



No. 12-069627- -00004-0000

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DIRECCIÓN DE NUEVAS CREACIONES
PRESENTACIÓN DE OPOSICIÓN

1. Oposición a solicitud de:

☒ Patente de invención
☐ Registro de Diseño Industrial
☐ Patente de Modelo de Utilidad
☐ Esquema de Trazado de Circuitos Integrados

Número de expediente: 12 069.627
Solicitante: REXAM HEALTHCARE LA VERPILLIERE
Apoderado: GILDA OGBASTA PUERTA
Título de la Nueva Creación: "Dispositivo de Distribución de Líquido
Gaceta: 653 del 28-09-12 Bajo forma de gotas"

2. Datos del Opositor

☐ Persona Natural ☒ Persona Jurídica

PRODUCTORES DE ENVASES FARMACEUTICOS SAS PRUENFAR SAS

Nombre o denominación / Razón social completa

Nombre del representante legal

Documento de identificación: C.C. ☐ C.E. ☐ NIT ☒ Otro ☐Cuál

Número: 860-513-290-1

Dirección: Calle 10 N° 34A-13 Ciudad: BOGOTÁ

Teléfono: 6736990 Fax: 6734930 Correo electrónico: Fmedina@pruenfar.com

☐ Autorizo expresamente a la Superintendencia de Industria y Comercio para que todas las comunicaciones sean enviadas a través de la dirección de correo electrónico

3. Datos del representante o apoderado:

OGBASTA PUERTA GILDA 41.683.468 37.875

Apellidos y Nombre	Documento de identificación	Tarjeta profesional
Dirección del representante		
<u>Carrera 7 N° 156-80, Piso 8, Bogotá</u>		
Dirección electrónica	No. Fax	Número telefónico
<u>GILDA@PRUENFAR.COM</u>	<u>6734930</u>	<u>6736990</u>

En caso de haber presentado poder general para asuntos que se adelanten ante la Delegatura de Propiedad Industrial, sírvase indicar el número de su radicación o protocolo de poder general: _____

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4. Fundamentos de la oposición

Causal: La solicitud de patente de invención del Expediente N° 12-069.627 No cumple con requisitos de patentabilidad establecidos por los artículos 14, 16 del título II de LAS PATENTES DE INVENCION y la Decisión 486 de la Comisión de la Comunidad Andina.

Justificación: Ver DOCUMENTO Adjunto

Prórroga: SI ☐ NO ☒

5. Anexos

☒ Comprobante de pago de la tasa.

☒ Poder, si fuera el caso.

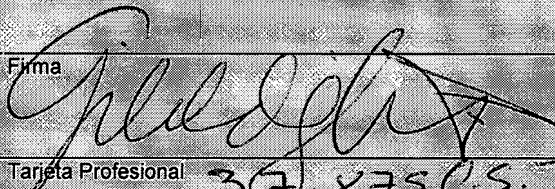
☒ Fundamentos de la oposición. Se anexan 9 folios (obligatorios indicar cuántos).

☒ Anexo de fundamentos de la oposición. Se anexan 28 folios (obligatorios indicar cuántos)

☒ Copias para traslado.

☐ Copia de la solicitud y sus anexos en formato magnético.

☒ CERTIFICADO DE EXISTENCIA Y REPRESENTACIÓN LEGAL OPOSITOR

6. Firma	
Nombre del Firmante	Firma
<u>GILDA OGLINSTEIN PUERTA</u>	
CC <u>41.683.468</u>	Tarjeta Profesional <u>37.875 C.S.J.</u>

Bogotá, D.C., 27 de diciembre de 2012

SEÑOR
SUPERINTENDENTE DE INDUSTRIA Y COMERCIO
E. S. D.

REFERENCIAS:

Expediente: No. 12-069.627
Asunto: OPOSICION concesión solicitud de Patente de Invención: "DISPOSITIVO DE DISTRIBUCIÓN DE LIQUIDO BAJO FORMA DE GOTAS"
Solicitante: REXAM HEALTHCARE LA VERPILLIERE
Gaceta No.: 653 del 28 de septiembre de 2012

GILDA OGIASTRI PUERTA, mayor de edad, vecina de Bogotá, identificada como aparece al pie de mi firma, con Tarjeta Profesional de Abogado No. 37.875, en mi condición de Apoderada de la sociedad **PRODUCTORES DE ENVASES FARMACÉUTICOS S.A.S. PROENFAR S.A.S.**, organizada y existente de conformidad con las leyes colombianas y domiciliada en la ciudad de Bogotá, en ejercicio de la acción de **OPOSICIÓN** establecida en el Artículo 42 de la Decisión 486 de la Comisión de la Comunidad Andina y estando dentro del término de sesenta (60) días establecido por el artículo 42, respetuosamente solicito a esa Superintendencia declarar fundadas y en consecuencia resolver favorablemente las pretensiones contenidas en la presente **OPOSICIÓN** contra la solicitud de Patente de Invención de la referencia.

I. SOLICITUD DE PATENTE DE INVENCION CONTRA LA CUAL SE PRESENTA OPOSICION.

La solicitud de Patente de Invención contra la cual se presenta **OPOSICION** corresponde a la contenida en el expediente No. 12-069.627 titulada "**DISPOSITIVO DE DISTRIBUCIÓN DE LIQUIDO BAJO FORMA DE GOTAS**", cuyo solicitante es la sociedad **REXAM HEALTHCARE LA VERPILLIERE**, que corresponde a la solicitud **PCT/FR2010/052258** presentada el día 22 de Octubre de 2010, la cual entró en fase nacional en Colombia el 29 de Mayo de 2012, publicada en la página 382 de la Gaceta de Propiedad Industrial No. 653 del 28 de Septiembre de 2012 y el término para presentar oposiciones fundamentadas vence el 27 de Diciembre de 2012.

II. PRETENSIONES.

1. Que se declare la falta de novedad y nivel inventivo del objeto reivindicado en la solicitud de Patente de Invención que obra en el expediente No. 12-069.627 consistente en un "**DISPOSITIVO DE DISTRIBUCIÓN DE**

LIQUIDO BAJO FORMA DE GOTAS", como se demostrará a través del presente memorial.

2. Que con fundamento en dicha declaración, se **niegue el privilegio de Patente de Invención** para el objeto reivindicado en la solicitud que obra en el expediente **12-069.627**.

III. LEGÍTIMO INTERÉS PARA LA PRESENTACIÓN DE LA OPOSICIÓN.

Nuestro mandante la sociedad **PRODUCTORES DE ENVASES FARMACÉUTICOS S.A.S. PROENFAR S.A.S.** es una compañía de origen colombiano con cerca de 30 años en el mercado especializada en la fabricación y comercialización de empaques para la industria farmacéutica y cosmética; está conformada por más de 1000 empleados y sus productos se distribuyen a nivel nacional y a nivel internacional a países como Venezuela, Ecuador, Perú, Argentina, México, Chile, Paraguay, República Dominicana, entre otros. Dentro de su portafolio de productos cuenta con envases oftálmicos, nasales, óticos y orales. En su línea de productos oftálmicos se destacan los envases goteros los cuales ha desarrollado y fabricado por cerca de 30 años, llegando a obtener patentes en este tipo de empaques. **PROENFAR S.A.S.** cuenta con certificaciones ISO 9001 y tiene productos registrados ante la Food and Drug Administration – FDA. Actualmente, **PROENFAR S.A.S.** suministra productos a empresas del sector farmacéutico como Pfizer, Merck, Boehringer Ingelheim, Schering y otras empresas importantes de carácter nacional.

De esta manera, a mi representada le asiste legítimo interés para oponerse a la solicitud de patente de invención **"DISPOSITIVO DE DISTRIBUCIÓN DE LIQUIDO BAJO FORMA DE GOTAS"** que se menciona en la referencia, por cuanto entre sus actividades principales se encuentra **la fabricación y comercialización de envases goteros** como los que se reclaman en la solicitud de patente de invención ahora objetada; toda vez que si se llega a conceder el privilegio de patente de invención a la solicitud de la referencia, se estaría desconociendo la existencia del conocimiento técnico que ha venido y seguirá evolucionando desde hace varios años atrás, no solamente afectando nuestros intereses comerciales sino también de los demás empresarios que constituyen este ramo de la industria.

IV. HECHOS.

Los hechos en los cuales se fundamenta la presente **OPOSICIÓN** son los siguientes:

El día 22 de Octubre de 2010, la sociedad **REXAM HEALTHCARE LA VERPILLIERE**, presentó la solicitud de patente de invención 382 de la Gaceta de Propiedad Industrial No. 653 del 28 de Septiembre de 2012, la cual en su capítulo reivindicatorio describe: "El dispositivo de distribución de líquido incluye: un depósito (12) de líquido, deformable para distribuir líquido por apoyo sobre el depósito (12); una boquilla (10) de distribución de líquido montada sobre el depósito (12); un canal de paso de líquido (24, 50); un canal de paso de aire (26) desde el exterior hacia el interior del depósito (12), el canal de paso

de aire (26) está obturado por una pieza mecánica (28) realizada en material de polímero permeable al aire, ese material no es poroso, la pieza mecánica (28) se denomina pieza mecánica (28) permeable al aire.

V. LA PATENTE DE INVENCION SOLICITADA NO CONSTITUYE UNA PATENTE SEGÚN LAS NORMAS ANDINAS.

De conformidad con los artículos 14 y 16 de la Decisión 486 de la Comisión de la Comunidad Andina, que dicen:

"Artículo 14.- Los Países Miembros otorgarán patentes para las invenciones, sean de producto o de procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial". (el resaltado es nuestro)

"Artículo 16.- Una invención se considerará nueva cuando no está comprendida en el estado de la técnica.

El estado de la técnica comprenderá todo lo que haya sido accesible al público por una descripción escrita u oral, utilización, comercialización o cualquier otro medio antes de la fecha de presentación de la solicitud de patente o, en su caso, de la prioridad reconocida...." (el resaltado es nuestro)

"Artículo 18.- Se considerará que una invención tiene nivel inventivo, si para una persona del oficio normalmente versada en la materia técnica correspondiente, esa invención no hubiese resultado obvia ni se hubiese derivado de manera evidente del estado de la técnica". (el resaltado es nuestro)

"Artículo 19.- Se considerará que una invención es susceptible de aplicación industrial, cuando su objeto pueda ser producido o utilizado en cualquier tipo de industria, entendiéndose por industria la referida a cualquier actividad productiva, incluidos los servicios". (el resaltado es nuestro)

La solicitud de Patente de Invención de la Sociedad **REXAM HEALTHCARE LA VERPILLIERE**, Expediente No. 12-069.627, no es susceptible de patentabilidad porque **CARECE DE NOVEDAD Y NIVEL INVENTIVO** puesto que su **objetivo se viene desarrollando e implementando en la industria de empaques** tanto para la industria farmacéutica como la cosmética, desde hace varios años, tal como se demostrará a continuación:

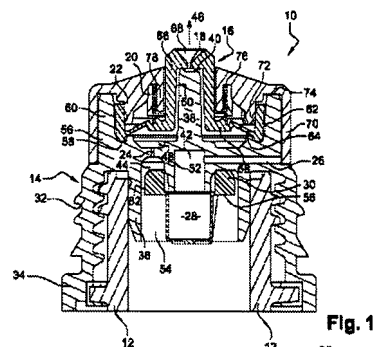
1. El objeto de la solicitud de patente de invención **"DISPOSITIVO DE DISTRIBUCIÓN DE LIQUIDO BAJO FORMA DE GOTAS"**, Exp. No. 12-069.627, es: ofrecer un recipiente para suministro de soluciones, por ejemplo oftalmológicas, que no tengan conservantes. Por lo tanto, el recipiente que se busca proteger con esta solicitud debe garantizar la esterilidad del producto a lo largo de la utilización del frasco que contiene la solución.

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Para cumplir con este propósito, la invención presenta un dispositivo para entregar o distribuir líquido que comprende: un depósito de líquido (12) que puede deformarse con el fin de distribuir el líquido presionando sobre el depósito (12); una boquilla (10) de distribución de líquidos montado sobre el depósito (12); un canal (24, 50) para el paso de líquido; un canal (26) para el paso de aire desde el exterior hacia el interior del depósito (12), estando este canal (26) para el paso de aire, obturado por una pieza mecánica (28) realizada en un material de polímero permeable al aire, siendo este material no poroso, este órgano (28) se denomina órgano permeable al aire (28).

