972. Such a known eyedropper will however fail to diminish concentration of preservatives in every dosage of eyedrops, if the preservatives are contained so rich in a fluid content as to enhance sterilization effect. Those known eyedroppers are designed to permit in-flow of ambient air contaminated with microbes, presuming the preservatives at a considerable concentration thereof to be sufficiently disinfectant. In such a case, concentration of the preservatives cannot necessarily be reduced well to avoid any residual amount of them from remaining in the drops of eyewash having flown through the filter.

[0007] Utility Model Laying-Open Gazette No. 63-184037 discloses a hydrophilic filter membrane disposed in a discharging channel. This membrane permits through-flow of eye drops liquid from a container body but prevents inward permeation of bacteria and air. A distal end portion of the container body is of a depressed tubular or otherwise foldable shape so that effective volume of said body will reduce in response to decreased quantity of the eyewash remaining therein. In the eyedropper of this type, ambient air is shut out in order to prevent bacteria from entry to the container during use thereof. Concentration of preservatives can thus be rendered as low as possible in the fluid medicine. However, the container body is of such a single-layer structure as enabling its plastic deformation. It is difficult for any known plastic materials to form this container body, and therefore a certain proper aluminum tube must be used to make it, failing to afford transparency of the container. Such a depressed container cannot stand itself and will not be convenient for succeeding uses thereof.

[0008] Japanese Patent Laying-Open Gazettes No. 9-175566 and No. 10-165222 disclose a dispensing container that comprises a delaminating bottle having a mouth to which a plug assembly is attached. This bottle is composed of an outer cylindrical layer and an inner layer laminated thereon to be capable of reversibly peeling from the outer layer. The interior of inner layer will function as a reservoir for a liquid content, and the outer layer has a vent formed therein to suck ambient air. A channel or passage is formed through the plug assembly for exuding a liquid content stored in the reservoir. A check valve disposed in the flow passage will inhibit back-flow of the content accompanied by ambient air into the reservoir. But, the ambient air is sucked sideways through the vent to flow in between the layers, with the inner layer consequently shrinking as the liquid content is gradually forced out and dispensed. A major portion of a liquid content staying in the reservoir will be kept unspoiled with bacteria or the like, without aid of any amount of preservatives. However, a small quantity of liquid content will inevitably remain between the check valve and a dispensing outermost opening. Such a residual amount of liquid content will be contaminated with true fungi and/or viruses, in the course of time and before the next use.

## SUMMARY OF THE INVENTION

[0009] An object of the present invention made in view of the drawbacks inherent in the prior art structures is therefore to provide an improved dispensing container that comprises a delaminating bottle having a mouth to which a plug assembly is attached. The plug assembly in the present invention has to comprise a valvular nozzle mechanism that has an outlet opening formed therein to afford a sealing interruption between ambient air and a liquid content stored in the delaminating bottle, during non-operation thereof. Residual quantity of a liquid content remaining downstream of the outlet opening after every use of this container should be diminished herein to avoid the dispensing of a fresh dose contaminated with polluted residue.

[0010] A dispensing container of the present invention comprises a bottle, an interior bag of the bottle and a plug assembly. The bottle may comprise a barrel and a mouth. The bag may be containable a liquid content. The bag may be placed in the barrel of the bottle. The plug assembly may be disposed in the mouth of said bottle. The outlet opening

may be connected to the mouth of said bottle. Preferably, an open end of the outlet opening may be closely connected all around to an open end of the mouth of the bottle. The interior bag is capable of deflating as its liquid content decreases in volume. The outlet opening may be adhered all around to an inner periphery of the mouth to thereby inhibit deformation of the adhered portion of the interior bag.

[0011] The bottle may have at least one vent for intake of ambient air in between the bottle and the interior bag. A plurality of such vents may either be formed in place of the mouth. The vent may be formed in a sidewall of the barrel or a bottom of the bottle. A check valve may be disposed in each of vents. Alternatively, check valves may not be built in said vents to render same normally open, thereby causing users to close those vents with their fingers when using this container.

[0012] The plug assembly may comprise a flexible nozzle having an outlet hole for dispensing the liquid content out of the bottle, and a closer capable of closing the outlet hole. The closer may be fixed in the mouth of the bottle, and the nozzle may be capable of elastic deformation away from a normal position such that the outlet hole is displaced outwards relative to the closer in response to a pressure raised in the bag and disengage from the closer.

[0013] In operation, the users may let the flexible nozzle face downwards and depress the exterior bottle to directly compress the interior bag filled with a liquid content, or otherwise compress the air intervening between said bottle and the bag that has then shrunk itself more or less. The internal pressure thus raised in the interior bag will cause the flexible nozzle to elastically deform itself so that its outlet hole moves outwards relative to the closer until disengagement therefrom. As a result, the outlet hole of the nozzle in liquid communication with the interior bag will open to dispense the liquid content out of this bag. Once the user ceases to depress the exterior bottle, it will instantly start to restore its normal shape due to elasticity. Thus, the vents will allow an amount of ambient air to enter a cavity between the bag and bottle, with the flexible nozzle simultaneously moving towards its normal position so that its outlet hole consequently creeps back inwards to be tightly closed again with the closer. It will now be apparent that the interior bag shrinks gradually and more or less whenever the user dispenses its liquid content to any desired target objects. Also importantly, the flexible nozzle cooperates at the same time with the closer to function like a check valve, lest any amount of ambient air should flow into the interior bag. Any preservatives need no longer be added to the liquid content stored in this interior bag. The vents permit introduction of a neat amount of ambient air into the annular cavity between the interior bag and the exterior bottle, normally keeping air pressure at atmospheric level around said bag. Thanks to this feature, the exterior bottle temporarily depressed for dispensation of liquid content will readily and smoothly regain its natural form, and this form will be maintained until complete exhaustion of said liquid content.

[0014] In the dispensing container of the invention, the closer may be a generally rod-shaped valve body, viz., 'needle' (as in usual needle valves) of a 'given length' inserted in the outlet hole so as to normally close it. The inner peripheral surface of the flexible nozzle is designed to temporarily produce a negative pressure in interior bag.

Such a negative pressure appearing in this bag will act on the nozzle to be retracted inwardly towards the container's bottom. An inner region of interface present between the nozzle inner surface and the needle periphery stands always in fluid communication with the interior of the bag. Air-tightness and liquid-tightness are never broken between the nozzle and the closer, even if the nozzle's outlet hole closed with the needle (as the closer) might occasionally be displaced along it within a certain range. Thus, neither any inadvertent inflow of ambient air into, nor any inadvertent effluence of liquid content out of, the interior bag is likely to take place. The flexible nozzle moving, after one dispensing operation, towards its normal position to retract its outlet hole may possibly encounter a frictional resistance or the like caused by the needle or any other happening. Even in such an event, the flexible nozzle having the smooth inner periphery will be retained at an inner position where its outlet hole remains closed with the needle (i.e., rod-shaped valve body), by virtue of a negative pressure produced in the interior bag. This motion will be effected in unison with the inflow of ambient air through the vents. Internal pressure of the bag may unintentionally rise within a considerable range due to raised temperatures or due to vibration or shock when carrying the container. Such an inadvertently raised internal pressure will however be cancelled by the flexible nozzle's outward displacement relative to the needle but not beyond the 'given length' thereof (noted hereinbefore). Thus, the outlet hole remains closed not to cause any undesirable discharge of liquid content during storage or handling of the container.

[0015] The flexible nozzle may be made of any pliable and elastic material such as rubbers. It is not necessary for the nozzle to be flexible in its entirety, but it may have an elastically deforming thinned portion. Consequently, a thicker base of the flexible nozzle may be formed as a cylindrical part fitting in the exterior bottle's mouth. A sleeve may be disposed in such a base within the bottle mouth so that this portion is strongly and firmly gripped by and between the sleeve and the mouth inner periphery. Air-tightness and liquid-tightness all around the base of flexible nozzle are thus enhanced. Typically, the closer formed as the rod-shaped valve body (viz., needle) may be formed integral with such a sleeve. In this case, simple installment of the sleeve suffices well to fix both the cooperating flexible nozzle and closer in place, thus simplifying structure and reducing the number of component parts is carried out.

[0016] The plug assembly may comprise a sleeve made integral with the closer and fitted in the mouth of the bottle, the nozzle formed of a pliable and elastic material such as a rubber has a cylindrical base, and the base surrounds the closer and is in an airtight and liquid-tight contact with the sleeve. In this case, further simplifying structure and simplification of assembly process is carried out.

[0017] Additionally, a cap may be employed in combination with the already discussed parts of the dispensing container. The cap detachably mounted on the mouth of exterior bottle will cover an exterior surface of the flexible nozzle. The cap may have an inner periphery adjacent to top of the cap, wherein the periphery is substantially in conformity with upper end regions which the nozzle and the closer define in state what the cap is mounted on the mouth and the cap in the mounted state does closely contact end faces of

the upper end regions. After every use of this dispensing container, the cap will be attached thereto so as to press inwards the outwards-facing end of an opening defining the outlet hole in said flexible nozzle. Any residual amount of liquid content remaining on such an outlet hole end will thus be forced off this hole, so as not give rise to the problem of contamination of said residual liquid. Preferably and typically, the flexible nozzle has a (bill-shaped) cylindrical nozzle portion protruding outwards and longitudinally of the container, with a bore of this cylindrical portion serving as the outlet hole. Also in this case, the cap has an upper portion whose inner periphery coincides with and closely contacts all around the bill-shaped nozzle portion. Any residual amount of liquid content adhering to outlet hole will be pushed down away from this hole's end towards a lower end of the bill-shaped portion. Preferably, the end of nozzle's outlet hole may be formed in flush with the upper end of closer, and the cap has at its top an inner surface in a plane contact with both the outlet hole's end and the closer's upper end. In this case, a residual amount of liquid content adhering to outlet hole can more surely be forced off the opening end of said outlet hole.