Preferiblemente, el material polimérico que se utiliza en el objeto de la invención es silicona.

La figura 1 de la invención es la siguiente:



2. El estado de la técnica aplicable a la solicitud de patente de invención **Exp.12-069.627**, es antes de la **fecha de prioridad reivindicada** en la solicitud **PCT/FR2010/052258**, es decir antes del día **29 de Octubre de 2009**, comprobándose la existencia de publicaciones anteriores a ésta fecha que afectan la **novedad y nivel inventivo de la invención** objeto de esta oposición.

2.1 Falta de Novedad de la solicitud de patente de REXAM HEALTHCARE LA VERPILLIERE

Documento D1 (US 5373972), título de la invención: **"SISTEMA DE ENTREGA DE FLUIDO ESTÉRIL SIN PRESERVATIVOS."** a nombre de la sociedad **JSP PARTNERS, L.P.**, con fecha de publicación: **20 de Diciembre de 1994.**

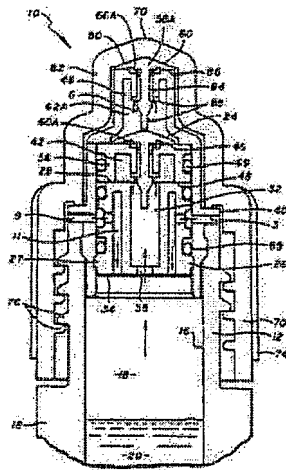
Las características contenidas en las reivindicaciones de la solicitud de patente de invención ahora objetada no son nuevas con respecto a lo publicado en **US5373972** por cuanto esta patente divulga un sistema de

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entrega de fluido estéril libre de conservantes o preservativos que comprende:

- un recipiente que tiene una superficie exterior y una superficie interior y que tiene un compartimiento de depósito para almacenar una solución estéril y un compartimiento adaptado para entregar la solución estéril; este recipiente es elásticamente deformable;
- un conjunto de válvula doble auto-sellante en donde dicha válvula comprende: un conjunto de membrana que tiene un alojamiento de dicha membrana; un soporte de membrana hidrofóbica conectado a dicho alojamiento membrana; dicho soporte de membrana hidrofóbica teniendo además una superficie superior, una superficie inferior y un canal central de fluido para permitir el paso de la solución estéril; una membrana hidrófoba herméticamente sellada que además se conecta a un puerto de flujo central que a su vez se comunica con canal de fluido para permitir que la solución pase a través; y también tiene una vía de paso situada en dicho soporte de membrana hidrofóbica para la entrada de aire desde el exterior de dicho recipiente a través de dicha membrana hidrofóbica; un conjunto de válvula que comprende un soporte carcasa de la válvula con una superficie superior e inferior; dicha superficie inferior de dicho soporte carcasa de la válvula conectada además a dicha superficie superior de dicho soporte de membrana hidrofóbica; una primera válvula de cierre automático y sellado hermético; una segunda válvula de cierre automático y sellado hermético y en serie con dicha primera válvula en el que una salida de dicha primera válvula abre a una entrada de dicha segunda válvula para permitir que la solución pase a través de ella; y una salida del sistema de la solución o fluido estéril.



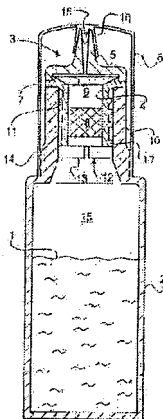
Esta publicación estadounidense muestra todas las características del dispositivo de distribución de líquido de la solicitud correspondiente al expediente 12-069.627 como son:

- el depósito de líquido (12) que en la solicitud estadounidense se ilustra en las figuras con el número 18,
- la boquilla (10) de distribución del líquido montada sobre el depósito (12) y que en el documento del estado de la técnica se muestra con el número 22,
- un canal para el paso de los líquidos (24,50) equivalente al canal 32 de la anterioridad,
- un canal de paso de aire (26) que es correspondiente al canal de paso de aire 40 y tiene un órgano (28) equivalente a la membrana 34, que también está elaborado en un material polimérico tal y como se muestra en la descripción de dicho documento columna 5 líneas 43 a 47.

De acuerdo a lo expresado anteriormente, se encuentra que la publicación del documento **D1** **revela todas las características de la reivindicación 1 de la solicitud de patente de invención objeto de la oposición**, por lo que se concluye que el **documento D1** afecta el requisito de **NOVEDAD**.

2.2 Falta de Nivel Inventivo de la solicitud de patente de REXAM HEALTHCARE LA VERPILLIERE

Documento D2 (WO 2006/000897), título de la invención: "CONTENEDOR PARA EMBALAJE DE UN LÍQUIDO QUE SE DISTRIBUYE EN FORMA DE GOTAS QUE SE DEFORMA DE MANERA REVERSIBLE POR LA ENTRADA DE AIRE." a nombre de la sociedad THEA LAB., con fecha de publicación: 5 de Enero de 2006.



Esta invención se refiere a un recipiente para envasar un líquido (1) a ser entregado en gotas, siendo este recipiente deformable, reversiblemente, por la entrada de aire. Este recipiente está equipado con un cabezal (3) para distribuir el líquido a través de una abertura (5). El cabezal (3) comprende un cuerpo ahuecado (4) que está anidado dentro de un cuello

(10) del contenedor y que tiene una almohadilla hidrófoba microporosa (8) dispuesta arriba de una cámara (9). Dicha cámara (9) está provista de un depósito de aire para impedir que el líquido pase a través de la almohadilla microporosa entre dos operaciones de entrega de líquido cuando la boquilla (5) está obstruida herméticamente con una tapa (6) y para el secado de una membrana de filtrado parcialmente hidrofílica e hidrofóbica (7) que está dispuesta en la cabeza de distribución (3).

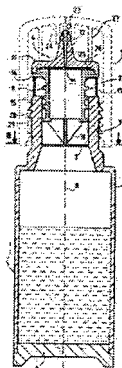
La presente invención y la publicación WO2006/000897 comparten muchas características que permiten deducir los resultados de la presente invención a partir de las divulgaciones hechas en WO2006/000897 en forma evidente para una persona normalmente versada en la materia técnica correspondiente, dejando sin actividad inventiva al dispositivo de distribución de líquido de la sociedad Rexam Healthcare La Verpilliere.

Precisamente el objeto de la publicación PCT es obtener un recipiente que para envasado y distribución de líquidos, tales como soluciones farmacéuticas y en gotas para los ojos en particular. Esta publicación también se da preponderancia al hecho de que estas soluciones deben estar protegidas del medio ambiente exterior que puede contener contaminantes, incluyendo bacterias.

Tanto el dispositivo de distribución de líquido de la presente solicitud como el de la publicación WO2006/000897 comprenden una membrana microporosa hidrofóbica ilustrada con el número 8 en la publicación del arte previo y con el número 28 en la presente invención. Estas membranas son de las mismas características y tienen la misma función en ambos frascos y es la de impedir el paso del líquido, pero dejar pasar el aire que permite la salida del líquido a través de la boquilla en forma de gotas.

De esta manera, la publicación hecha en WO2006/000897 impide que la presente invención tenga actividad inventiva.

Documento D3 (US2004074925), título de la invención: "DOSIFICADOR POR GOTEÓ." a nombre del solicitante FAURIE MICHEL, con fecha de publicación: 22 de Abril de 2004.



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Esta invención se refiere también a un dispositivo de envasado para un líquido que se va a dispensar gota a gota, que comprende un recipiente (1) con paredes manualmente elásticamente deformables, que termina en un cuello rígido (3) en el que un cabezal (4) para dispensar la líquido está montado. Este dispositivo además cuenta con una membrana (31) que es tanto hidrófilo e hidrófobo, ventajosamente antibacteriana, que está dispuesta en la cabeza de distribución (4). Esta membrana permite que el aire exterior entre en el recipiente (1) una vez que el líquido ha pasado a través de ella en la fase de expulsión, y la botella vuelve elásticamente a su forma inicial después de cada operación de dispensación.

De esta manera, esta publicación del arte previo a la invención objeto del presente análisis, también divulga la posibilidad de disponer una membrana en el paso de aire proveniente del exterior en los dispositivos dispensadores de líquidos en gotas para evitar la contaminación del líquido contenido en el depósito del dispositivo de distribución en gotas; impidiendo entonces que se le pueda atribuir actividad inventiva a la solución que ahora propone la solicitud correspondiente al expediente 12-069.627

CONCLUSION.

*Por todo lo anteriormente expuesto se concluye que la solicitud contenida en el **Exp.12-069.627** no es novedosa por cuanto todas sus características técnicas que pretende reclamar en la reivindicación 1, ya habían sido previamente divulgadas en el documento de patente US5373972.*

Adicionalmente, una persona versada en la materia técnica correspondiente podría haber tomado las enseñanzas divulgadas en WO2006/000897 y US2004074925 y, de manera evidente, haber propuesto la solución contenida en la solicitud de patente objeto de esta observación.

*Por lo tanto, se deben tener en cuenta los argumentos técnicos expuestos en el presente memorial de **OPOSICIÓN** y se proceda a **NEGAR** el privilegio solicitado en la Patente de Invención titulada **"DISPOSITIVO DE DISTRIBUCIÓN DE LIQUIDO BAJO FORMA DE GOTAS"** a nombre de la sociedad **REXAM HEALTHCARE LA VERPILLIERE**, descrita en el **Exp.12-069.627** puesto que la tecnología propuesta en dicha solicitud existe con anterioridad a la fecha de presentación de la solicitud en*

estudio, **afectando la NOVEDAD y NIVEL INVENTIVO DE LA INVENCION** y por consiguiente, la misma no cumple con los requisitos de patentabilidad establecidos por los **artículos 14, 16, del Título II de las Patentes de Invención de la Decisión 486 de la Comisión de la Comunidad Andina.**

VI. ANEXOS.

Para los efectos correspondientes anexo al presente escrito los siguientes documentos:

ANEXO 1. Poder.

ANEXO 2. Certificado de Existencia y Representación Legal de la sociedad **PRODUCTORES DE ENVASES FARMACÉUTICOS S.A.S. PROENFAR S.A.S.** expedido por la Cámara de Comercio de Bogotá.

ANEXO 3. Comprobante en el cual consta que se ha pagado el valor correspondiente a la tasa por tramitación de la presente oposición.

ANEXO 4. Copia de la presente oposición para el traslado del solicitante.

VII. PRUEBAS.

Copia de la publicación US5373972

Copia de la publicación WO2006/000897

Copia de la publicación US2004074925

VIII. NOTIFICACIONES.

Mi poderdante y la suscrita, las recibiremos en mi oficina situada en la carrera 7 No. 156-80, Piso 8, de la ciudad de Bogotá D.C.

Atentamente,



GILDA OGLIASTRI PUERTA
C.C. No. 41.683.468 de Bogotá
T.P. No. 37.875 C.S. de la J.

PODER

El suscrito, FERNANDO GUSTAVO MEDINA GARAVITO, mayor de edad, identificado como aparece al pie de mi firma, obrando en nombre y representación de PRODUCTORES DE ENVASES FARMACEUTICOS S.A.S. PROENFAR S.A.S., con NIT 860.513.290-1, en mi calidad de representante legal, sociedad organizada y existente de conformidad con las leyes de Colombia, domiciliada en la Calle 10 No. 34 A - 13, de Bogotá, Colombia, por el presente otorga a GILDA OGIASTRI PUERTA, mujer mayor de edad, domiciliada en Bogotá, identificada con cédula de ciudadanía No. 41.683.468 expedida en Bogotá y con Tarjeta Profesional de Abogado No. 37.875 expedida por el Consejo Superior de la Judicatura, Poder amplio y suficiente para presentar una Oposición a la Solicitud de Patente de Invención No. 12-069.627 radicada ante la Superintendencia de Industria y Comercio por la sociedad REXAM HEALTHCARE LA VERPILLIERE, a cuyo efecto la autorizamos para que nos represente ante cualquier entidad o personas, ejerzan o no jurisdicción, especialmente ante las del orden administrativo, contencioso administrativo y judicial, así como los tribunales de arbitramento, en todo lo concerniente a la presentación de dicha oposición a solicitud de patente de invención en Colombia, así como la facultamos para presentar solicitudes, peticiones y demandas, interponer recursos, reclamos, pagar impuestos y tasas, recibir, transigir y desistir, incluyendo facultades para entrar en acuerdos amigables, conciliaciones y transacciones, abandonar solicitudes y renunciar a derechos de propiedad industrial, y en general, a dar ante las autoridades competentes todos los pasos necesarios para la debida protección de nuestros intereses. Asimismo, se concede a la mencionada apoderada poder suficiente para recibir notificaciones a nombre de mi representada, otorgar poderes a quienes vayan a representar a la compañía judicial y extrajudicialmente, responder en juicio a todas las reclamaciones o demandas que por motivo de la oposición a dicha solicitud de patente se presentaren y hacer cuanto fuere necesario ante las autoridades administrativas o judiciales de cualquier orden para el cumplimiento de este mandato, dándole igualmente facultad para sustituir el presente poder y en caso necesario, revocar dichas sustituciones y, demás facultades requeridas.

Bogotá, D.C., Colombia

26 DEC 2012

PRODUCTORES DE ENVASES FARMACEUTICOS S.A.S. PROENFAR S.A.S.
FERNANDO GUSTAVO MEDINA GARAVITO
C.C. No. 79.146.438 de Usaquén
Representante Legal

Acepto el Poder,

GILDA OGIASTRI PUERTA
C.C. No. 41.683.468 de Bogotá
T.P. 37.875 C.S. de la J.





CAMARA DE COMERCIO DE BOGOTA

SEDE NORTE

6 DE DICIEMBRE DE 2012 HORA 11:16:40

R036567668 PAGINA: 1 de 4

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CERTIFICADO DE EXISTENCIA Y REPRESENTACION LEGAL O INSCRIPCION DE DOCUMENTOS

LA CAMARA DE COMERCIO DE BOGOTA, CON FUNDAMENTO EN LAS MATRICULAS E INSCRIPCIONES DEL REGISTRO MERCANTIL

NOMBRE : PRODUCTORES DE ENVASES FARMACEUTICOS S A S PROENFAR S A S, CON SIGLA PROENFAR S A S

SIGLA : PROENFAR S A S

N.I.T. : 860513290-1

DOMICILIO : BOGOTA D.C.

MATRICULA NO: 00190577 DEL 19 DE MAYO DE 1983

RENOVACION DE LA MATRICULA : 29 DE MARZO DE 2012

ULTIMO AÑO RENOVADO: 2012

ACTIVO TOTAL REPORTADO: \$107,349,736,811

DIRECCION DE NOTIFICACION JUDICIAL: CL 10 NO. 34A-13

MUNICIPIO : BOGOTA D.C.

EMAIL DE NOTIFICACION JUDICIAL : orlandor@proenfar.com

DIRECCION COMERCIAL : CL 10 NO. 34A-13

MUNICIPIO : BOGOTA D.C.

EMAIL COMERCIAL : orlandor@proenfar.com

CONSTITUCION: ESCRITURA PUBLICA NO. 399, NOTARIA 26 DE BOGOTA, EL 25 DE ABRIL DE 1.983, INSCRITA EL 19 DE MAYO DE 1.983, BAJO EL NO. 133161 DEL LIBRO IX, SE CONSTITUYO LA SOCIEDAD LIMITADA DENOMINADA "PRODUCTORES DE ENVASES LTDA." "PROENVASES"

QUE POR ESCRITURA PUBLICA NUMERO 1.324 OTORGADA EN LA NOTARIA 26 DE BOGOTA EL 24 DE SEPTIEMBRE DE 1.985, INSCRITA EN ESTA CAMARA DE COMERCIO EL 8 DE OCTUBRE DE 1.985, BAJO EL NUMERO 178.146 DEL LIBRO IX, LA SOCIEDAD CAMBIO SU NOMBRE DE "PRODUCTORES DE ENVASES LTDA. PROENVASES" POR EL DE "PRODUCTORES DE ENVASES FARMACEUTICOS LTDA. PROENFAR LTDA."

QUE POR E.P. NO. 61 NOTARIA 26 DE BOGOTA DEL 20 DE ENERO DE 1.988 INSCRITA EL 8 DE FEBRERO DE 1.988 BAJO EL NO. 228.231 DEL LIBRO IX LA SOCIEDAD ADICIONO EN NOMBRE ASI: "PRODUCTORES DE ENVASES FARMACEUTICOS LIMITADA - PROENFAR LTDA" (QUE PODRA USAR EN FORMA ABREVIADA COMO "PROENFAR LTDA" E INTRODUJO OTRAS REFORMAS AL ESTATUTO SOCIAL.

CERTIFICA: QUE POR ACTA NO. 85 DE LA ASAMBLEA DE ACCIONISTAS DEL 30 DE JULIO DE 2009, INSCRITA EL 20 DE AGOSTO DE 2009 BAJO EL NUMERO 1320764 DEL

LIBRO IX, LA SOCIEDAD DE LA REFERENCIA CAMBIO SU NOMBRE DE:
PRODUCTORES DE ENVASES FARMACEUTICOS S.A. PROENFAR S.A. Y PODRA
UTILIZAR LA SIGLA PROENFAR S.A., POR EL DE: PRODUCTORES DE ENVASES
FARMACEUTICOS S.A.S. PROENFAR S.A.S., CON SIGLA PROENFAR S.A.S.

CERTIFICA:

QUE POR ESCRITURA PUBLICA NO 3529 DE LA NOTARIA 41 DE SANTAFE DE
BOGOTA, DEL 18 DE NOVIEMBRE DE 1997, INSCRITO EL 19 DE NOVIEMBRE DE
1997, BAJO EL NO. 610860 DEL LIBRO IX, LA SOCIEDAD PRODUCTORES DE
ENVASES FARMACEUTICOS LTDA PROENFAR LIMITADA, SE TRANSFORMO EN ANONIMA
BAJO EL NOMBRE DE PRODUCTORES DE ENVASES FARMACEUTICOS S.A. PROENFAR
S.A. Y PODRA UTILIZAR LA SIGLA PROENFAR S.A.

CERTIFICA:

QUE POR ACTA NO. 85 DE LA ASAMBLEA DE ACCIONISTAS, DEL 30 DE JULIO DE
2009, INSCRITA EL 20 DE AGOSTO DE 2009 BAJO EL NÚMERO 1320764 DEL
LIBRO IX, LA SOCIEDAD DE LA REFERENCIA SE TRANSFORMO DE SOCIEDAD
ANONIMA A SOCIEDAD POR ACCIONES SIMPLIFICADA BAJO EL NOMBRE DE:
PRODUCTORES DE ENVASES FARMACEUTICOS S.A.S. PROENFAR S.A.S., CON SIGLA
PROENFAR S.A.S.

CERTIFICA:

REFORMAS:

ESCRITURAS NO.	FECHA	NOTARIA	INSCRIPCION
731	9-VII-1.983	26 BTA	3-VIII-1983 NO.136854
1.316	24- IX-1.985	26 BTA	8- X -1985 NO.178146
1.324	24- IX-1.985	26 BTA	8- X -1985 NO.178146
659	14--V--1.986	26 BTA.	20-V--1986 NO.190420
1.132	6-VIII-1.986	26 BTA.	25-VIII-1986 NO.195967
61	20- I-1.988	26 BTA.	8- II-1988 NO.228231
1.738	12-VIII-1.988	26 BTA.	19-VIII-1988 NO.243382
3.276	26-XII -1.989	26 BTA.	28-XII -1989 NO.283271
2.133	18-VIII-1.992	26 STAFE BTA.	27-VIII-1992 NO.376206
1.160	30- IV -1.996	41 STAFE BTA	14- V -1996 NO.537721
3.305	28-X --1.996	41 STAFE BTA	30- X -1996 NO.560301

CERTIFICA:

REFORMAS:

E.P. NO.	FECHA	NOTARIA	CIUDAD	FECHA	NO. INSC.
0003529	1997/11/18	0041	BOGOTA D.C.	1997/11/19	00610860
0001078	1999/05/19	0041	BOGOTA D.C.	1999/05/27	00681865
0002743	1999/11/19	0041	BOGOTA D.C.	1999/11/19	00704557
0000001	1999/11/22	0000	BOGOTA D.C.	1999/11/26	00705362
0001514	2000/07/25	0041	BOGOTA D.C.	2000/07/31	00739009
0001325	2003/06/18	0041	BOGOTA D.C.	2003/07/04	00887075
0001262	2004/06/25	0041	BOGOTA D.C.	2004/06/28	00940731
0000731	2005/04/12	0041	BOGOTA D.C.	2005/04/13	00985830
0001500	2007/06/26	0041	BOGOTA D.C.	2007/06/28	01141024
0001647	2008/08/26	0041	BOGOTA D.C.	2008/08/28	01238074
753	2009/05/11	0041	BOGOTA D.C.	2009/05/12	01296465
85	2009/07/30	0000	BOGOTA D.C.	2009/08/20	01320764
87	2009/09/30	0000	BOGOTA D.C.	2009/10/01	01331260
90	2011/09/23	0000	BOGOTA D.C.	2011/09/29	01516256

CERTIFICA:

VIGENCIA: QUE EL TERMINO DE DURACION DE LA SOCIEDAD ES INDEFINIDO

CERTIFICA:

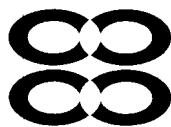
OBJETO SOCIAL: LA SOCIEDAD TENDRÁ POR OBJETO SOCIAL PRINCIPAL EL
SIGUIENTE: A. LA FABRICACIÓN O COMERCIALIZACIÓN DE TODA CLASE DE
MATERIALES, ARTÍCULOS O DISPOSITIVOS PLÁSTICOS PARA TODO TIPO DE
INDUSTRIA Y EMPRESAS DE SERVICIOS EN GENERAL Y EN ESPECIAL PARA LA



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Cámara
de Comercio
de Bogotá

CÁMARA DE COMERCIO DE BOGOTÁ

SEDE NORTE a la calle del Comercio en Bogotá

6 DE DICIEMBRE DE 2012 HORA 11:16:40

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INDUSTRIA FARMACÉUTICA, COSMÉTICA, VETERINARIA Y DE SERVICIOS RELACIONADOS CON EL CUIDADO DE LA SALUD; B. LA EXPORTACIÓN, IMPORTACIÓN, DISTRIBUCIÓN Y VENTA DE MATERIALES, ARTÍCULOS O DISPOSITIVOS PLÁSTICOS, METÁLICOS, DE VIDRIO, O DE CUALQUIER OTRA CLASE Y DE LAS MATERIAS PRIMAS NECESARIAS PARA LA ELABORACIÓN DE LOS MISMOS; C. REPRESENTACIÓN DE FABRICANTES, IMPORTADORES O EXPORTADORES DE LOS PRODUCTOS ANTES MENCIONADOS; O QUE COMERCIALIZEN LAS MATERIAS PRIMAS RESPECTIVAS Y DE EQUIPOS O TECNOLOGÍAS RELACIONADOS CON LOS MISMOS; D. LA FABRICACIÓN DE TODA CLASE DE MOLDES, SU EXPORTACIÓN, IMPORTACIÓN Y VENTA; E. LA PRESTACIÓN DE SERVICIOS DE DECORACIÓN DE ENVASES, SU ESTERILIZACIÓN Y SU LLENADO Y CUALQUIER OTRO PROCESO REQUERIDO POR TODO TIPO DE INDUSTRIA Y POR EMPRESAS DE SERVICIOS EN GENERAL Y EN ESPECIAL PARA LA INDUSTRIA FARMACÉUTICA, COSMÉTICA, VETERINARIA Y DE SERVICIOS RELACIONADOS CON EL CUIDADO DE LA SALUD; F. LA FABRICACIÓN O COMERCIALIZACIÓN DE MÁQUINAS Y APARATOS PARA TRABAJAR PLÁSTICO, CAUCHO Y OTROS MATERIALES, ASÍ COMO DE MÁQUINAS Y APARATOS PARA IMPRIMIR POR SERIGRAFÍA TAMPOGRÁFICA, OFFSET, HOTSTAMPING O CUALQUIER OTRA TÉCNICA DE IMPRESIÓN; G. INVERSIONES EN OTRAS COMPAÑÍAS O NEGOCIOS DE CARÁCTER INDUSTRIAL, AGRÍCOLA, COMERCIAL, DE SERVICIOS, FINANCIERO E, INMOBILIARIO, CUALQUIERA QUE FUERE SU OBJETO; H. LA VENTA, EL OTORGAMIENTO DE LICENCIAS, LA ASISTENCIA TÉCNICA Y CUALQUIER OTRO TIPO DE ACTO DE COMERCIO RELACIONADO CON SU TECNOLOGÍA. I. GARANTIZAR OBLIGACIONES DE SUS FILIALES, SUBORDINADAS, CONTROLADAS O, DE AQUELLAS SOCIEDADES EN LAS QUE TENGA PARTICIPACIÓN ACCIONARIA.