[0018] Also preferably, the barrel of exterior bottle is capable of elastic deformation to reversibly reduce its volume. Compression of the interior bag will be caused by such an exterior bottle to exude the liquid content through the flexible nozzle outlet hole at its elastically deformed position. When the barrel subsequently regains its normal shape, the flexible nozzle returns to its normal position and the ambient air sucked through the vents flows in between the bottle and bag.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0019] FIG. 1(a) is a plan view of a dispensing container provided in a first embodiment of the present invention;

[0020] FIG. 1(b) is a cross section taken along the line A-A in FIG. 1(a);

[0021] FIG. 2 is a cross section taken along the line B-B in FIG. 1(a);

[0022] FIG. 3(a) is a plan view of a dispensing container provided in a second embodiment;

[0023] FIG. 3(b) is a cross section taken along the line C-C in FIG. 3(a);

[0024] FIG. 4 is a cross section taken along the line D-D in FIG. 3(a);

[0025] FIG. 5(a) is a plan view of a dispensing container provided in a third embodiment;

[0026] FIG. 5(b) is a cross section taken along the line E-E in FIG. 5(a);

[0027] FIG. 6 is a cross section taken along the line F-F in FIG. 5(a); and

[0028] FIG. 7 is an enlarged, fragmentary and vertical cross section of a dispensing container provided in a fourth embodiment.

#### THE PREFERRED EMBODIMENTS

[0029] The dispensing container of the present invention may be manufactured by previously forming an exterior

bottle and an interior bag, and then fixing the latter in the former. However, it is more preferable that the present container is composed mainly of a delaminating bottle whose inner layer as the interior bag is laminated on an outer layer serving as the exterior bottle.

[0030] Also preferably installed in each of vents is a check valve that will permit inflow of ambient air into a clearance between the exterior bottle and interior bag. The check valve inhibits outflow of the ambient air having entered the clearance. Thanks to such a check valve, the ambient air in this clearance or gap will be compressed by squeezing the exterior bottle, to thereby raise air pressure therein. As a result, an amount of liquid content corresponding to the degree of compression of interior bag will flow out through a discharging channel or passage. If no check valves are used, then a user of this container need to close the vents when he or she squeezes the exterior bottle.

[0031] The laminated delaminating bottle may be molded to have a mouth and a barrel continuing thereto. Any proper method such as the injection-blow molding, the direct blow molding or the injection molding method can be employed for this purpose. An inner layer preform and an outer layer preform may be produced previously and discretely so that the former is inserted in the latter to prepare a laminated parison. In this case, the parison will be subjected to the blow molding process to give a container of any desired shape. The resulting container will be of a laminated structure such that both the inner and outer layers extend from top to bottom of said container. A laminated mouth will thus continue from a similarly laminated barrel. In an alternative mode, a previously molded film-like interior bag is placed in a raw exterior bottle having the mouth and barrel, before subjected to a similar finishing process.

[0032] The mouth is rendered higher in rigidity, by thickening both the exterior bottle and interior bag at this region. On the other hand in the barrel portion, the exterior bottle (viz., outer layer) should be made capable of squeezing and elastic recovery. The interior bag (viz., inner layer) has to readily shrink, like usual films, following decrease in volume of the liquid content. Each of exterior bottle and interior bag may either be of a single-layer or of a multi-layer structure.

[0033] The interior bag can be formed of any plastics such as a polyethylene (PE), a polypropylene (PP) or any other polyolefin. The exterior bottle can be molded using the other type of plastics such as saturated polyesters including a polyethylene terephthalate (PET) and a polyethylene naphthalate (PEN). In case of using the container as an eyedropper, it is compulsory that a proper raw material is selected to forming each of these exterior bottle and interior bag to render the container transparent and non-permeable to water. Because the interior bag directly contacts pharmaceutical contents, it must be made from a certain plastics (for example a PE) highly resistant to chemicals. In contrast, higher transparency and lower water permeation are properties desirable for the plastics as the material (e.g., a PET or a soft glass) of exterior bottle.

[0034] The vents may be formed either in the mouth, in the barrel or in a bottom portion of the exterior bottle. The check valve preferably disposed in each vent can be of any proper structure. For example, the exterior bottle may have in each vent a plug-shaped valve. Alternatively, the interior bag

portions facing the vents may serve themselves as check valves for temporarily closing same from inside. A negative pressure produced in between the exterior bottle and interior bag will push such bag portions inwardly to open those vents. It is preferable that those portions of interior bag return to normal position to tightly close said vents again. Alternatively, the vents may be formed in the bottle mouth and reversibly closed with corresponding areas of a thickened mouth portion (viz., outlet opening) of interior bag. Shrinkage of the bag's barrel region in response to progressive decrease in volume of the liquid content will not be hindered in this case, too.

[0035] In still another fashion employable herein, such check valves are dispensed with by rendering the diameter of each vent in the exterior bottle much smaller than that of a discharging channel formed through the interior bag. In this case, the exterior bottle can be squeezed to compress the air intervening between it and the interior bag, thereby depressing the latter to batch-wise exude (and drop) the liquid content through its discharging channel. In detail, each vent is made as a small orifice having a diameter for instance of about 0.1 mm to 0.5 mm. A compression rate of squeezing the exterior bottle in this case is rendered higher than an exhaustion rate at which the intervening air will be forced out through the vents. Therefore, said intervening air is compressed to centripetally depress the interior bag to shrink and thereby discharge the liquid content through the channel formed in the plug assembly. Effective cross-sectional area of this discharging channel is made so larger than those of vents that the flow resistance against the liquid content being exuded is much lower than that which will be imparted to the air being exhausted.

[0036] The invention can be practiced to provide not only the eyedropper or the like pharmaceutical dispenser, but also and alternatively a cosmetics container, a detergent container, or any other appropriate one. As already discussed above, the container may substantially consist of a delaminating bottle composed of an exterior bottle and an interior bag. A flexible nozzle is fixed in the mouth of such a delaminating bottle, and further a cap may detachably be attached to the mouth so as to cover the nozzle and closely contact the opening end of an outlet hole formed in and through said nozzle.

[0037] The flexible nozzle may either be constructed as an integral one-piece or be composed of two or more parts combined with each other. The nozzle may be fitted in or on the bottle mouth, wherein a small-diameter cylindrical portion is formed as one principal part of this nozzle. Such a nozzle portion protrudes upwards, with the bore thereof serving as a discharging channel. Desirably, the flexible nozzle may have a cylindrical base fitted in the bottle mouth, in addition to the upwardly protruding small-diameter portion and an intermediate portion continuing from those two former portions and functioning as an elastic deformation region. The outlet hole is subject to inward and outward displacement as a result of axial movement of the intermediate portion. This intermediate portion can be bellows-shaped, dome-shaped or be of any other proper shape.

[0038] Now, the best modes of carrying out the present invention will be described referring to the drawings.

[0039] FIGS. 1(a), 1(b) and 2 show an eyedropper 1 as the dispensing container provided in a first embodiment. One of

principal parts of this eyedropper 1 is a laminated bottle 2 capable of exfoliation and comprising a mouth 2a and a barrel 2b. A plug assembly 3 having an outlet hole 3a formed therethrough is secured to the mouth 2a, together with a cap 40. The outlet hole 3a normally remains closed, but can be opened if a user removes the cap 40 and then puts the container 1 upside down to subsequently squeeze the barrel 2b. When the user operates the container in this way, eye drops (viz., drops of a liquid content) retained in the bottle 2 will be dispensed (in a dripping manner) through the outlet hole 3a of plug assembly 3. Once he or she stops depressing the barrel 2b, this hole 3a will be closed again.

[0040] The delaminating bottle 2 consists of an exterior bottle 21 as the outer layer and an interior bag 22 as the inner layer laminated on the former layer. Since the main part of dispensing container in this embodiment is such a laminated bottle, the exterior bottle (or bottle body) will hereinafter be simply referred to as an 'outer layer', with the interior bag being referred to as an 'inner layer'. However, it will be understood that any other containers whose bottle body and interior bag are not laminated one on another but merely adjoined to each other are also included in the scope of present invention.

[0041] Both the outer and inner layers 21 and 22 have their cylindrical mouth portions 21a and 22a in addition to their barrel portions 21b and 22b elliptic in transverse cross section. In other words, the mouth 2a consists of these mouth portions 21a and 22a, with the barrel 2b consisting of these barrel portions 21b and 22b. The outer layer 21 is made of a relatively harder plastics such as a PET or an EVOH, whilst the inner layer 22 is made of a typically softer plastics (for example a polyolefin such as PE) ready to be delaminated from the outer layer. The outer layer barrel portion 21b is capable of elastic squeezing when depressed in the direction of its minor axis, with the inner layer mouth portion 22a defining an outlet opening in the interior bag.

[0042] The upper end of the inner layer mouth portion 22a is firmly secured to that of the outer layer mouth portion 21a. Inner periphery of the latter portion 21a may be knurled in axial direction to have longitudinal grooves and ridges at angular intervals. In this case, the inner layer mouth portion 22a is protected from any inadvertent rotation relative to the outer layer mouth portion 21a.

[0043] For introduction of ambient air into a clearance or gap between the outer and inner layer barrel portions 21b and 22b, at least one vent(s) 4 is(are) formed in the outer layer mouth portion 21a. Two such vents in the present embodiment face one another in diametrical direction. Each vent 4 penetrates only the outer layer 21 transversely, not to injure the inner layer 22. Formed on and around the outer periphery of outer layer mouth portion 21a is a screw thread 21c.

[0044] The inner layer barrel portion 22b is a film-like part and is therefore ready to shrink as the volume of liquid content decreases during use of this container. The mouth portion 22a of inner layer made noticeably thicker than its barrel portion 22b can restore its really cylindrical configuration at every cycle of operation of this container. Although the inner layer barrel portion 22b may not be seen clearly in the drawings due to its extreme small thickness, the inner periphery of outer barrel portion 21b is laminated on and fully covered with such a thin inner barrel portion.

[0045] The inner mouth portion 22a is normally at its position to close from inside the vents 4 in outer mouth portion 21a. Thus, the inner portion 22a works as closing members for the respective vents 4 in one of its states. However, said inner portion will serve on the other hand as a check valve, because atmospheric pressure urges it to open those intakes when a negative pressure arises in between the barrel portions 21b and 22b.

[0046] Though not shown in the drawings, the inner layer's 22 bottom may have at its center a latching member formed integral therewith. This member is firmly engaged with the bottom center of outer layer 21 to thereby protect the inner layer from curling upwards.