CERTIFICA:

CAPITAL:

** CAPITAL AUTORIZADO **

VALOR : \$20,000,000,000.00
NO. DE ACCIONES : 2,000,000.00
VALOR NOMINAL : \$10,000.00

** CAPITAL SUSCRITO **

VALOR : \$13,635,730,000.00
NO. DE ACCIONES : 1,363,573.00
VALOR NOMINAL : \$10,000.00

** CAPITAL PAGADO **

VALOR : \$13,635,730,000.00
NO. DE ACCIONES : 1,363,573.00
VALOR NOMINAL : \$10,000.00

CERTIFICA:

** JUNTA DIRECTIVA: PRINCIPAL (ES) **

QUE POR ACTA NO. 85 DE JUNTA DE SOCIOS DEL 30 DE JULIO DE 2009, INSCRITA EL 24 DE AGOSTO DE 2009, BAJO EL NUMERO 01321455 DEL LIBRO IX, FUE (RON) NOMBRADO (S):



VALOR
NO. DE ACCIONES
VALOR NOMINAL

NOMBRE	IDENTIFICACION
PRIMER RENGLON	
DURAN ECHEVERRI DARIO ALBERTO	C.C. 000000079397873
SEGUNDO RENGLON	
KURLA VARGAS JORGE ALEXIS	P.P. 000000004293391
QUE POR ACTA NO. 91 DE ASAMBLEA DE ACCIONISTAS DEL 30 DE MARZO DE 2012, INSCRITA EL 22 DE MAYO DE 2012 BAJO EL NUMERO 01635752 DEL LIBRO IX, FUE (RON) NOMBRADO (S):	

NOMBRE	IDENTIFICACION
TERCER RENGLON	
CARRILLO RODRIGUEZ ALEJANDRO	C.C. 000000079948084
QUE POR ACTA NO. 85 DE JUNTA DE SOCIOS DEL 30 DE JULIO DE 2009, INSCRITA EL 24 DE AGOSTO DE 2009 BAJO EL NUMERO 01321455 DEL LIBRO IX, FUE (RON) NOMBRADO (S):	

NOMBRE	IDENTIFICACION
CUARTO RENGLON	
GEDEON GHISAYS RODOLFO WADY	C.C. 000000003795186
QUINTO RENGLON	
MORENO ESCALLON MAURICIO LIBORIO	C.C. 000000019309062

CERTIFICA:

REPRESENTACION LEGAL: LA SOCIEDAD TENDRA UN PRESIDENTE QUE SERA ELEGIDO POR LA ASAMBLEA GENERAL. EL PRESIDENTE TENDRA DOS SUPLENTE QUE REEMPLAZARAN AL PRINCIPAL, EN SUS FALTAS ACCIDENTALES, TEMPORALES O ABSOLUTAS. EL PRESIDENTE TENDRA A SU CARGO LA REPRESENTACION LEGAL DE LA SOCIEDAD, LA ADMINISTRACION Y GESTION DE LOS NEGOCIOS SOCIALES CON SUJECCION A LA LEY, A ESTOS ESTATUTOS, Y A LOS REGLAMENTOS Y RESOLUCIONES DE LA ASAMBLEA DE ACCIONISTAS Y DE LA JUNTA DIRECTIVA.

CERTIFICA:

**** NOMBRAMIENTOS ****

QUE POR ACTA NO. 85 DE JUNTA DE SOCIOS DEL 30 DE JULIO DE 2009, INSCRITA EL 24 DE AGOSTO DE 2009 BAJO EL NUMERO 01321561 DEL LIBRO IX, FUE (RON) NOMBRADO (S):

NOMBRE	IDENTIFICACION
PRESIDENTE	
VERGARA CORRADINE MARIO	C.C. 000000019439733
PRIMER SUPLENTE DEL PRESIDENTE	
MEDINA GARAVITO FERNANDO GUSTAVO	C.C. 000000079146438
SEGUNDO SUPLENTE DEL PRESIDENTE	
RAMIREZ REYES LUIS ORLANDO	C.C. 000000003020961

CERTIFICA:

FACULTADES DEL REPRESENTANTE LEGAL: EL PRESIDENTE DE LA SOCIEDAD EJERCERA TODAS LAS FUNCIONES PROPIAS DE LA NATURALEZA DE SU CARGO, Y EN ESPECIAL, LAS SIGUIENTES: A. REPRESENTAR A LA SOCIEDAD ANTE LOS ACCIONISTAS, ANTE TERCEROS Y ANTE TODA CLASE DE AUTORIDADES DEL ORDEN ADMINISTRATIVO Y JURISDICCIONAL; B. EJECUTAR TODOS LOS ACTOS U OPERACIONES CORRESPONDIENTES AL OBJETO SOCIAL, DE CONFORMIDAD CON LO PREVISTO EN LAS LEYES Y EN ESTOS ESTATUTOS; C. AUTORIZAR CON SU FIRMA TODOS LOS DOCUMENTOS PUBLICOS O PRIVADOS QUE DEBAN OTORGARSE EN DESARROLLO DE LAS ACTIVIDADES SOCIALES O EN INTERES DE LA SOCIEDAD; D. PRESENTAR A LA ASAMBLEA GENERAL EN SUS REUNIONES ORDINARIAS, LOS ESTADOS FINANCIEROS DE EJERCICIO, JUNTO CON UN INFORME ESCRITO SOBRE LA SITUACION DE LA SOCIEDAD, UN DETALLE COMPLETO DE LA CUENTA DE PERDIDAS Y GANANCIAS Y UN PROYECTO DE DISTRIBUCION DE UTILIDADES OBTENIDAS; E. PRESENTAR PARA APROBACION DE LA JUNTA DIRECTIVA, A MAS TARDAR EL ULTIMO DIA DEL MES DE ENERO DE CADA AÑO, UN PRESUPUESTO GENERAL DE GASTOS Y COSTOS GENERALES DEL AÑO. UNA VEZ APROBADO EL



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CAMARA DE COMERCIO DE BOGOTA

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PRESUPUESTO SERÁ REVISADO DE CONFORMIDAD CON LA AGENDA ESTABLECIDA CONJUNTAMENTE CON LA JUNTA DIRECTIVA PARA ESTE PROPOSITO; F. NOMBRAR Y REMOVER LOS EMPLEADOS DE LA SOCIEDAD QUE NO DEBAN SER DESIGNADOS POR LA JUNTA DIRECTIVA O LA ASAMBLEA GENERAL DE ACCIONISTAS; G. TOMAR TODAS LAS MEDIDAS QUE RECLAME LA CONSERVACIÓN DE LOS BIENES SOCIALES, VIGILAR LA ACTIVIDAD DE LOS EMPLEADOS DE LA ADMINISTRACIÓN DE LA SOCIEDAD E IMPARTIRLES LAS ÓRDENES E INSTRUCCIONES QUE EXIJA LA BUENA MARCHA DE LA COMPAÑÍA; H. CONVOCAR LA ASAMBLEA GENERAL A REUNIONES EXTRAORDINARIAS CUANDO LO JUZGUE CONVENIENTE O NECESARIO Y HACER LAS CONVOCATORIAS DEL CASO CUANDO LO ORDENEN LOS ESTATUTOS, LA JUNTA DIRECTIVA O EL REVISOR FISCAL DE LA SOCIEDAD; I. CONVOCAR A LA JUNTA DIRECTIVA CUANDO LO CONSIDERE NECESARIO O CONVENIENTE Y MANTENERLA INFORMADA DEL CURSO DE LOS NEGOCIOS SOCIALES; J. CUMPLIR LAS ÓRDENES E INSTRUCCIONES QUE LE IMPARTAN LA ASAMBLEA GENERAL O LA JUNTA DIRECTIVA, Y, EN PARTICULAR, SOLICITAR AUTORIZACIONES PARA LOS NEGOCIOS QUE DEBEN APROBAR PREVIAMENTE LA ASAMBLEA O LA JUNTA DIRECTIVA SEGÚN LO DISPONEN LAS NORMAS CORRESPONDIENTES DEL PRESENTE ESTATUTO; K. CUMPLIR O HACER QUE SE CUMPLAN OPORTUNAMENTE TODOS LOS REQUISITOS O EXIGENCIAS LEGALES QUE SE RELACIONEN CON EL FUNCIONAMIENTO Y ACTIVIDADES DE LA SOCIEDAD. L. CERTIFICAR QUE LOS ESTADOS FINANCIEROS Y OTROS INFORMES RELEVANTES PARA EL PÚBLICO NO CONTIENEN VICIOS, IMPRECISIONES O ERRORES QUE IMPIDAN CONOCER LA VERDADERA SITUACIÓN PATRIMONIAL O LAS OPERACIONES DE LA SOCIEDAD. M. ADQUIRIR O HACERSE PARTE EN SOCIEDADES DE CUALQUIER NATURALEZA, ADQUIRIENDO DERECHOS SOCIALES O ACCIONES Y ENAJENARLOS. PARÁGRAFO. LIMITACIONES: EL PRESIDENTE DEBERÁ PEDIR AUTORIZACIÓN A LA JUNTA DIRECTIVA PARA EJECUTAR ACTOS Y CELEBRAR CONTRATOS EN NOMBRE Y REPRESENTACIÓN DE LA COMPAÑÍA POR UN VALOR SUPERIOR A MIL SALARIOS MÍNIMOS LEGALES MENSUALES VIGENTES.

CERTIFICA:

** REVISOR FISCAL **

QUE POR DOCUMENTO PRIVADO DE REVISOR FISCAL DEL 28 DE ENERO DE 2010, INSCRITA EL 3 DE FEBRERO DE 2010 BAJO EL NUMERO 01358872 DEL LIBRO IX, FUE (RON) NOMBRADO (S):

NOMBRE

IDENTIFICACION

REVISOR FISCAL PRINCIPAL

GALLEGO MORALES MARLLY SARELA

C.C. 000000043200122

REVISOR FISCAL SUPLENTE

GUERRERO OLMOS ANGELA MARIA

C.C. 000000052851266

QUE POR ACTA NO. 86 DE ASAMBLEA DE ACCIONISTAS DEL 2 DE SEPTIEMBRE DE 2009, INSCRITA EL 1 DE FEBRERO DE 2010 BAJO EL NUMERO 01358309 DEL LIBRO IX, FUE (RON) NOMBRADO (S):

NOMBRE

IDENTIFICACION

REVISOR FISCAL

ERNST & YOUNG AUDIT LTDA

N.I.T. 000008600088905



CERTIFICA:

QUE POR RESOLUCION NO. SL-03741 DE LA SUPERINTENDENCIA DE SOCIEDADES DEL 7 DE ABRIL DE 1.988, INSCRITA EL 21 DE ABRIL DE 1.988--BAJO EL NO. 233989 DEL LIBRO IX, SE CONCEDIO PERMISO DEFINITIVO--DE FUNCIONAMIENTO A LA SOCIEDAD.-

CERTIFICA:

QUE POR DOCUMENTO PRIVADO NO. 1000000 DE REPRESENTANTE LEGAL DEL 6 DE SEPTIEMBRE DE 2007, INSCRITO EL 7 DE SEPTIEMBRE DE 2007 BAJO EL NUMERO 01156465 DEL LIBRO IX, SE COMUNICO QUE SE HA CONFIGURADO UNA SITUACION DE CONTROL POR PARTE DE LA SOCIEDAD MATRIZ: PRODUCTORES DE ENVASES FARMACEUTICOS S A S PROENFAR S A S, CON SIGLA PROENFAR S A S, RESPECTO DE LAS SIGUIENTES SOCIEDADES SUBORDINADAS:

- PLASTICOS BDS SRL

DOMICILIO: (FUERA DEL PAIS)

QUE POR DOCUMENTO PRIVADO NO. DE REPRESENTANTE LEGAL DEL 12 DE FEBRERO DE 2010, INSCRITO EL 23 DE FEBRERO DE 2010 BAJO EL NUMERO 01363933 DEL LIBRO IX, SE COMUNICO QUE SE HA CONFIGURADO UNA SITUACION DE CONTROL POR PARTE DE LA SOCIEDAD MATRIZ: PRODUCTORES DE ENVASES FARMACEUTICOS S A S PROENFAR S A S, CON SIGLA PROENFAR S A S, RESPECTO DE LAS SIGUIENTES SOCIEDADES SUBORDINADAS:

- PROENFAR S R L

DOMICILIO: (FUERA DEL PAIS)

QUE POR DOCUMENTO PRIVADO DE REPRESENTANTE LEGAL DEL 15 DE ABRIL DE 2010, INSCRITO EL 16 DE ABRIL DE 2010 BAJO EL NUMERO 01376428 DEL LIBRO IX, SE COMUNICO QUE SE HA CONFIGURADO UNA SITUACION DE CONTROL POR PARTE DE LA SOCIEDAD MATRIZ: PRODUCTORES DE ENVASES FARMACEUTICOS S A S PROENFAR S A S, CON SIGLA PROENFAR S A S, RESPECTO DE LAS SIGUIENTES SOCIEDADES SUBORDINADAS:

- COMERCIALIZADORA DE ENVASES FARMACEUTICOS S A C COENFAR S A C

DOMICILIO: (FUERA DEL PAIS)

QUE POR DOCUMENTO PRIVADO DE REPRESENTANTE LEGAL DEL 25 DE OCTUBRE DE 2011, INSCRITO EL 1 DE NOVIEMBRE DE 2011 BAJO EL NUMERO 01524502 DEL LIBRO IX, SE COMUNICO QUE SE HA CONFIGURADO UNA SITUACION DE CONTROL POR PARTE DE LA SOCIEDAD MATRIZ: PRODUCTORES DE ENVASES FARMACEUTICOS S A S PROENFAR S A S, CON SIGLA PROENFAR S A S, RESPECTO DE LAS SIGUIENTES SOCIEDADES SUBORDINADAS:

- BIS PLAST S A DE C V

DOMICILIO: (FUERA DEL PAIS)

- BODEGA COSME S A DE C V

DOMICILIO: (FUERA DEL PAIS)

- EROMOLD S A DE C V

DOMICILIO: (FUERA DEL PAIS)

- INNOVAPLAST S A DE C V

DOMICILIO: (FUERA DEL PAIS)

FECHA DE CONFIGURACION DE LA SITUACION DE CONTROL : 2011-09-26

CERTIFICA:

QUE POR ESCRITURA PUBLICA NO. 51 DE NOTARIA UNICA DE (FUERA DEL PAIS) DEL 13 DE ENERO DE 2010, INSCRITO EL 23 DE FEBRERO DE 2010 BAJO EL NUMERO 01363929 DEL LIBRO IX, COMUNICO LA SOCIEDAD MATRIZ:

- ZINGER INVESTMENTS S L

DOMICILIO: (FUERA DEL PAIS)

QUE SE HA CONFIGURADO UNA SITUACION DE CONTROL CON LA SOCIEDAD DE LA REFERENCIA.

CERTIFICA:

ACLARACIÓN SITUACIÓN DE CONTROL

SE ACLARA LA SITUACIÓN DE CONTROL INSCRITA EL DIA 23 DE FEBRERO DE



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CAMARA DE COMERCIO DE BOGOTA

SEDE NORTE

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2010 BAJO EL NUMERO 01363929 DEL LIBRO IX, EN EL SENTIDO DE INDICAR QUE LA MISMA SE CONFIGURÓ A PARTIR DEL DIA 21 DE MAYO DE 2009.

ACLARACIÓN SITUACIÓN DE CONTROL

SE ACLARA LA SITUACIÓN DE CONTROL INSCRITA EL DIA 23 DE FEBRERO DE 2010 BAJO EL NUMERO 01363933 DEL LIBRO IX, EN EL SENTIDO DE INDICAR QUE LA MISMA SE CONFIGURÓ A PARTIR DEL DIA 21 DE MAYO DE 2009.

ACLARACIÓN SITUACIÓN DE CONTROL

SE ACLARA LA SITUACIÓN DE CONTROL INSCRITA EL DIA 16 DE ABRIL DE 2010 BAJO EL NUMERO 01376428 DEL LIBRO IX, EN EL SENTIDO DE INDICAR QUE LA MISMA SE CONFIGURÓ A PARTIR DEL DIA 16 DE MARZO DE 2010.

CERTIFICA:

QUE LA SOCIEDAD TIENE MATRICULADOS LOS SIGUIENTES ESTABLECIMIENTOS:

NOMBRE : FABRICA DE PLASTICOS EL PIPE S.A. PLASPIPE

MATRICULA NO : 00548330 DE 17 DE MAYO DE 1993

RENOVACION DE LA MATRICULA : EL 29 DE MARZO DE 2012

ULTIMO AÑO RENOVADO : 2012

NOMBRE : MOLDES UNIVERSALES

MATRICULA NO : 01055832 DE 20 DE DICIEMBRE DE 2000

RENOVACION DE LA MATRICULA : EL 29 DE MARZO DE 2012

ULTIMO AÑO RENOVADO : 2012

NOMBRE : PRODUCTORES DE ENVASES FARMACEUTICOS S.A. PROENFAR S.A

MATRICULA NO : 00857972 DE 20 DE MARZO DE 1998

RENOVACION DE LA MATRICULA : EL 29 DE MARZO DE 2012

ULTIMO AÑO RENOVADO : 2012

NOMBRE : PRODUCTORES DE ENVASES FARMACEUTICOS LTDA PROENFAR LTDA

MATRICULA NO : 00550379 DE 1 DE JUNIO DE 1993

RENOVACION DE LA MATRICULA : EL 29 DE MARZO DE 2012

ULTIMO AÑO RENOVADO : 2012

NOMBRE : PRODUCTORES DE ENVASES FARMACEUTICOS S.A. PROENFAR S.A Y PODRA

UTILIZAR LA SIGLA PROENFAR S.A.

MATRICULA NO : 01884129 DE 31 DE MARZO DE 2009

RENOVACION DE LA MATRICULA : EL 29 DE MARZO DE 2012

ULTIMO AÑO RENOVADO : 2012

CERTIFICA:

DE CONFORMIDAD CON LO ESTABLECIDO EN EL CODIGO DE PROCEDIMIENTO ADMINISTRATIVO Y DE LO CONTENCIOSO Y DE LA LEY 1962 DE 2005, LOS ACTOS ADMINISTRATIVOS DE REGISTRO AQUÍ CERTIFICADOS QUEDAN EN FIRME DIEZ (10) DIAS HABILES DESPUES DE LA FECHA DE INSCRIPCIÓN, SIEMPRE QUE NO SEAN OBJETO DE RECURSOS.



* * * EL PRESENTE CERTIFICADO NO CONSTITUYE PERMISO DE * * *
* * * FUNCIONAMIENTO EN NINGUN CASO * * *

INFORMACION COMPLEMENTARIA

LOS SIGUIENTES DATOS SOBRE PLANEACION DISTRITAL SON INFORMATIVOS
FECHA DE ENVIO DE INFORMACION A PLANEACION DISTRITAL : 13 DE ABRIL DE 2010

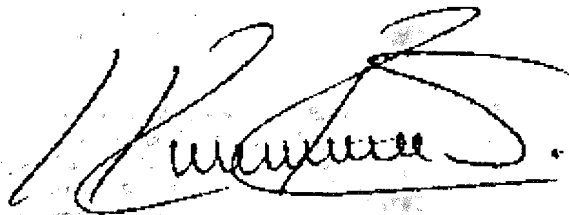
SEÑOR EMPRESARIO, SI SU EMPRESA TIENE ACTIVOS INFERIORES A 30.000 SMLMV Y UNA PLANTA DE PERSONAL DE MENOS DE 200 TRABAJADORES, USTED TIENE DERECHO A RECIBIR UN DESCUENTO EN EL PAGO DE LOS PARAFISCALES DE 75% EN EL PRIMER AÑO DE CONSTITUCION DE SU EMPRESA, DE 50% EN EL SEGUNDO AÑO Y DE 25% EN EL TERCER AÑO. LEY 590 DE 2000 Y DECRETO 525 DE 2009.

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CONSIGNACION	BANCO DE BOGOTA	062754387	516959063	12/12/2012	630.000.00

*** Conceptos Pagados ***

CANT.	RENTISTICO	CONCEPTO	Vr.UNDITARIO	Vr.CONCEPTO
1	50005-01-04	PRESENTACION DE OBSERVACIONES A SOLICITUDES	1632	OPOSICION NUEVA CRACION / PRESENTACION
			315.000.00	315.000.00
				\$315.000.00

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United States Patent [19]

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Bystrom et al.

[45] Date of Patent: * Dec. 20, 1994

- [54] PRESERVATIVE-FREE STERILE FLUID DISPENSING SYSTEM
- [75] Inventors: Steven R. Bystrom, El Toro; Peter W. Chan, Northridge; F. Jesus Martinez, Mission Viejo, all of Calif.
- [73] Assignee: JSP Partners, L.P., Northridge, Calif.
- [*] Notice: The portion of the term of this patent subsequent to May 10, 2011 has been disclaimed.
- [21] Appl. No.: 39,655
- [22] Filed: Mar. 30, 1993

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Attorney, Agent, or Firm—Robbins, Berliner & Carson

Related U.S. Application Data

- [63] Continuation-in-part of Ser. No. 792,989, Nov. 15, 1991, Pat. No. 5,310,094.
- [51] Int. Cl.⁵ B65D 37/00
- [52] U.S. Cl. 222/212; 137/512; 137/846; 222/1; 222/476; 222/494
- [58] Field of Search 222/189, 212, 215, 476, 222/487, 494, 1; 137/512, 846, 849

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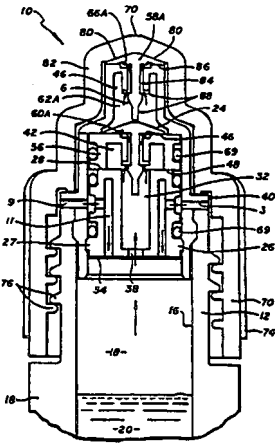
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[57] ABSTRACT

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 either positive acting, normally closed duckbill and/or umbrella valve(s) 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. The fluid dispensing system with an umbrella valve near the system outlet has close to zero dead space volume thereby practically eliminated possible contamination of the sterile fluid under the circumferential seal head portion of the umbrella valve and in the container. A hydrophobic filter is provided to sterilize the replacement air which enters the container upon release of the squeezing pressure.