[0047] The plug assembly 3 comprises a generally cylindrical flexible nozzle 31 having the outlet hole 3a to be closed with a rod-shaped valve body (as a closer) 32. A cylindrical sleeve 33 possessed by the plug assembly 3 functions to secure both the nozzle 31 and valve body 32 to the bottle mouth. Connection ribs 34 are formed integral with both the sleeve 33 and valve body 32. These three parts 32, 33 and 34 constitute a one-piece integral body made of a suitable plastics. The short rod-shaped closer 32 extending coaxially with the bottle mouth 2a is disposed out of the opened end of this mouth.

[0048] The flexible nozzle 31 has a cylindrical base 31a fitted in the bottle mouth 2a, and a flange 31b in contact with the upper end of mouth 2a. The nozzle further has a bellows-shaped intermediate portion 31c and a nozzle portion 31d continuing therefrom longitudinally and outwardly of the bottle. The bellows-shaped portion 31c ready to elastic deformation does continue from the base 31a longitudinally in outward ('upward' in the drawings) direction of the bottle. Such a nozzle 31 is a one-piece made of a flexible material such as a silicone rubber. The flexible nozzle 31 has an axis in parallel with the axis of bottle mouth 2a, and in the illustrated example, the nozzle portion 31d lies coaxial with said mouth 2a. The outlet hole 3a mentioned above is a bore of nozzle portion 31d, and receives the rod-shaped valve body (as the closer) 32 inserted in this hole to serve as a closing member. So long as the outlet hole 3a remains closed, its open end stands in flush with the upper end of valve body 32. Due to this feature, an overall outer and upper configuration of the flexible nozzle 31 and valve body 32 closing it and retained therein does coincide with and closely contact the inner and upper periphery of the cap 40. The sleeve 33 disposed inside and all around the flexible nozzle's base 31a presses it outwards in a centrifugal direction to the inner periphery of bottle mouth 2a, whereby air-tightness and liquid-tightness are ensured between the base 31a and bottle mouth 2a firmly adjoined thereto.

[0049] The elastically deforming intermediate zone 31c of flexible nozzle 31 is made considerably thinner than all of the remaining portions thereof, that is the base 31a, flange 31b and nozzle portion 31d. Such a thinned and bellows-shaped zone 31c is prone to make an elastic elongation in axial direction. This motion will bring about outward displacement of the outlet hole 3a a distance enough to disengage from the rod-shaped valve body or closer 32. With the intermediate zone 31c simultaneously moving in axial direction towards its inner home position, the outlet hole 3a will restore its inner normal position so as to be closed again with the closer 32.

[0050] Such an elastic deformation and displacement of the portions of flexible nozzle 31 occurs as the internal pressure of the inner layer 22 rises by operation of this container. In detail, the inner layer's pressure raised above atmospheric pressure will act on a pressure-receiving area 5. This area facing downwards and formed as an upper and inner peripheral area of the elastically deforming intermediate portion 31c will consequently force the nozzle portion 31d outwards away from the barrel. A negative pressure produced in the inner layer 22 during introduction of ambient air through the intakes 4 will pull back the pressure-receiving area 5, returning the nozzle portion 31d to its inner (lower) position, thus letting the flexible nozzle 31 as a whole recover its normal configuration. As will now be apparent, the pressure-receiving area 5 is always in a fluid communication with the interior of inner layer 22 and thus exposed to the internal pressure thereof, whether the outlet hole 3a is opened or closed. Elastic forward deformation of flexible nozzle 31 will thus move the outlet hole 3a outwardly along the rod-shaped closer 32 towards or beyond a distal end thereof, when this hole is opened. Reverse deformation of said nozzle will likewise displace the outlet hole 3a but towards a proximal end of said closer, when this hole is closed.

[0051] The cap 40 is releasably screwed on the outer periphery of the outer layer mouth portion 21a. During non-use of this container 1, the cap will continue to seal the outer periphery of flexible nozzle 31 in order to protect it from dusts and bacteria. Inner shape of the cap 40 is analogous with the outer contour of nozzle 31 in its non-deformed state. The inner top surface of this cap lies in a plane including both the distal ends of nozzle portion 31d and rod-shaped closer 32. This means that, after use of the container, the cap 40 will and can be put on it to drive backwards the nozzle portion 31d along the closer until the outlet hole 3a is perfectly closed with the closer 32. The cap 40 tightly mounted in this manner will force a backward motion of nozzle portion 31d, effectively repelling any residual amount of liquid content around the forward end of outlet hole 3a. Any noticeable amount of residue of eye drops will not be left around and outside the outlet hole, thus protecting a fresh dose of the liquid content from contamination when using later the container again.

[0052] When the user wants to exude and dispense eye drops through the outlet hole 3a of eyedropper 1 of the present embodiment, he or she has to remove at first the cap 40 and then cause the bottle 2 to take a position reversed upside-down. Subsequently, he or she depresses the barrel 2b in a centripetal direction along its minor axis. Internal pressure of the inner layer 22 will be raised in this way to elastically deform the flexible nozzle 31 and open the outlet hole, supplying 'eye drops' from the distal tip of nozzle portion 31d. If and when the user simply ceases to depress the delaminating bottle 2, the outer layer will almost instantly restore its normal shape. However, any amount of ambient air will not flow into the inner layer 22 through the outlet hole 3a, because this hole 3a is then in a closed state due to elastic recovery of natural shape of the flexible nozzle 31. The inner layer does not restore its normal un-shrunk shape, even if the liquid content is consumed further and later when demanded. In contrast, the outer layer 21 will be allowed to take its normal shape again, giving rise to a certain degree of negative pressure between the outer and inner layer barrel portions 21b and 22b. Consequently,

atmospheric pressure deforms in a centripetal direction the inner layer mouth portion's 22a area facing the vents 4, thereby opening them in outer layer 21 so as to permit inflow of a certain amount of ambient air through said intakes. It is to be noted here that the negative pressure still remains within the interior bag 22 for a time. Such a remaining negative pressure will act on the pressure-receiving area 5, to thereby cause the flexible nozzle to restore its natural shape until it perfectly closes the outlet hole 3a. As a sufficient amount of ambient air sucked inwards through the vents 4 permits recovery of natural shape of the outer layer barrel portion 21b, the inner layer mouth portion 22a will spontaneously regain its home position. Any extent of temporary deformation will not be left in this mouth portion 22a, but it surely closes the vents 4.

[0053] Later, the user may operate again this container by depressing its bottle 2, whose inner layer mouth portion 22a has been and is still closing the vents 4. The air retained in the gap between the outer and inner layer barrel portions 21b and 22b can not escape out by such a resumed operation, but will be compressed by depressing the outer barrel portion 21b. The air thus compressed again within the outer barrel will work to squeeze the inner barrel portion 22b and dispense the eye drops in the exuding manner as detailed above.

[0054] It will now be apparent that the dispensing container of the described embodiment has a flexible nozzle 31 and a rod-shaped valve body (viz., closer) cooperating therewith as if they were component parts of a check valve. Ambient air is excluded from the interior of inner layer 22, and therefore it will shrink to protect the liquid content from contamination with bacteria that are possibly present in the ambient air. On the other hand, the vents 4 enable ambient air to flow in between the outer and inner layers 21 and 22. Depression of the outer layer 21 will not produce any permanent deformation thereof after this layer is released from the user's fingers or the like means having been squeezing it. Elastic recovery of the outer layer 21 is ensured so that its natural shape can last until the liquid content is thoroughly consumed to empty the inner layer 22. Thus, this dispensing container 1 will continue to stand unchanged in appearance from outside after every cycle of operation from start to end of use, highly convenient to users. The liquid content of inner layer 22 is shut from ambient air so that any preservatives for sterilization need no longer be added to the content. Any appropriate materials may be used to form the inner and outer layers, taking into account requirements which they have to meet in respect of transparency, gas barrier property and water permeation. This dispensing container affords optimal features widely in many uses, for example as an eyedropper, a detergent container or the like.

[0055] FIGS. 3(a) to 4 show a dispensing container 1 provided in a second embodiment. Its structural elements that are the same as or similar to those described above in the first embodiment will not be discussed again, but merely be denoted with the same reference numerals. Only elements and functions peculiar to the second embodiment will be described below.

[0056] The flexible nozzle 31 comprises, for the purpose of its elastic deformation, an intermediate portion 31c that is dome-shaped. This elastic intermediate portion can be stretched forwards in order to bring the outlet hole 3a into

its position disengaged from the rod-shaped closer 32. A recess will appear ahead the distal end face of the closer 32 and in the forward end region of outlet hole 3a. A little residual amount of liquid content will stay in this recess, unless the cap 40 has a portion fitting in it. Therefore, a lug 41 protruding downwards is formed in this embodiment to be integral with the cap at its center of ceiling. With such a cap 40 being put on the bottle mouth, the lug 41 will completely repel the residue out of said recess so as to avoid the problem of contamination.

[0057] FIGS. 5(a) to 6 show still another dispensing container 1 in a third embodiment of the present invention. Its nozzle portion 31d rendered thicker than that in the first embodiment has an improved dimensional stability. The outlet hole 3a has a noticeably reduced diameter, and correspondingly, the rod-shaped closer 32 in this container is much thinner and more elongated. Other structural elements not differing from those in the first and second embodiments are denoted with the same reference numerals, and description thereof is not repeated.

[0058] FIG. 7 illustrates a dispensing container 1 provided in a fourth embodiment. Also, its structural elements that are the same as or similar to those in the first embodiment are merely denoted with the same reference numerals. Only details of other elements peculiar to the fourth embodiment will be given here.

[0059] The flexible nozzle 31 in this container 1 is composed of two portions, that is a cylindrical base 37 and an elastically deforming portion 38 made integral therewith and arc-shaped in vertical cross section. The base or base 37 is formed as a kind of double cylinder whose outer and large-diameter section 35 extends coaxial with and surrounds an inner and small-diameter section 36. The deforming portion 38 continuing from the top end of said base 37 may be regarded as a complex of the nozzle portion 31d and intermediate portion 31c integral therewith in the preceding embodiments. Such a flexible nozzle 31 fixed on the upwardly protruding top end 33a of a sleeve 33 is not directly attached to the bottle mouth 2a but indirectly connected thereto by the sleeve 33 in this embodiment. An outlet hole 3a is a central round opening of the elastically deforming portion 38. This portion 38 normally takes a convex position bulging inwardly of the bottle as shown in FIG. 7, so that its outlet hole 3a remains closed with the closer 32. When pressure in the bottle rises, the deforming portion's inner face (viz., lower face in the drawings and serving as if it were a pressure-receiving area 5 in the former embodiments) will be pressed up to deform itself elastically to take a reversed convex shape facing outwards. In this state, the outlet hole 3a is raised and displaced away from the closer 32 so as to open. On the other hand, the rod-shaped closer 32 in this embodiment gradually increases its diameter towards its basal 'lower' end. When any degree of negative pressure is produced inside the bottle, the central region of elastically deforming portion 38 then at its position shown in FIG. 7 will slide down ('inwards') along the closer. However, the outlet hole 3a will remain sealed with the closer 32 not to undesirably and inadvertently open to any extent.

[0060] The large- and small-diameter sections 35 and 36 of the nozzle base 37 firmly grip and sandwich the upwardly protruding end 33a of the sleeve 33, from outside and inside.

Thus, an airtight and liquid-tight connection is provided between these members connected to each other.

[0061] The present invention is not delimited to the foregoing embodiments or examples but may be modified within the spirit and scope set forth in the appendant claims.

[0062] In summary, the present container is of a relatively simple structure, but can nevertheless dispense a liquid pharmaceutical content or the like, without permitting any inflow of ambient air into the interior bag. None of ordinary bacteria often present in the environment will grow within this bag, even if preservatives are not added at all to the liquid content. Once internal pressure of the bag returns to atmospheric pressure, the flexible nozzle temporarily deformed to have its outlet hole displaced up away from the container body will regain its normal position. In other words, the outlet hole moves inwardly towards the container body until closed again with the closer. With the outlet hole being closed in this manner, the amount of liquid content that has been dispensed through the outlet hole would have dropped off the nozzle almost in its entirety. Thus, any notice-able residual amount of the liquid once dispensed will not stay outside and around said hole, causing no problem of contamination of such a residue.

1. A dispensing container comprising a bottle, an interior bag of the bottle and a plug assembly,

the bottle comprising a barrel and a mouth,

the bag being containable a liquid content,

the bag being placed in the barrel of the bottle,

the bag having an outlet opening for dispensing the liquid content,

the plug assembly being disposed in the mouth of said bottle,

the outlet opening being connected to the mouth of said bottle,

the bottle having at least one vent for intake of ambient air in between the bottle and the bag,

the plug assembly comprising a nozzle having an outlet hole for dispensing the liquid content out of the bottle, and a closer capable of closing the outlet hole,

the closer being fixed in the mouth of the bottle, and

the nozzle being capable of elastic deformation away from a normal position such that the outlet hole is displaced outwards relative to the closer in response to a pressure raised in the bag and disengage from the closer.

2. A dispensing container as defined in claim 1, wherein the closer is a rod-shaped member inserted in and closing the outlet hole, and the nozzle has an inner surface always in communication with an interior of the interior bag such that a negative pressure arising therein will force the flexible nozzle backwards toward the normal position.

3. A dispensing container as defined in claim 1, wherein the plug assembly further comprises a sleeve made integral with the closer, the nozzle is formed of a pliable and elastic material such as a rubber, the nozzle has a cylindrical base fitted in the mouth of the bottle, and the sleeve is placed inside the base so as to press the base all around to an inner

periphery of the mouth to thereby ensure an airtight and liquid-tight connection thereof with the nozzle.

4. A dispensing container as defined in claim 1, wherein the plug assembly further comprises a sleeve made integral with the closer and fitted in the mouth of the bottle, the nozzle formed of a pliable and elastic material such as a rubber has a cylindrical base, and the base surrounds the closer and is in an airtight and liquid-tight contact with the sleeve.

5. A dispensing container as defined in claim 1, further comprising a cap detachably mounted on the mouth of the bottle and having an inner periphery adjacent to top of the cap, wherein the periphery is substantially in conformity with upper end regions which the nozzle and the closer define in state what the cap is mounted on the mouth and the cap in the mounted state does closely contact end faces of the upper end regions.

6. A dispensing container as defined in claim 1, wherein the barrel of the bottle is capable of elastic deformation to reduce its internal volume and to thereby compress the interior bag and elastically deform the nozzle, whereby the nozzle outlet hole thus opened will permit the liquid content to exude out therethrough, and when the barrel returns to its un-deformed normal position causing the nozzle towards its normal closed position, the vents allow ambient air to flow in between the exterior bottle and the interior bag.

7. A dispensing container as defined in claim 1, wherein an open end of the outlet opening is closely connected all around to an open end of the mouth of the bottle.

8. A dispensing container as defined in claim 1, wherein the outlet opening is adhered all around to an inner periphery of the mouth to thereby inhibit deformation of the adhered portion of the interior bag.

9. A dispensing container as defined in claim 1, wherein the at least one vent is disposed in the mouth of the bottle.

10. A dispensing container as defined in claim 1, further comprising a check valve that allows inflow of the ambient air into a clearance between the exterior bottle and the interior bag, but prevents outflow of the ambient air having entered the clearance.

11. A dispensing container as defined in claim 1, wherein the closer is fixed in place relative to the mouth of the bottle.

12. A dispensing container as defined in claim 1, wherein the nozzle comprises a cylindrical base fitted in the mouth, a nozzle portion having a bore as the outlet hole, and an elastically deformable intermediate portion provided between the nozzle portion and the base in a connected row arrangement such that elastic deformation of the intermediate portion displaces the outlet hole outwardly of the container.

13. A dispensing container as defined in claim 12, wherein the elastically deformable intermediate portion is bellows-shaped.

14. A dispensing container as defined in claim 12, wherein the elastically deforming intermediate portion is dome-shaped.

15. A dispensing container as defined in claim 1, wherein the nozzle comprises a cylindrical base and an arc-shaped elastically deformable portion connected to an upper end of the base, the base being a double cylinder comprising a first cylindrical section and a second cylindrical section smaller than the first cylindrical section in diameter.

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United States Patent [19]  
Kanner et al.

[11] Patent Number: 5,431,310  
[45] Date of Patent: Jul. 11, 1995

[54] LIQUID DISPENSER NOZZLE ASSEMBLY

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[73] Assignee: Ryder International Corporation, Arab, Ala.

[21] Appl. No.: 245,043

[22] Filed: May 17, 1994

Related U.S. Application Data

[60] Continuation-in-part of Ser. No. 71,510, Jun. 2, 1993, Pat. No. 5,320,254, which is a division of Ser. No. 972,411, Nov. 5, 1992, Pat. No. 5,255,826, which is a division of Ser. No. 664,347, May 4, 1991, Pat. No. 5,183,184, which is a continuation-in-part of Ser. No. 406,053, Sep. 11, 1989, Pat. No. 5,025,957, which is a continuation-in-part of Ser. No. 255,365, Oct. 7, 1988, abandoned.

[51] Int. Cl.<sup>6</sup> B67D 5/58; B65D 37/00

[52] U.S. Cl. 222/212; 222/494

[58] Field of Search 222/212, 213, 189, 490, 222/494, 491, 492, 420, 421

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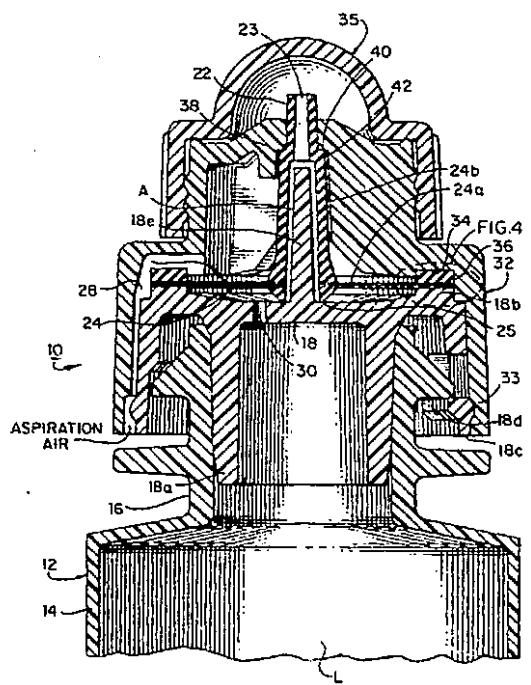
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Attorney, Agent, or Firm—Trexler, Bushnell, Giangiorgi & Blackstone, Ltd.

[57] ABSTRACT

A liquid dispensing nozzle assembly is provided for mounting on a liquid container and dispenser having a flexible wall and liquid storage cavity for manually squeezed dispensing of liquid from the cavity through the nozzle assembly. The nozzle assembly maintains the liquid, such as contact lens cleaning and conditioning solutions in sterile condition during storage and repeated dispensing of the liquid from the container cavity. The nozzle assembly includes a liquid conduit for communication from the container cavity to a liquid discharge port from the nozzle assembly to enable dispensing of the liquid displaced by manually squeezing the flexible wall of the container. The nozzle assembly also includes a sealing element for sealing the liquid conduit against liquid leakage in which the sealing element has a composition comprising polytetrafluoroethylene which can provide sealing engagement directly against a molded plastic surface of either a molded component of the nozzle assembly or the container-dispenser. The sealing element can be provided by a peripheral portion of a polytetrafluoroethylene flow control diaphragm to provide an integral, sealing ring thereon.