53 Claims, 3 Drawing Sheets



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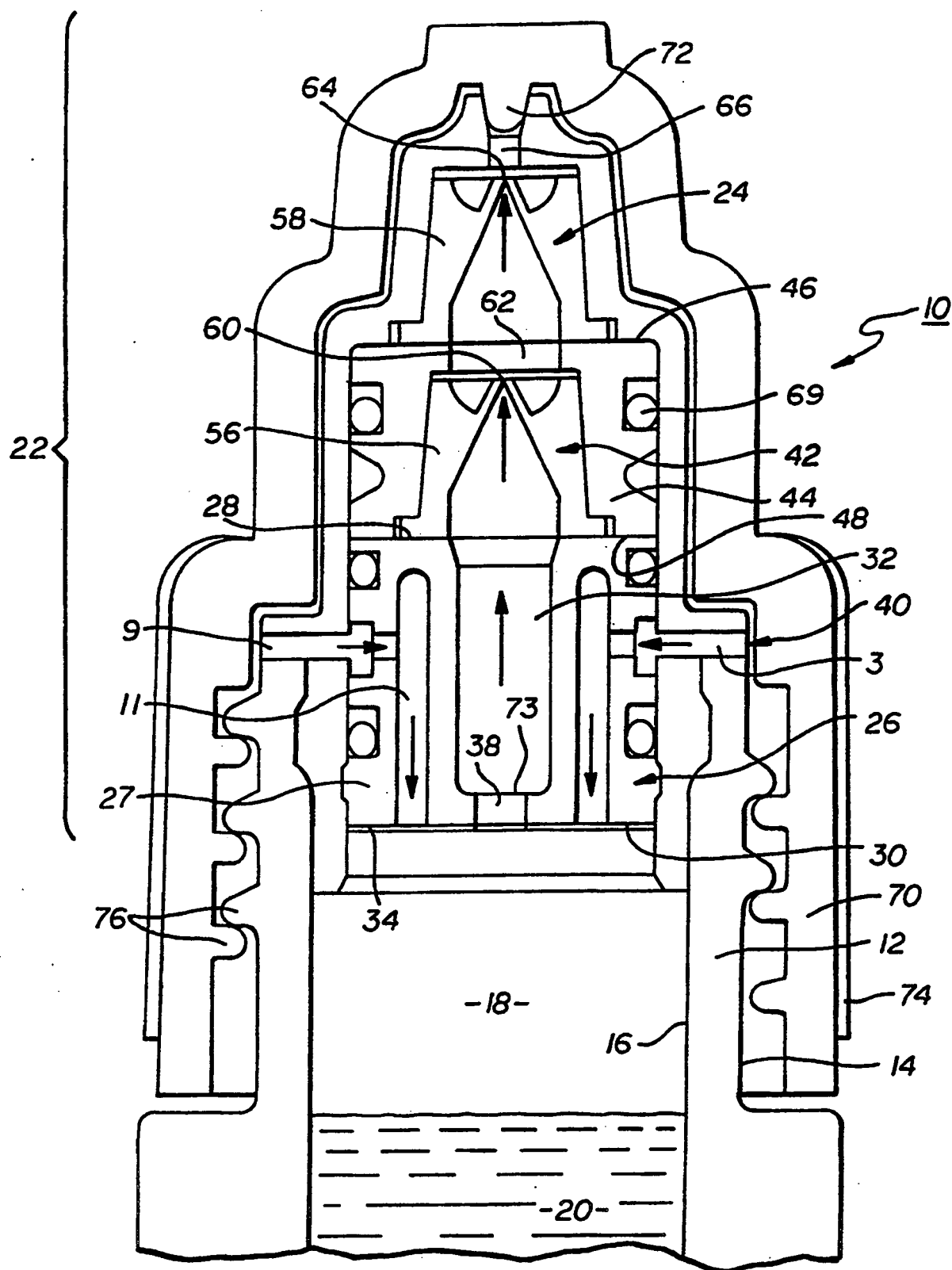
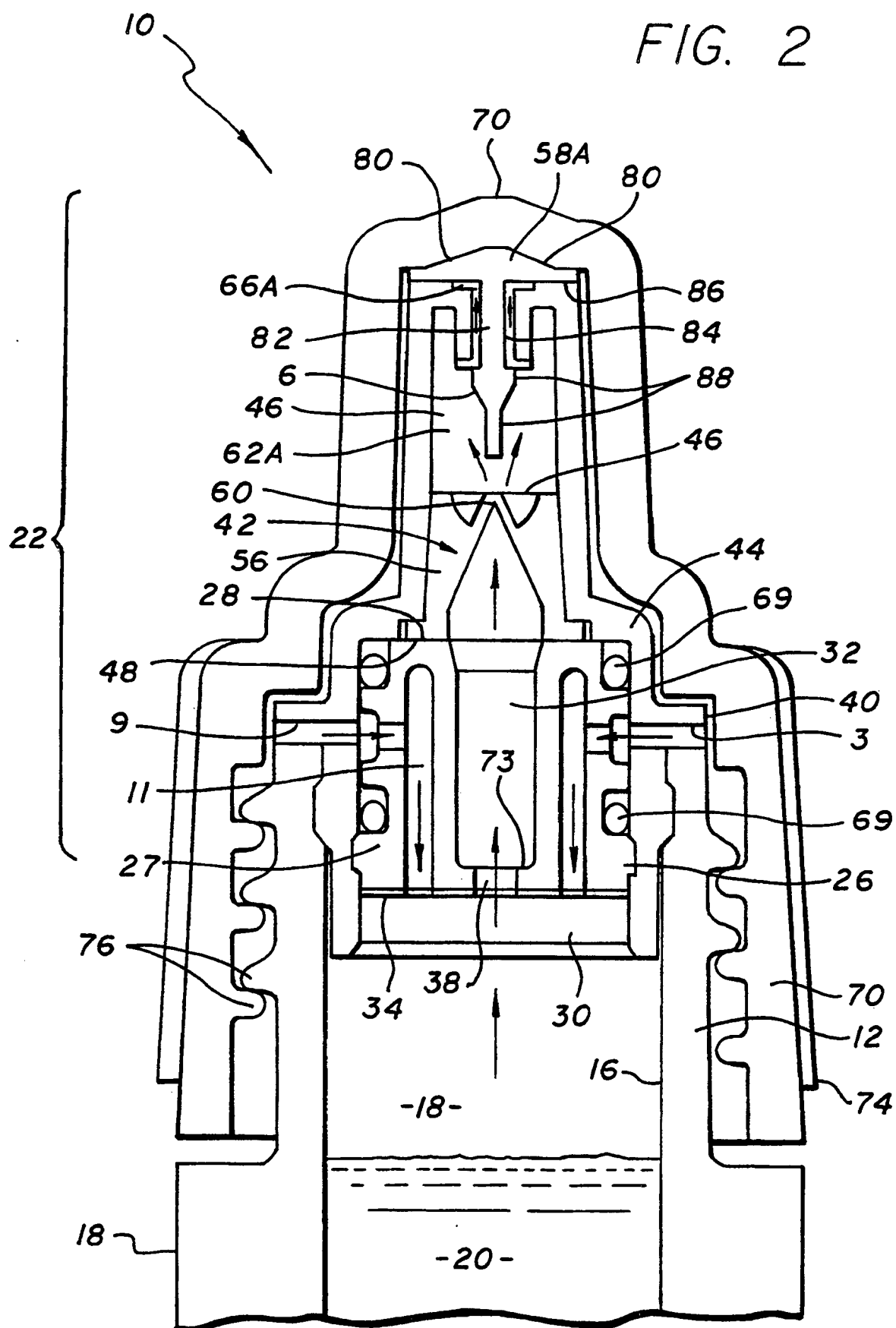
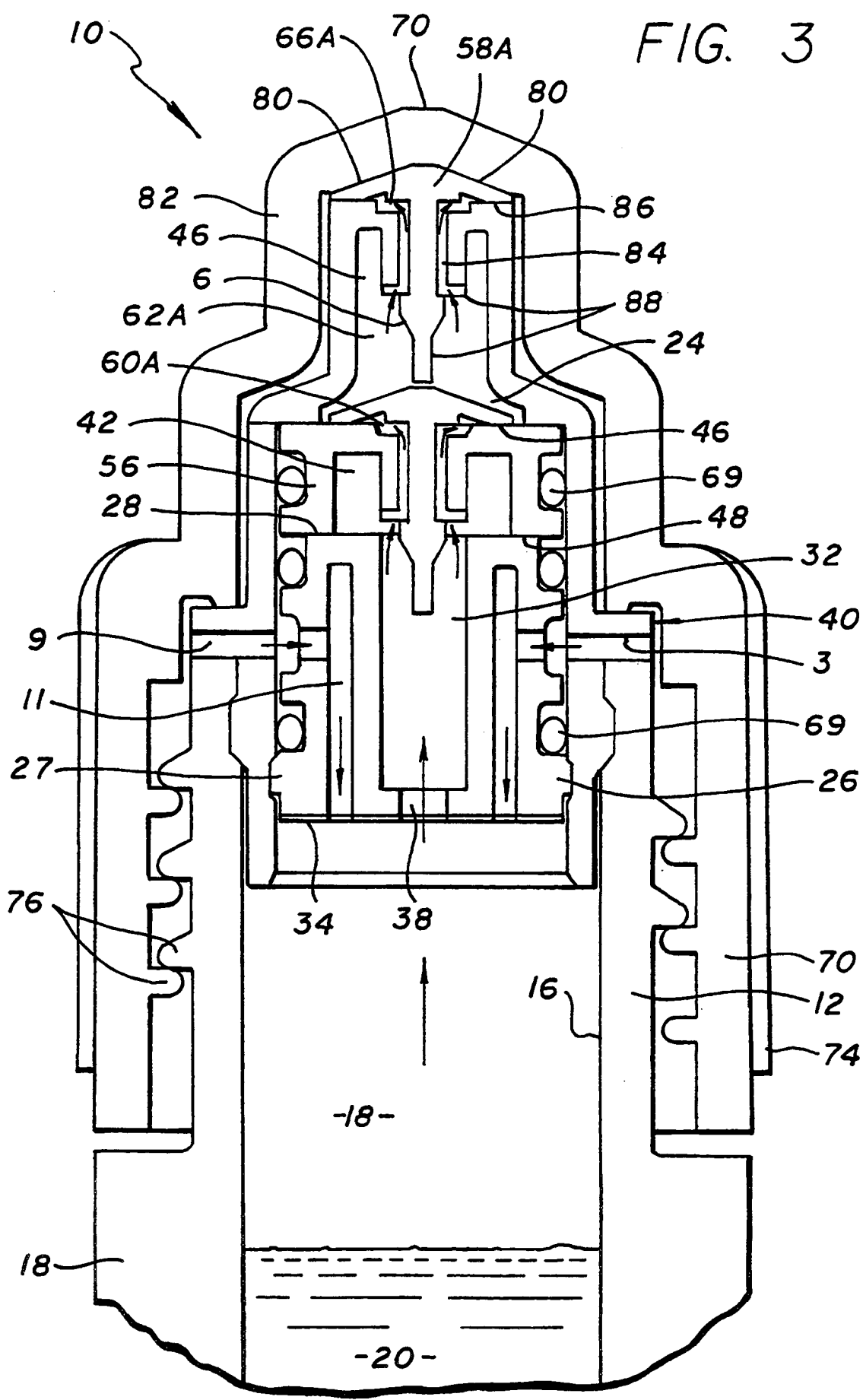


FIG. 1





PRESERVATIVE-FREE STERILE FLUID DISPENSING SYSTEM

This application is a continuation-in-part of parent U.S. application Ser. No. 07/792,989, filed Nov. 15, 1991, now U.S. Pat. No. 5,310,094.

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 with about zero dead space volume 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.

As used herein, the term "dead space" means the space which is formed by the tip compartment surrounding the system outlet on the outside of the contamination after stops at the closure of the top self-sealing valve.

As used herein, the term "dead space volume" means the volume of area which lies within this "dead space" which contains and allows remaining fluid to be exposed to the outside environment through the system outlet.

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 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 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 deliver 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. Patent 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.

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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.

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 duckbill and/or umbrella valve(s) positioned between the system fluid outlet and a hydrophobic filter positioned at the end of the air inlet passageway, the duckbill and/or umbrella valve(s) being openable upon the application of pressure built up within the container and being automatically sealed upon release of the pressure.

It is another object of the present invention to provide a novel fluid dispensing system with about zero dead space volume having a container with a system outlet and an air passageway, positive acting, normally closed umbrella valve(s) in combination with or without a duckbill valve positioned between the system fluid outlet and a hydrophobic filter positioned at the end of the air inlet passageway, the umbrella valve(s) and/or the duckbill valve being operable 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

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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 one embodiment of the present invention showing a preservative-free sterile fluid dispensing system with two duckbill valves in series; and

FIG. 2 is a perspective cross-sectional view of another embodiment of the present invention showing the preservative-free sterile fluid dispensing system with one duckbill valve in series with an umbrella valve.

FIG. 3 is a perspective cross-sectional view of yet another embodiment the present invention showing the preservative-free sterile fluid dispensing system with two umbrella valves in series.

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 cm² and preferably about 0.13 cm². 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 56 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 X6079 and can be obtained from Vernay Laboratories, Inc. While a duckbill valve is described and disclosed in the drawings herein, it should be appreciated that any suitable one-way self-sealing valve may be utilized in the present invention. 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 (membrane housing), 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, 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.

When two duckbill type self-sealing valves are used as in the present preferred embodiment, a dead space of about 5.36 μ l is calculated when a cap 70 with bayonet extension 72 is in position of closing off the system outlet 66. A dead space of 6.4 μ l is calculated for the system without the cap 70 in place over the system outlet 66.

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 the 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.

FIG. 2 shows another embodiment of the preservative-free fluid dispensing system 10 having a dual self-sealing valve dispensing assembly 24 with the second self-sealing duckbill valve 58 (as shown in FIG. 1), replaced with an umbrella valve 58A, such as are known in the art. As can be seen clearly in FIG. 2, umbrella valve 58A is comprised of a circumferential seal head portion 80 attached to a stem portion 82 which slidably is positioned in a bore 84 through a top wall 86 of the container. A biasing member 88, in the form of an elastomeric spring and a lock step holds umbrella valve 58A in the position shown in FIG. 2. During the dispensing cycle, according to the manner previously described with the first embodiment, container 12 is squeezed in an inverted position with sterile fluid 20, flowing through central solution flowport 38, through

outlet 60 of first self-sealing valve 56, through inlet 62A of umbrella valve 58A and finally through an opening 66A formed by the upward movement of the head portion of the umbrella valve. Once the solution is dispensed from container 18, upon the release of pressure, 5 biasing member 88 would force umbrella valve 58A back to a covering relation over the bore 84.