15 Claims, 4 Drawing Sheets



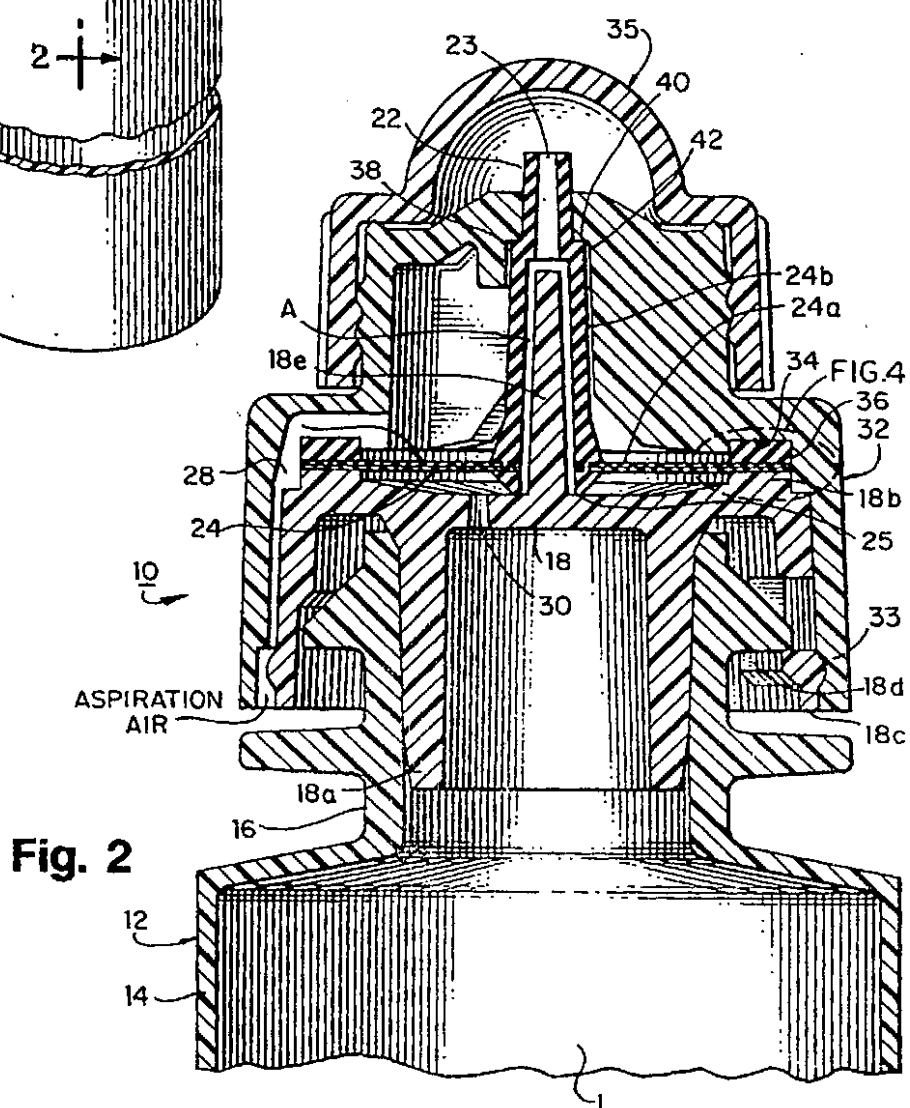
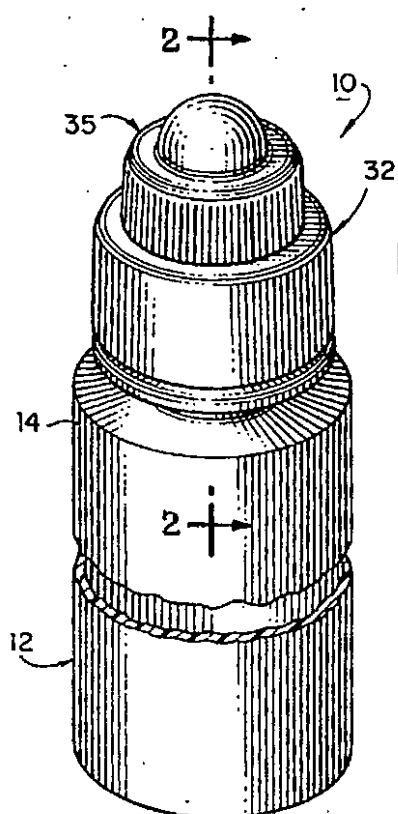


Fig. 3

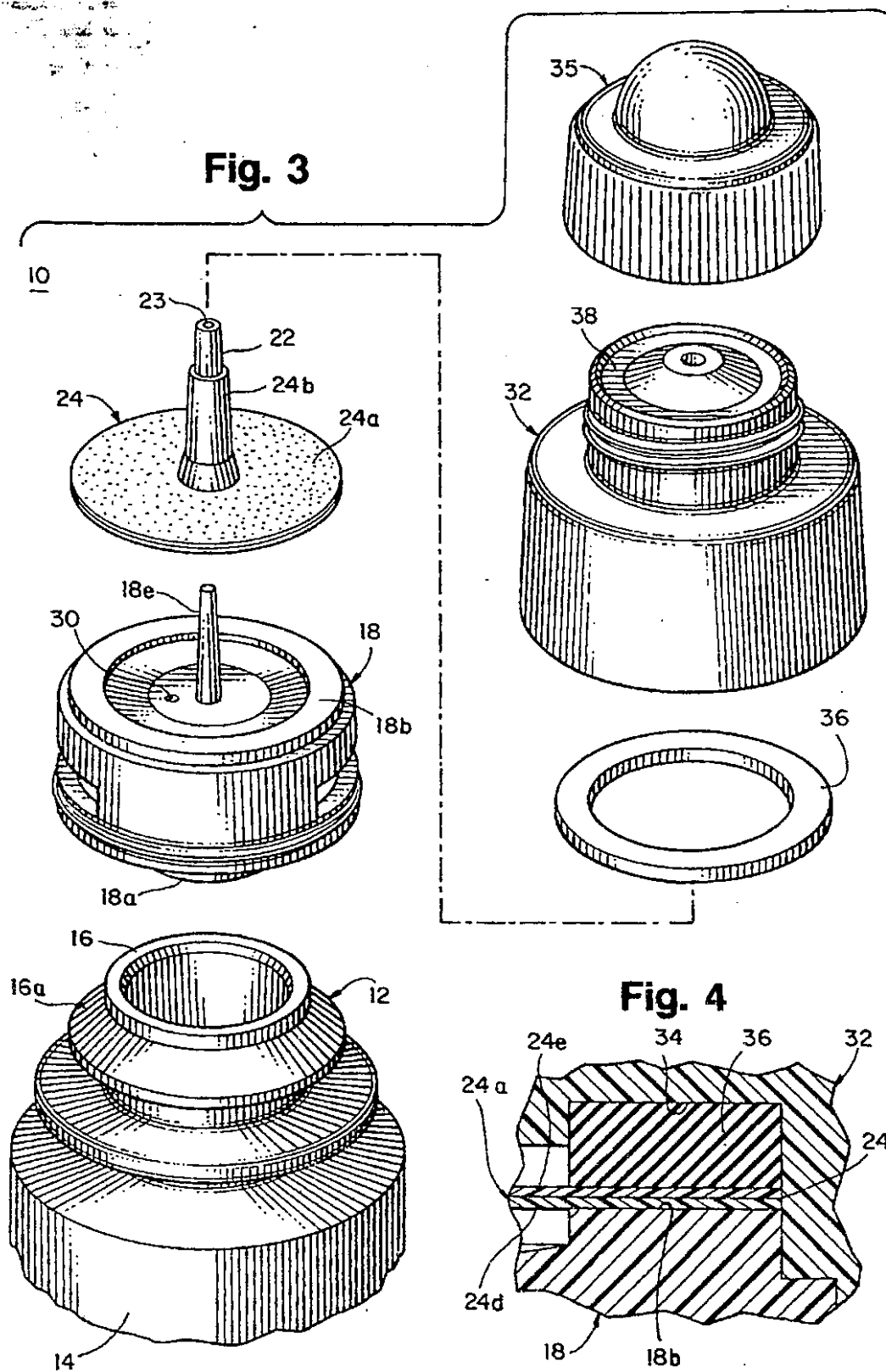
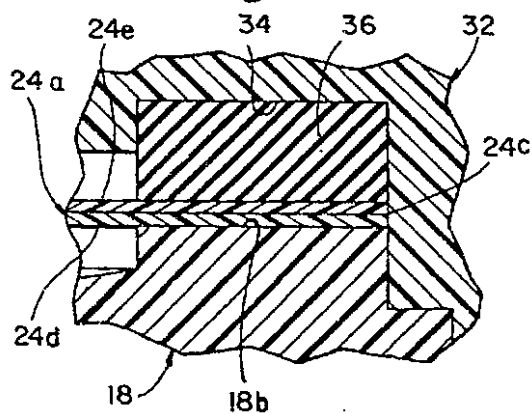
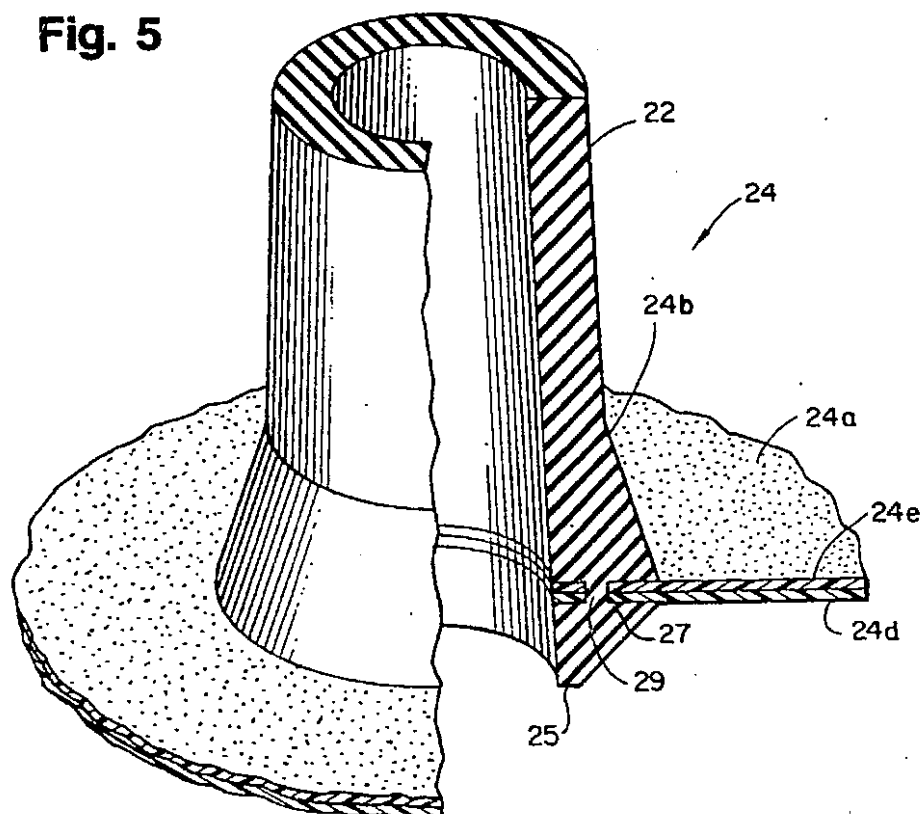
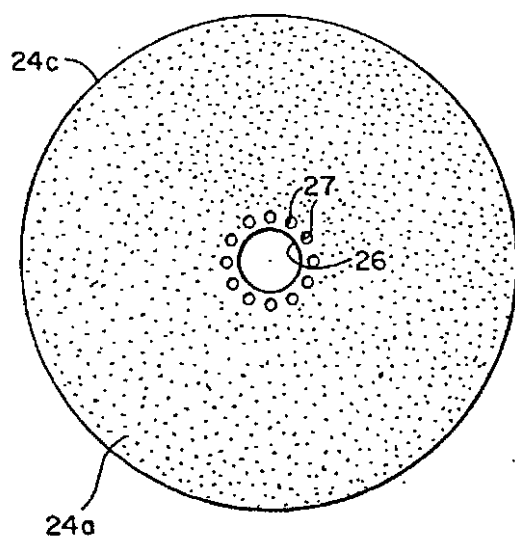
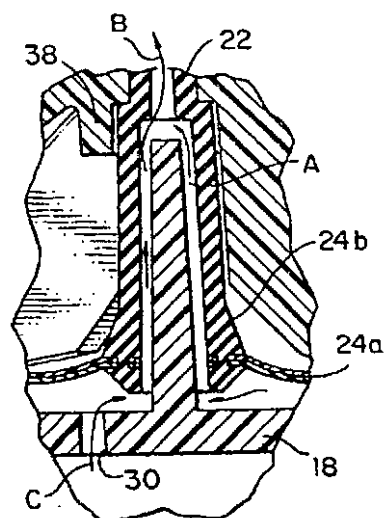
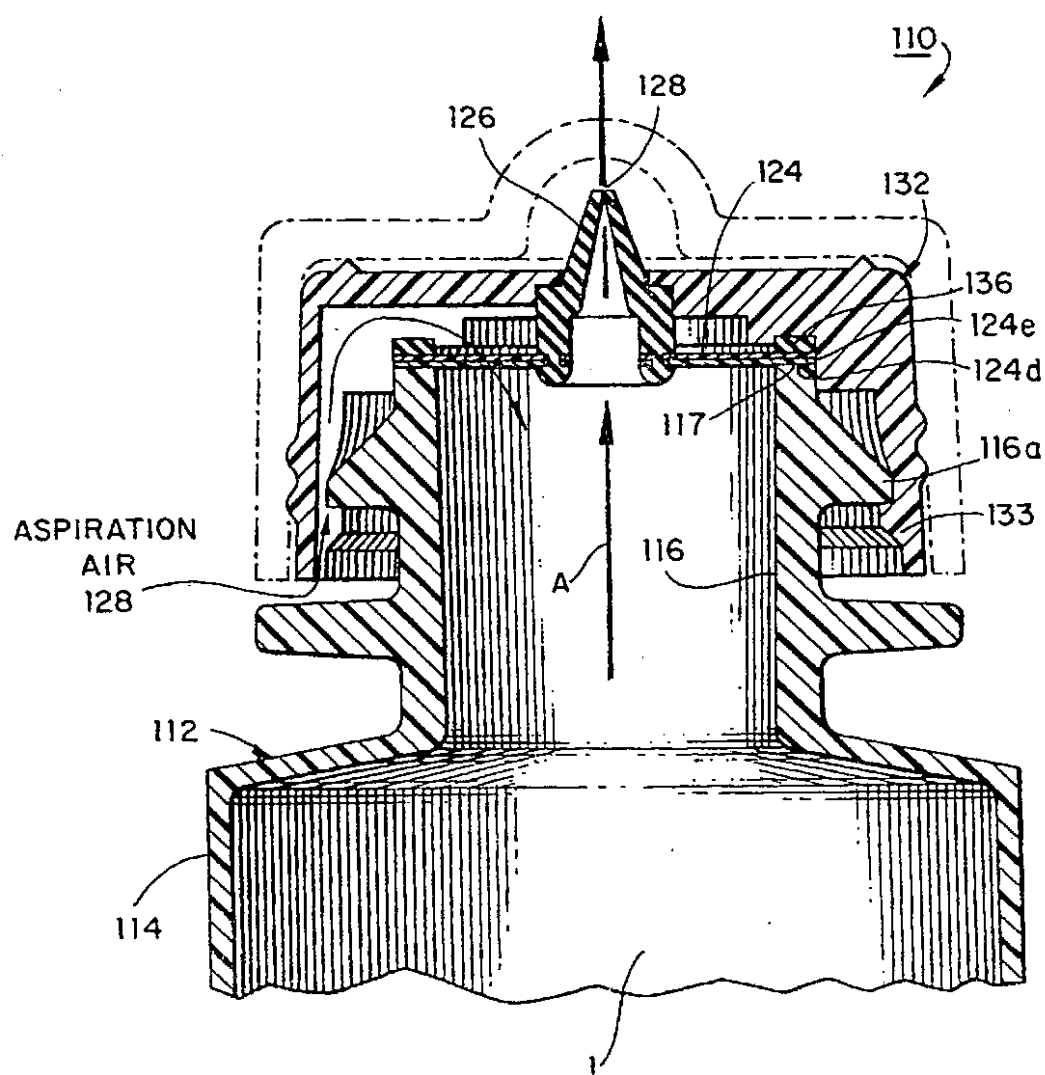