The unique design of the umbrella valve 58A allows the sterile fluid 20 to pass through a center shaft with the stem of the umbrella at its center position. In addition, the umbrella valve 58A is positioned close to the top of the tip compartment 22. In such embodiments, the preservative-free fluid dispensing system has dead space volume close to zero. This is because the pressure of the container 12 during compression provides for a 10 spontaneous expulsion of fluid 20, while release of the pressure during decompression causes a spontaneous closure of the 360° opening of the circumferential seal head position 80 of the umbrella valve 58A. Thus the umbrella valve 58A only opens as the fluid 20 is allowed 15 to flow out during the pressurized phase of fluid expulsion. At closure, all fluid 20 is isolated from the outside, thereby preventing possible contamination of the sterile fluid 20 under the circumferential seal head position 80 of the umbrella valve 58A and in the container. 20

Pressure equilibrium during the decompression stage is similar to before, 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 against circumferential seal 80 on membrane housing body 26. 25

FIG. 3 shows yet another embodiment of the preservative-free fluid dispensing system 10 having a dual self-sealing valve dispensing assembly 24 with both the first and second self-sealing valve being that of an umbrella type. As can be seen clearly in FIG. 3, two umbrella valves 56A and 58A are used to dispense sterile preservative-free eye care fluids from the container 12. The dispensing cycle of the dual umbrella-valve dispensing system is essentially similar to that of the first and second embodiments described above. 30

EXAMPLES

The performance of the dual self-sealing valve dispensing assembly was tested under the following conditions: 35

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 robing 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 calorimetric 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- 40 45 50 55 60 65

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. 15 20 25

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 cm² 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. 30 35 40 45 50

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. 55 60

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 65

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; wherein said second sealing valve is a normally closed umbrella valve; 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 about 0.01 to about 1 micron.

9. A fluid dispensing system of claim 24, 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 26, 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 cm².

11. 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 0.2 cm².

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 cap is further provided with antislip knurls and threads for sealing to said outlet.

15. A fluid dispensing system of claim 16, 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.

16. 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;

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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;
- 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 0.2 cm²;
- 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; and
- a second normally closed umbrella 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 umbrella valve to allow the solution to pass through.

17. 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;

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- 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; wherein said first self-sealing valve is a normally closed umbrella valve;
- 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; wherein said second sealing valve is a normally closed umbrella valve; and
- a system outlet from which the solution from an outlet of said second umbrella valve passes through.

18. A fluid dispensing system of claim 17, wherein said membrane housing is constructed of a thermoplastic material.

19. A fluid dispensing system of claim 18, wherein said thermoplastic material is selected from the group consisting of polyethylene, polypropylene, polystyrene, ethylene-vinyl acetate and combinations thereof.

20. A fluid dispensing system of claim 18, wherein said hydrophobic support is constructed of a thermoplastic material.

21. A fluid dispensing system of claim 20, wherein said thermoplastic material is selected from the group consisting of polyethylene, polypropylene, polystyrene, ethylene-vinyl acetate and combinations thereof.

22. A fluid dispensing system of claim 20, wherein said hydrophobic membrane is constructed of a hydrophobic polymer.

23. A fluid dispensing system of claim 22, wherein said hydrophobic polymer is selected from the group consisting of polyfluorolefins, polyolefins and combinations thereof.

24. A fluid dispensing system of claim 22, wherein said hydrophobic membrane further has a pore size about 0.01 to about 1 micron.

25. A fluid dispensing system of claim 23, wherein said hydrophobic membrane further has a pore size about 0.2 to about 0.24 micron.

26. A fluid dispensing system of claim 24, 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 cm².

27. A fluid dispensing system of claim claim 26, wherein said hydrophobic membrane is suitable for resisting the passage of bacterial and microbial contamination and has a surface area of about 0.2 cm².

28. A fluid dispensing system of claim 25, wherein said housing support is constructed of polyolefins and combinations thereof.

29. A fluid dispensing system of claim 28, wherein said cap is further provided with antislip knurls and threads for sealing to said outlet.

30. A fluid dispensing system of claim 29, wherein said cap is further rendered bactericidal with an agent selected from the group consisting of silver oxide, gold oxide and copper oxide.

31. 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;
- 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 0.2 cm²;
- 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 umbrella valve hermetically sealed to said bottom surface of said housing support; and
- a second normally closed umbrella valve hermetically sealed to said top surface of said valve housing support and in series with said first normally closed umbrella valve wherein an outlet of said first normally closed umbrella valve opens to an outlet of said second normally closed umbrella valve to allow the solution to pass through.

32. A method for dispensing sterile preservative-free solution comprising the steps of:

- (a) storing a sterilize solution in a container having an outer surface and an inner surface; said container further having a tip compartment adapted to dispense the sterilize solution;
- (b) compressing said container to dispense the sterilize solution through a dual self-sealing valve dis-

pensing 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 front 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; wherein said second sealing valve is a normally closed umbrella valve; and
 - a system outlet from which the solution from an outlet of said second valve passes through;
 - (c) releasing the pressure in said container so as to return said container to its original state.
33. A method for dispensing sterile preservative-free solution comprising the steps of:
- (a) storing a sterilize solution in a container having an outer surface and an inner surface; said container further having a tip compartment adapted to dispense the sterilize solution;
 - (b) compressing said container to dispense the sterilize solution through 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 comprising:
 - a membrane assembly having a polyethylene membrane housing;
 - a polyethylene hydrophobic membrane support connected to said polyethylene membrane housing;
 - 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

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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 cm²;
 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; and
 a second normally closed umbrella 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 umbrella valve to allow the solution to pass through.

34. A method for dispensing sterile preservative-free solution comprising the steps of:
 (a) storing a sterilize solution in a container having an outer surface and an inner surface; said container further having a tip compartment adapted to dispense the sterilize solution;
 (b) compressing said container to dispense the sterilize solution through 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; wherein said first self-sealing valve is a normally closed umbrella valve;
 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

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second valve to allow the solution to pass through; wherein said second sealing valve is a normally closed umbrella valve; and
 a system outlet from which the solution from an outlet of said second umbrella valve passes through;
 (c) releasing the pressure in said container so as to return said container to its original state.

35. A method for dispensing sterile preservative-free solution comprising the steps of:
 (a) storing a sterilize solution in a container having an outer surface and an inner surface; said container further having a tip compartment adapted to dispense the sterilize solution;
 (b) compressing said container to dispense the sterilize solution through 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;
 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 cm²;
 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 umbrella valve hermetically sealed to said bottom surface of said housing support; and
 a second normally closed umbrella valve hermetically sealed to said top surface of said valve housing support and in series with said first normally closed umbrella valve wherein an outlet of said first normally closed umbrella valve opens to an outlet of said second normally closed umbrella valve to allow the solution to pass through;
 (c) releasing the pressure in said container so as to return said container to its original state.

36. 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; wherein said first self-sealing valve is a normally closed umbrella valve;
 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.

37. A fluid dispensing system of claim 36, wherein said membrane housing is constructed of a thermoplastic material.

38. A fluid dispensing system of claim 37, wherein said thermoplastic material is selected from the group consisting of polyethylene, polypropylene, polystyrene, ethylene-vinyl acetate and combinations thereof.

39. A fluid dispensing system of claim 37, wherein said hydrophobic support is constructed of a thermoplastic material.

40. A fluid dispensing system of claim 39, wherein said thermoplastic material is selected from the group consisting of polyethylene, polypropylene, polystyrene, ethylene-vinyl acetate and combinations thereof.

41. A fluid dispensing system of claim 39, wherein said hydrophobic membrane is constructed of a hydrophobic polymer.

42. A fluid dispensing system of claim 41, wherein said hydrophobic polymer is selected from the group consisting of polyfluorolefins, polyolefins and combinations thereof.

43. A fluid dispensing system of claim 43, wherein said hydrophobic membrane further has a pore size about 0.01 to about 1 micron.

44. A fluid dispensing system of claim 42, wherein said hydrophobic membrane further has a pore size of about 0.2 to about 0.24 micron.

45. A fluid dispensing system of claim 44, 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 cm².

46. A fluid dispensing system of claim 45, wherein said hydrophobic membrane is suitable for resisting the passage of bacterial and microbial contamination and has a surface area of about 0.2 cm².

47. A fluid dispensing system of claim 44, wherein said housing support is constructed of polyolefins and combinations thereof.

48. A fluid dispensing means of claim 47, wherein said second-sealing valve is a normally closed deformable duckbill valve.

49. A fluid dispensing system of claim 48, wherein said cap is further provided with antislip knurls and threads for sealing to said outlet.

50. A fluid dispensing system of claim 49, 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.

51. 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;
 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 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 0.2 cm²;
 a passageway located in said hydrophobic membrane support the 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 umbrella valve hermetically sealed to said bottom surface of said housing support; and

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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 umbrella valve wherein an outlet of said first normally closed umbrella valve opens to an outlet of said second normally closed deformable self-sealing duckbill valve to allow the solution to pass through.

52. A method for dispensing sterile preservative-free solution comprising the steps of:

(a) storing a sterilize solution in a container having an outer surface and an inner surface; said container further having a tip compartment adapted to dispense the sterilize solution;

(b) compressing said container to dispense the sterilize solution through 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; wherein said first sealing valve is a normally closed umbrella valve;

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;

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(c) releasing the pressure in said container so as to return said container to its original state.

53. A method for dispensing sterile preservative-free solution comprising the steps of:

(a) storing a sterilize solution in a container having an outer surface and an inner surface; said container further having a tip compartment adapted to dispense the sterilize solution;

(b) compressing said container to dispense the sterilize solution through 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 comprising:

a membrane assembly having a polyethylene membrane housing;

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

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 0.2 cm²;

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 umbrella valve hermetically sealed to said bottom surface of said housing support; and

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 umbrella valve wherein an outlet of said first normally closed umbrella valve opens to an outlet of said second normally closed deformable self-sealing valve to allow the solution to pass through;

(c) releasing the pressure in said container so as to return said container to its original state.

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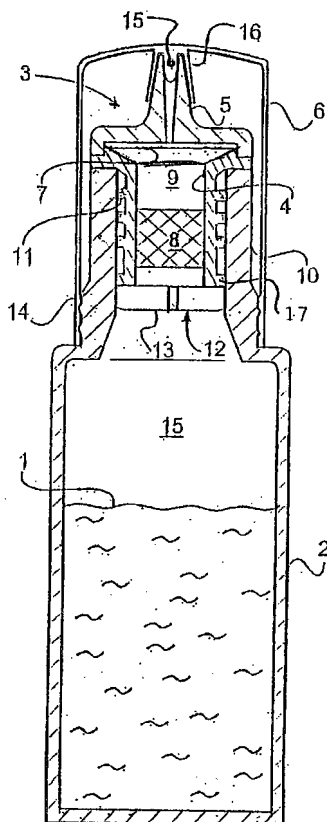
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(54) Title: CONTAINER FOR PACKAGING A LIQUID TO BE DISPENSED IN DROPS REVERSIBLY DEFORMED BY AIR INPUT

(54) Titre : RÉCIPIENT POUR LE CONDITIONNEMENT D'UN LIQUIDE A DISTRIBUER GOUTTE A GOUTTE, A DE-
FORMATION REVERSIBLE PAR ADMISSION D'AIR



(57) Abstract: The invention concerns a container for packaging a liquid (1) to be dispensed in drops, said container being reversibly deformed by air input and being equipped with a head (3) for dispensing liquid through a nozzle (5). The latter (3) comprises a recessed body (4) which is nested inside a neck (10) of the container and which holds a hydrophobic microporous pad (8) arranged upstream of a chamber (9). Said chamber (9) is provided with an air reservoir for preventing the liquid from passing through the microporous pad between two liquid dispensing operations when the nozzle (5) is sealingly obstructed with a cap (6) and for drying a partly hydrophilic and hydrophobic filtering membrane (7) arranged in the dispensing head (3).