Fig. 4



**Fig. 5****Fig. 6****Fig. 7**

**Fig. 8**



LIQUID DISPENSER NOZZLE ASSEMBLY

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of application Ser. No. 071,510 filed Jun. 2, 1993, now U.S. Pat. No. 5,320,254 which is a divisional of Ser. No. 972,411 filed Nov. 5, 1992, now U.S. Pat. No. 5,255,826, which is a divisional of application Ser. No. 664,347 filed May 4, 1991, now U.S. Pat. No. 5,183,184, which is a continuation-in-part of application Ser. No. 406,053 filed Sep. 11, 1989, now U.S. Pat. No. 5,025,957, which is a continuation-in-part of application Ser. No. 255,365 filed Oct. 7, 1988, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to liquid storage containers for manually dispensing liquids such as cleaning solutions for contact lenses, and more particularly relates to dispensing nozzles on containers for liquid which must be stored in sterile condition.

Liquids, for example, solutions for cleaning and conditioning contact lenses, have typically been stored in manually squeezable bottles from which the user can repeatedly dispense the stored liquid. These liquids must be uncontaminated by microorganisms such as bacteria. Accordingly, expensive bactericidal agents have sometimes been included in liquid formulation, as for example, in saline formulations for cleaning contact lenses. Furthermore, the squeezable dispensing bottles have sometimes been provided with nozzles including diaphragm structures which control the dispensing flow as well as sealing the liquid cavity during storage, as described in the afore-mentioned U.S. Pat. Nos. 5,255,826, 5,183,184 and 5,025,957. These patents describe nozzle structures which can be employed on dispensing containers to provide for either air aspirated liquid dispensing capability or non-aspirated liquid dispensing.

The dispensing nozzle structures in accordance with the present invention provide nozzle improvements particularly in sealing configuration and materials.

SUMMARY OF THE INVENTION

In accordance with the present invention, a liquid dispensing nozzle assembly is provided for mounting on a liquid container and dispenser having a flexible wall and liquid storage cavity for manually squeezed dispensing of liquid from the cavity through the nozzle assembly. The nozzle assembly maintains the liquid, such as contact lens cleaning and conditioning solutions in sterile condition during storage and repeated dispensing of the liquid from the container cavity. The nozzle assembly includes a liquid conduit for communication from the container cavity to a liquid discharge port from the nozzle assembly to enable dispensing of the liquid displaced by manually squeezing the flexible wall of the container. The nozzle assembly also includes a sealing element for sealing the liquid conduit against liquid leakage in which the sealing element has a composition comprising polytetrafluoroethylene which can provide sealing engagement directly against a molded plastic surface of either a molded component of the nozzle assembly or the mouth of container-dispenser.

In one embodiment, the sealing element is provided by a peripheral portion of a polytetrafluoroethylene

flow control diaphragm to provide an integral, sealing ring thereon.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of one embodiment of the liquid nozzle assembly in accordance with the invention, mounted on a liquid storage and dispensing container;

FIG. 2 is a sectional view along a plane indicated by line 2-2 in FIG. 1;

FIG. 3 is an exploded, perspective view of the nozzle assembly in FIGS. 1 and 2;

FIG. 4 is an enlarged, fragmentary sectional view of the sealing portion of the nozzle assembly as indicated in FIG. 2;

FIG. 5 is an enlarged, fragmentary partially sectional view of the integral diaphragm structure as shown in FIGS. 2 and 3;

FIG. 6 is a plan view of a portion of the diaphragm structure in FIG. 5;

FIG. 7 is an enlarged, fragmentary sectional view of the deflection of a valve element shown in FIG. 2 which opens the liquid dispensing conduit in the nozzle assembly; and

FIG. 8 is a sectional view through a second embodiment of a liquid nozzle assembly in accordance with the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIGS. 1 and 2, an embodiment of the nozzle assembly in accordance with the invention and designated generally by reference character 10 is shown mounted on a molded plastic bottle container 12 for sterile liquid L with a squeezable wall 14. The container 12 opens at the top from a neck portion 16. An adapter portion 18 of the nozzle assembly generally closes the mouth of the neck 16 and has a cylindrical wall 18a which projects downwardly into the opening of the neck and securely seals against the interior surface of the neck. The raised upper annular surface 18b of the adapter 18 supports a diaphragm structure 24 which integrally includes both a diaphragm portion 24a and a valve element portion 24b as more fully described hereinafter. The annular diaphragm portion 24a is peripherally clamped and sealed against a raised annular portion 18b of the upper surface of the adapter 18 as more fully described hereinafter. In the illustrated embodiment, the adapter 18 has a downwardly extending cylindrical skirt portion 18c with radially inwardly projecting feet or lugs 18d which are forced under coupling flange 16a on the neck 16 to enable an interference fit coupling of the nozzle assembly 10 on the bottleneck 16.

Referring to FIGS. 3, 5 and 6, in the illustrated embodiment, the annular diaphragm portion 24a of the integrated diaphragm structure 24 has a particularly beneficial composition comprising polytetrafluoroethylene (PTFE) which I have discovered will provide extraordinary mechanical purchase or grip as well as a liquid-tight seal under clamped engagement against high gloss or polished surface of the molded plastic annular upper surface portion 18b of the adapter 18 as particularly shown in FIGS. 2 and 4; as a result, the peripheral edge portion 24c of the diaphragm portion 24a grips the annular surface of adapter portion 18b and withstands the lateral tension forces imposed therein during resilient deflection of the diaphragm portion 24a during dispensing of the liquid as more fully described

hereinafter. The peripheral edge portion 24c of the diaphragm portion 24a also provides an integral sealing ring while allowing the necessary resilient deflection. In the illustrated embodiment, a housing cap 32 has an internal, annular seat 34 fitting a clamping ring 36 which is clamped against the diaphragm support layer 24e to secure the sealed engagement of the expanded PTFE layer 24d against the adapter surface 18b as best shown in FIG. 4. The clamp by the cap 32 is provided by the snap lug arrangement 33 thereof cooperating with the adapter skirt 18c. A threaded cover 35 removably fits over the tubular nozzle 22 and cap boss 38.

As in the illustrated embodiment, the diaphragm portion 24a has expanded PTFE layer 24d laminated to a support layer 24e of suitable material including polypropylene, polyethylene, polyester, nylon or rayon. A particularly suitable laminate material serving as the diaphragm portion 24a is commercially available from W. L. Gore and Associates, Inc. of Elkton, Md. under the tradename GORE-TEX®RST as polytetrafluoroethylene materials including an expanded, hydrophobic PTFE membrane laminated on one side with a non-woven polyester support layer enabling improved handling. Both the expanded PTFE layer 24d and support layer 24e of the laminate can be air permeable to enable air aspiration therethrough when beneficial to aspirate a container.

In the particularly preferred embodiment illustrated, the diaphragm portion 24a is inserted during molding of the valve element portion 24b for example from elastomeric material, such as silicone rubber. As shown in FIGS. 5 and 6, the diaphragm portion 24a has a central aperture 26 which is surrounded by an annular series of smaller punched or otherwise fabricated holes 27 which provide passageway for liquid elastomer during the molding operation to form the valve element portion 24b so that the resulting integral coupling links 29 as best shown in FIG. 5, project through the holes 27 to form molded mechanical interlock of the valve portion 24b and the diaphragm portion 24a. Integrally molded with the valve portion 24b is a tubular, liquid discharge nozzle portion having a dispensing discharge orifice 23. The support layer 24e of the diaphragm portion 24a is preferably a composition such as polyester which will withstand the elevated molding heat required for insertion during molding of the valve member portion 24b.

Referring again to FIG. 2, the cap 32 also has an annular boss portion 38 which has an internal annular surface 40 which seats against and compresses the annular upper surface 42 of the columnar diaphragm valve portion 24b so that the clamping by the cap 32 also compresses the diaphragm valve portion 24b to force the normal sealing engagement of the bottom, tapered sealing ring surface 25 against the upper wall surface of the adapter 18 which serves as the valve seat.

The normal seal by the sealing ring 25 under compression by the cap boss portion 38 prevents leakage of the stored liquid L within the container even under hydrostatic pressure when the container is inverted during handling, and to prevent any backflow of non-sterile air or liquid from the clearance space A into the bottleneck 16. The backflow of liquid is additionally prevented by the projection of the conically shaped nipple portion 18e which projects upwardly from the upper wall of the adapter 18. The clearance space A leads to the central bore of the tubular portion 22 and discharge orifice 23, and the nipple portion 18e minimizes the volume of liquid remaining in the clearance

space A when the dispensing flow is stopped. The small amount of liquid remaining in the clearance space A, which can be exposed to contamination by air, will be flushed out before the next dispensing.

Referring to FIG. 7, when the flexible container wall 14 is squeezed to dispense the liquid L from the inverted container 12 and nozzle assembly 10, the liquid flows through the passageway bore 30 as indicated at arrow C, and exerts the necessary threshold hydraulic pressure against the liquid-impermeable hydrophobic PTFE portion 24a of the diaphragm structure 24 which is resiliently deflected to further compress the tubular valve portion 24b against the boss; the additional compression of the valve portion 24b thereby displaces and unseats the annular sealing ring 25, on the surface of the adapter 18 to enable the liquid flow therebetween into the adjacent portion of the annular clearance space A (which is enlarged by the diaphragm deflection). Optionally, the cap 32 has a narrow vent groove 28 as shown in the left half of FIG. 2 which is located on the dry or non-liquid side above the diaphragm 24a to enable air aspiration of the container 12.

The liquid flow through the clearance space A leads to discharge of the liquid through the tubular nozzle 22 as indicated by the arrow B. The elastomeric valve portion 24b and sealing ring 25 perform as a one-way valve allowing only outflow of dispensed liquid when the flexible container wall 14 is squeezed. Once the additional compression of the valve portion 24b is relaxed when the manual squeeze is released, the residual compression of the valve portion 24b will cause the sealing ring 25 to reseat and firmly seal against the wall of the adapter 18 to close the one-way valve and prevent any backflow of liquid or air. Such backflow might otherwise occur, for example, should the dispenser become exposed to non-sterile fluids such as by dropping into contaminated liquid. The valve portion column 24b thus acts as an integral and elastomeric biasing spring on the sealing ring 25.

In aspirated embodiments for reinflation of the squeezed flexible container wall 14 and to replace the liquid dispensed, ambient air is drawn into the entrance passageway 28 and is downwardly directed and filtered through the diaphragm portion 24a above the passageway bore 30 through which the air flows through the adapter skirt 18 and container neck 16. The filtering portion 24a of the diaphragm 24 thus serves dual function as both the aspiration air filter as well as the hydraulically deflectable portion of the diaphragm valving in the liquid dispensing conduit. Accordingly, the integration of the hydraulically deflectable air filter within the diaphragm structure enables particularly uncomplicated flow path of the air aspiration conduit and a simplified nozzle assembly without jeopardizing contamination of the sterile liquid during storage and successive dispensing. The expanded PTFE diaphragm portion 24a preferably has a pore size of approximately 0.45 micron which is impenetrable by bacteria so that the aspirating air is filtered to prevent entrained bacteria from contaminating the sterile liquid during aspiration of the container 12.

Referring now to FIG. 8, a second embodiment of a nozzle assembly in accordance with the present invention is designated generally by reference character 110 and is mounted on a molded plastic bottle container 112 with a squeezable wall 114 and neck portion 116. In this embodiment, the expanded PTFE diaphragm layer 124d is clamped to grip and seal directly against the

annular end wall surface 117 of the container neck 116. The cap 132 and coupling skirt 133 thereof are directly clamped to the coupling flange 116a. A clamping ring 136 fitted into the cap 132 is clamped against the optional diaphragm support layer 124e laminated to the PTFE layer 124d.

The diaphragm portion 124 is integrated with a one-way liquid dispensing valve 126, preferably by insert molding thereof from elastomeric composition for example silicone rubber. In the illustrated embodiment, the one-way valve portion 126 terminates in a "duck-bill" discharge structure 128 which opens with hydraulic discharge pressure of the dispensed liquid flow indicated by arrows A when the container wall 114 is squeezed. Alternative one-way valve structures may also be employed for example one-way flow "flapper" valves or other suitable valves which close to prevent flow when liquid dispensing from a container 12 is discontinued. In this illustrated embodiment, the nozzle assembly 110 provides air aspiration of the container 112 through an ambient air entrance passageway 128 in the cap 132. The PTFE diaphragm layer 124d filters the aspirating air as in the first embodiment of the nozzle assembly 10.

While a preferred embodiment of the present invention is shown and described, it is envisioned that those skilled in the art may devise various modifications of the present invention without departing from the spirit and scope of the appended claims.

The Invention Claimed Is:

1. A liquid dispensing nozzle assembly for mounting on a liquid container and disperser having a flexible wall and liquid storage cavity for manually squeezed dispensing of liquid from the cavity through the nozzle assembly and for maintaining the liquid, such as contact lens saline solution, in sterile condition during storage and repeated dispensing of the liquid from the container cavity, said nozzle assembly comprising:

a discharge port;

liquid conduit means for flow communication from the container cavity to said discharge port to enable dispensing of said liquid therethrough during said squeezed liquid dispensing;

a base member supporting said nozzle assembly and securable to a liquid delivery portion of said container; and

a seal element in sealing engagement against said base member for sealing said liquid conduit means against liquid leakage therefrom, wherein said seal element has a composition comprising polytetrafluoroethylene, wherein said seal element comprises a laminate incorporating a first layer of said polytetrafluoroethylene and a second, support layer therefor.

2. A nozzle assembly according to claim 1, wherein said seal element forms a portion of a diaphragm structure arranged to control liquid flow through said liquid conduit means.

3. A nozzle assembly according to claim 2, wherein said seal element comprises a peripheral portion of said diaphragm structure surrounding a valve portion of said diaphragm structure which is deflectable to permit said liquid flow through said liquid conduit means.

4. A nozzle assembly according to claim 3, wherein said seal element comprises an annular portion peripherally joined to said valve portion.

5. A nozzle assembly according to claim 2, wherein said seal element and said valve portion are integrally joined in said diaphragm structure.

6. A nozzle assembly according to claim 5, wherein said seal element is integrated by insertion during molding of said valve portion.

7. A nozzle assembly according to claim 1, wherein said seal element is clamped between said base member and a nozzle housing comprised within said nozzle assembly.

8. A nozzle assembly according to claim 7, further comprising a clamping member clamped between said seal element and said nozzle housing.

9. A nozzle assembly according to claim 1, wherein said second support layer has a composition comprising heat resistant material.

10. A nozzle assembly according to claim 1, wherein said second, support layer has a composition comprising polyester.

11. A nozzle assembly according to claim 1, wherein said base member includes at least one through passageway forming a portion of said liquid conduit means.

12. A nozzle assembly according to claim 1, wherein said seal element is arranged on said nozzle assembly to enable sealing engagement against the liquid container.

13. A liquid dispensing nozzle assembly for mounting on a liquid container and disperser having a flexible wall and liquid storage cavity for manually squeezed dispensing of liquid from the cavity through the nozzle assembly and for maintaining the liquid, such as contact lens saline solution, in sterile condition during storage and repeated dispensing of the liquid from the container cavity, said nozzle assembly comprising:

a discharge port;

liquid conduit means for flow communication from the container cavity to said discharge port to enable dispensing of said liquid therethrough during said squeezed liquid dispensing;

a base member supporting said nozzle assembly and securable to a liquid delivery portion of said container; and

a seal element in sealing engagement against said base member for sealing said liquid conduit means against liquid leakage therefrom, wherein said seal element has a composition comprising polytetrafluoroethylene, wherein said seal element and a valve portion are integrally joined in a diaphragm structure arranged to control liquid flow through said liquid conduit means, and wherein said seal element includes at least one aperture through which a coupling portion of said valve portion projects for mechanical interlock therebetween.

14. A nozzle assembly according to claim 13, wherein said seal element comprises a peripheral portion of said diaphragm structure surrounding a valve portion of said diaphragm structure which is deflectable to permit said liquid flow through said liquid conduit means.

15. A nozzle assembly according to claim 14, wherein said seal element comprises an annular portion circumscribing said valve portion.

\* \* \* \* \*



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FACTURA DE VENTA N° ZVE-0200006158  
INVOICE

52

PAGINA: 1 DE 1

IVA REGIMEN COMUN N° 03-3395-04  
Somos Grandes Contribuyentes.  
Autoreteneedores Resolución N° 296-86

| FECHA/DATE |     |      | VENCIMIENTO/EXPIRATION |     |      |
|------------|-----|------|------------------------|-----|------|
| DIA        | MES | AÑO  | DIA                    | MES | AÑO  |
| 26         | 09  | 2006 | 31                     | 01  | 2007 |

|                                 |                    |                     |               |                 |
|---------------------------------|--------------------|---------------------|---------------|-----------------|
| SEÑORES/TO:                     | R.F.C./R.U.C.      | CODIGO/ CODE:       | PAIS/COUNTRY: | C.PAIS/ C.CODE: |
| MEDIFARMA S.A.                  |                    | 111                 | Perú          | PE              |
| DIRECCION/ADDRESS:              | CIUDAD/CITY:       | TEL/PHONE:          |               |                 |
| CL ECUADOR NO 787 LIMA.         | LIMA               | (511) 3326200       |               |                 |
| ORDEN DE COMPRA/PURCHASE ORDER: | COD.POSTAL/Z.I.P.: | EMBARCADOR/SHIPPER: |               |                 |
| Ver detalle en la factura       |                    | PANALPINA S. A.     |               |                 |

| CODIGO<br>CODE                                         | DESCRIPCION DEL PRODUCTO<br>DESCRIPTION                                                                                                                                                                                                                              | CANTIDAD<br>QUANTITY                                                                                 | VALOR MILLAR<br>PRICE PER THOUSAND<br>(US\$) | VALOR TOTAL<br>TOTAL AMOUNT<br>(US\$) |
|--------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|----------------------------------------------|---------------------------------------|
| GO0261                                                 | Go Tap Seg 13 blanco Esteril (Emp.x500)<br>TAPA DE SEGURIDAD DE 13 MM BLANCO.<br>ESTERILIZACION XX - OXIDO DE ETILENO.<br>Codigo de Material del Cliente 09911130<br>OC: 2006/0219                                                                                   | 3,000                                                                                                | 27.00                                        | 81.00                                 |
| GO2138                                                 | Go Capilar 23 gotas x 1ml 125S NATURAL<br>CAPILAR 23 GOTAS X ML NATURAL<br>Codigo de Material del Cliente 09911129<br>OC: 2006/0219                                                                                                                                  | 3,000                                                                                                | 15.00                                        | 45.00                                 |
| GO1529                                                 | Go Corn Br 20 Gaseovet Fresa (153S)B<br>ENVASE GOTERO COMPLETO BRASILIA DE 20 ML.,<br>COMPUESTO POR ENVASE BLANCO, TAPA CON ANILLO<br>DE SEGURIDAD ROJO Y CAPILAR BLANCO.<br>PRESENTACION: GASEOVET FRESA, VP, 3 IMPRESIONES,<br>PARA LLENADO DE 15ML..<br>OC: CARTA | 27,000                                                                                               | 117.70                                       | 3,177.90                              |
| MARCAS/MARKS:<br>MEDIFARMA S.A. / PE - LIMA            |                                                                                                                                                                                                                                                                      | SUBTOTAL                                                                                             |                                              | US\$ 3,303.90                         |
|                                                        |                                                                                                                                                                                                                                                                      | GASTOS DE EXPORTACION<br>EXPORT CHARGES                                                              |                                              | US\$ 103.10                           |
| CONDICIONES DE PAGO:/PAYMENT TERMS:<br>pago a 120 días |                                                                                                                                                                                                                                                                      | FLETE TRANSPORTE<br>FREIGHT CHARGES                                                                  |                                              | US\$ 437.00                           |
| GARANTIA/WARRANTY:<br>Trasferencia Bancaria            |                                                                                                                                                                                                                                                                      | SEGURO/INSURANCE                                                                                     |                                              | US\$ 0.00                             |
| EMPAQUE / PACKING PESO NETO/NET WEIGHT                 |                                                                                                                                                                                                                                                                      | TOTAL CPT-LIMA                                                                                       |                                              | US\$ 3,844.00                         |
| TOTAL PACKING                                          | PESO BRUTO / GROSS WEIGHT                                                                                                                                                                                                                                            |                                                                                                      |                                              |                                       |
| Total Cajas 23                                         | 221.71 KG 185.88 KG                                                                                                                                                                                                                                                  |                                                                                                      |                                              |                                       |
| Total Pallet 0                                         |                                                                                                                                                                                                                                                                      |                                                                                                      |                                              |                                       |
| OBSERVACIONES/REMARKS:                                 |                                                                                                                                                                                                                                                                      | VALOR TOTAL/TOTAL AMOUNT TRES MIL OCHOCIENTOS<br>CUARENTA Y CUATRO DOLARES CON00 / 100<br>M.E.*****. |                                              |                                       |

NOTA: EL PAGO DEBE HACERSE A TRAVES DE TRANSFERENCIA A PROENFAR S.A.S Y DE SER EXTEMPORANEO, ESTA FACTURA CAUSARA INTERESES POR MORA. GARANTIZAMOS LOS PRODUCTOS POR SESENTA (60) DIAS A PARTIR DE LA FECHA DE SU RECEPCION. SE ENTIENDE POR GARANTIA LA REPOSICION DE MATERIAL DEFECTUOSO. NO RESPONDEMOS POR EL MANEJO O USO INADECUADO DEL PRODUCTO. DECLARAMOS QUE LOS DATOS PRECIOS Y CANTIDADES QUE CONTIENE ESTA FACTURA SON REFLEJO REAL DE LAS VENTAS. ESTA FACTURA SE CONSIDERA IRREVOCABLEMENTE ACEPTADA POR EL COMPRADOR, SI NO RECLAMARE EN CONTRA DE SU CONTENIDO, BIEN SEA MEDIANTE DEVOLUCION DE LA MISMA, Y DE LOS DOCUMENTOS DE DESPACHO, O BIEN MEDIANTE RECLAMO ESCRITO DIRIGIDO AL VENDEADOR, DENTRO DE LOS DIEZ (10) DIAS CALENDARIOS SIGUIENTES A SU RECEPCION.

NOTE: PAYMENT MUST BECOME THROUGH WIRE TRANSFER TO PROENFAR S.A.S, AND IF IT IS OUT OF TIME, THIS INVOICE IT WILL CAUSE THE CORRESPONDING DELAY INTERESTS. WE GUARANTEE OUR PRODUCTS FOR A TERM OF SIXTY (60) DAYS FROM THE DATE OF RECEPTION AT YOUR SITE. WARRANTY MEANS, REPLACEMENT OF ANY DEFECTIVE MATERIALS. WE ARE NOT RESPONSIBLE FOR THE HANDLING OR INADEQUATE USE OF THE PRODUCT. WE HEREBY DECLARE THAT THE DATA PRICES AND AMOUNTS CONTAINED IN THIS INVOICE ARE REAL INFORMATION OF SALES. THIS INVOICE IS CONSIDERED ACCEPTED BY THE BUYER IRREVOCABLY, IF THE CUSTOMER DOES NOT PROTEST AGAINST ITS CONTENT, EITHER BY MEANS RETURN OF THE SAME AND DOCUMENTS OF DELIVERY, OR BY MEANS OF WRITTEN CLAIM DIRECTED TO SALES REPRESENTATIVE, WITHIN THE TEN (10) DAYS CALENDARS FOLLOWING TO ITS RECEPTION.

FIRMA AUTORIZADA VENDEADOR

FACTURACION POR COMPUTADOR RESOLUCION DIAN No 310000053234 DE MAY.03.2011 DEL No. ZVE-200015001 AL ZVE-200019000

## ANEXO F



Lima, 5 de Diciembre de 2011

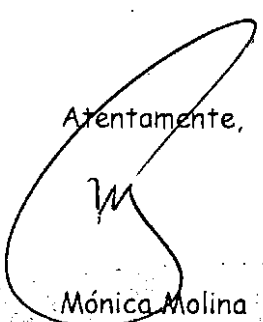
Señores  
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO - SIC  
División de Nuevas Creaciones  
Bogotá,  
Colombia.-

Estimados Señores:

La presente es para saludarlos y certificarles que la empresa Productores de Envases Farmacéuticos S.A.S. - Proenfar S.A.S.; identificado con Nit No. 860.513.290-1, es proveedor nuestro artículo : Capilar Ref. 125-S desde Setiembre del año 2,006 hasta la fecha.

Sin otro particular, quedamos de Uds.

Atentamente,



Mónica Molina  
Gerente de Logística

MEDIFARMA S.A.

Jr. Ecuador 787 - Lima 1 - Perú. Telf.: (511) 332-6200

República de Colombia 791, Edificio Plaza República, Piso 10 - San Isidro, Lima 27 - Perú. Telf.: (511) 207-0000

RUC: 20100018625