(57) Abrégé : L'invention a pour objet un récipient pour le conditionnement d'un liquide (1) à distribuer goutte à goutte, ce récipient étant à déformation réversible par admission d'air et étant équipé d'une tête (3) de distribution du liquide à travers une buse (5). Cette dernière (3) comporte un corps évidé (4) qui est emboîté à l'intérieur d'un col (10) du récipient et qui loge un tampon microporeux hydrophobe (8) disposé en amont d'une chambre (9). Cette chambre (9) ménage une réserve d'air pour, entre deux opérations de distribution de liquide, empêcher le liquide de traverser le tampon microporeux lorsque la buse (5) est obstruée de façon étanche par un capuchon (6) et assécher une membrane filtrante partiellement hydrophile et hydrophobe (7) que comporte la tête de distribution (3).

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En ce qui concerne les codes à deux lettres et autres abréviations, se référer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.

**RECIPIENT POUR LE CONDITIONNEMENT D'UN LIQUIDE A
DISTRIBUER GOUTTE A GOUTTE, A DEFORMATION
REVERSIBLE PAR ADMISSION D'AIR**

L'invention est du domaine du conditionnement et de la
5 distribution de liquides, tels que des solutions pharmaceutiques et
notamment des collyres. Elle a pour objet un récipient équipé d'une
tête de distribution, qui est organisé pour contenir un liquide en le
protégeant du milieu extérieur et pour délivrer ce liquide de manière
contrôlée, goutte à goutte notamment.

10 On connaît des récipients pour contenir un liquide, qui sont
organisés pour préserver ce liquide du milieu extérieur et pour le
délivrer de manière contrôlée, goutte à goutte notamment. Les
applications de tels récipients sont nombreuses, et une application
privilegiée, mais non restrictive quant à la portée de la présente
15 invention, réside dans la conservation et la distribution d'une
solution pharmaceutique, collyre notamment.

Au regard de la préservation du liquide, celui-ci doit être
protégé du milieu extérieur en évitant son contact avec l'air ambiant
qui est susceptible de contenir des agents polluants, bactéries
20 notamment. Pour la distribution du liquide, il est commun de
conférer au récipient un caractère déformable permettant de réduire
sa capacité, au moins temporairement, pour évacuer le liquide qu'il
contient. De tels récipients sont plus précisément à paroi souple,
pour provoquer une évacuation du liquide à partir d'une compression
25 exercée par l'utilisateur sur cette paroi, et ils sont équipés d'une
tête de distribution, pour atteindre les deux objectifs que sont la
préservation et la distribution contrôlée du liquide.

Cependant, les solutions apportées pour parvenir
spécifiquement à l'un et l'autre de ces objectifs sont susceptibles
30 d'être antagonistes, et les efforts des concepteurs dans le domaine
portent notamment sur la recherche d'un compromis entre les
différentes solutions. Il doit en outre être pris en compte une
structure souhaitée simple du récipient, dont le coût d'obtention ne

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doit pas être rédhibitoire eu égard à son caractère consommable, et dont l'utilisation doit être commode pour l'utilisateur.

On notera à ce stade de la description qu'il est commun dans le domaine d'utiliser une membrane filtrante pour empêcher le
5 passage d'agents polluants depuis l'extérieur du récipient vers le liquide qu'il contient. Cette membrane, placée au voisinage d'une buse que comporte la tête de distribution pour l'évacuation du liquide hors du récipient, autorise un passage du liquide à son travers sous l'effet de la compression exercée dans le récipient par
10 déformation de la paroi.

Selon une première approche, il a été proposé de conférer au récipient un caractère déformable irréversible, ou quasiment irréversible. Une paroi interne du récipient délimitant la capacité de réception du liquide est organisée en soufflet, et est enveloppée
15 d'une gaine extérieure. Ce récipient contient en outre une membrane filtrante qui présente un caractère imperméable à l'air, pour interdire une admission d'air extérieur vers le liquide contenu dans le récipient, sous l'effet d'un retrait de liquide délivré. On pourra par exemple se reporter aux documents de brevets FR 2 661 401 et
20 FR 2 770 495 (ou US 6,336,571), qui décrivent de tels récipients.

Se pose le problème à résoudre de la délivrance contrôlée du liquide. Selon le document FR 2 770 495 (US 6,336,571), un tampon microporeux jouant un rôle de régulateur de flux est disposé dans la tête de distribution d'un récipient à paroi à déformation
25 rigoureusement irréversible. Une réserve intermédiaire est ménagée en aval du tampon et en amont d'une membrane filtrante imperméable à l'air. Un tel récipient présente une structure complexe, et le coût de fabrication, tant du réservoir destiné à contenir le liquide à distribuer que de la tête de distribution, est
30 élevé. De plus, il n'est pas possible au moyen d'un tel récipient à paroi à déformation irréversible de distribuer l'intégralité du liquide contenu dans le réservoir. En effet, la forme en soufflets ne permet pas d'expulser les dernières gouttes, si bien qu'une partie du liquide est gaspillé.

35 Selon une deuxième approche, il a été proposé de conférer

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au récipient une faculté de déformation réversible. On pourra notamment se reporter au document FR 2 816 600 (ou US 2004/0074925), qui décrit un tel récipient. La structure de la tête de distribution de ce récipient est simple. Elle contient une membrane
5 filtrante qui vise à préserver le liquide des agents polluants susceptibles d'être présents dans l'air ambiant. Il est en outre prévu de préserver rigoureusement le liquide du milieu ambiant avant une première utilisation. A cet effet, la tête de distribution est montée mobile sur le col du récipient, en vue de la perforation d'un opercule
10 extemporanément à une première opération de délivrance. Il ressort cependant de cet aménagement, et plus particulièrement de la mobilité de la tête de distribution par rapport au récipient, un risque d'une perte d'étanchéité entre eux après perforation de l'opercule et assemblage par l'utilisateur de la tête de distribution à l'intérieur
15 d'un col du récipient, par emboîtement étroit notamment. Si ce risque peut être réduit, une telle démarche tend à accroître la complexité de la tête de distribution, au détriment de l'intérêt premier recherché de sa simplicité de structure. En outre, la présence résiduelle de l'opercule est susceptible de former un
20 obstacle inopportun à la délivrance contrôlée du liquide.

Il en ressort que les concepteurs du domaine restent confrontés à un compromis à trouver entre simplicité de la tête de distribution, préservation du liquide vis-à-vis d'agents polluants éventuellement présents dans l'air ambiant, faculté de dosage du
25 liquide délivré, et utilisation optimale de tout le liquide contenu dans le réservoir.

La présente invention s'inscrit dans cette recherche de compromis, et vise à proposer un récipient pour le conditionnement d'un liquide à distribuer goutte à goutte qui offre une solution
30 répondant à un tel compromis. L'invention s'inscrit plus spécifiquement dans le conditionnement d'un liquide sensible, tel qu'une solution pharmaceutique, biologique ou analogue, collyre notamment.

La démarche inventive de la présente invention a consisté
35 dans sa généralité, à choisir en premier lieu un récipient du type

comportant un réservoir à paroi à déformation élastiquement réversible par admission d'air à l'intérieur du récipient. Ce choix vise à permettre une délivrance du liquide sous l'effet d'une pression exercée contre cette paroi, et à autoriser un retour spontané du récipient à sa conformation initiale après délivrance d'une dose de liquide. Un tel réservoir à paroi à déformation réversible présente déjà en lui-même l'avantage d'une grande simplicité de fabrication, par rapport aux réservoirs à déformation irréversible de l'art antérieur, qui nécessitent un nombre de pièces et d'opérations d'assemblage important.

Dans sa généralité, on reconnaîtra un tel récipient selon la présente invention en ce qu'il est équipé d'une tête de distribution comprenant un corps évidé qui est muni d'une buse de délivrance du liquide et qui contient un tampon microporeux en matière hydrophobe placé en aval du réservoir en travers du corps de la tête de distribution. Ledit corps est assemblé de manière irréversible à l'intérieur du col du récipient.

Par ailleurs, il est proposé d'équiper le récipient d'un capuchon amovible d'obturation étanche de la buse qui, associé audit tampon microporeux en matière hydrophobe, fait obstacle à l'écoulement spontané du liquide hors de la capacité du récipient réservée à son stockage vers la buse. Ces dispositions sont telles que le passage spontané du liquide à travers le tampon microporeux hydrophobe est interdit lorsque le capuchon obture de manière étanche la buse, et cela pendant toute la durée d'utilisation du récipient. Inversement, le libre écoulement du liquide hors de la capacité du récipient réservée à son stockage, à travers le tampon microporeux hydrophobe, est autorisé lorsque la buse est dégagée, en vue de la délivrance souhaitée d'une dose de liquide par pression exercée contre la paroi du récipient. En outre, le passage de l'air est autorisé par aspiration à travers le tampon microporeux hydrophobe vers la capacité de stockage après délivrance d'une dose de liquide, cette aspiration étant provoquée par le retour élastique de la paroi du récipient à sa conformation initiale, retour par lequel le récipient reprend sa forme initiale nonobstant un retrait d'une dose de liquide.

On notera que le tampon microporeux est de préférence réalisé en polyéthylène, ou matériau analogue, qui lui confère un caractère hydrophobe de sorte qu'il ne soit pas mouillable, son caractère microporeux autorisant néanmoins le passage du liquide à son travers à condition que le différentiel de pression, induit par la pression exercée par l'utilisateur, soit suffisant.

Une telle configuration du récipient selon l'invention, et plus particulièrement la combinaison entre le réservoir à déformation réversible, le tampon microporeux et le capuchon d'obturation étanche, est tout à fait avantageuse. En effet, lorsque le capuchon est remis en position d'obturation étanche de la buse, après l'aspiration d'air consécutive à la délivrance d'une dose de liquide et le retour élastique de la paroi du récipient à sa conformation initiale, il se crée une différence de pression entre les parties en amont et en aval du tampon à travers lequel il se crée une perte de charge. Cette différence de pression empêche le liquide contenu dans le récipient de passer à travers le tampon, même si on presse accidentellement sur la paroi du récipient, et elle assure l'étanchéité du flacon, tout en protégeant le liquide qu'il contient des contaminations extérieures. De plus, une telle configuration évite toute stagnation de liquide en aval du tampon, puisque le liquide non expulsé est réaspiré vers la capacité du récipient.

Le récipient selon l'invention répond avantageusement à un objectif de l'invention, qui est d'assurer une utilisation optimale de tout le contenu du réservoir, et cela de deux façons différentes. D'une part, grâce à sa paroi à déformation élastiquement réversible, le récipient conserve une capacité d'expulsion du liquide intacte jusqu'à la dernière goutte de liquide. En effet, parce que de l'air est aspiré dans le récipient en remplacement de chaque dose de liquide expulsé, la pression d'expulsion disponible dans le flacon est toujours la même tout au long de l'utilisation, et ce jusqu'à la distribution de la dernière goutte. D'autre part, comme il a été exposé précédemment, il ne subsiste en aval du tampon aucune goutte de liquide susceptible d'être contaminée par des agents extérieurs, et qui devrait être éliminée avant toute nouvelle distribution d'une dose propre.

En outre, le tampon microporeux, à travers lequel se crée une perte de charge, joue un rôle de régulateur de flux, qui favorise la distribution contrôlée de doses de liquide. De plus, il empêche que le liquide contenu dans le flacon s'écoule lorsque le bouchon
5 est ôté, et ce même lorsque le flacon est en position retournée, la tête de distribution étant dirigée vers le bas, tant qu'aucune pression n'est exercée sur la paroi du récipient.

Dans le cadre d'une application du récipient à un liquide sensible, solution pharmaceutique notamment, la tête de distribution
10 est préférentiellement équipée d'une membrane filtrante destinée à protéger le liquide d'une admission d'agents polluants présents dans l'air ambiant, bactéries notamment. Suivant l'invention, on choisit alors une membrane au moins en partie hydrophile et au moins en partie hydrophobe, pour autoriser alternativement le passage du
15 liquide et de l'air à son travers, et que l'on dispose dans la tête de distribution en amont de la buse, entre celle-ci et le tampon. Le caractère partiellement hydrophile de la membrane permet de laisser passer le liquide à son travers sous l'effet de la compression exercée dans le récipient par déformation de la paroi, alors que son
20 caractère partiellement hydrophobe autorise une entrée de l'air extérieur dans le récipient, quand ce dernier reprend élastiquement sa forme initiale après chaque compression exercée par l'utilisateur.

La membrane constitue en outre avantageusement une perte de charge supplémentaire, qui assure, en combinaison avec le
25 tampon microporeux hydrophobe, qu'aucune fuite de liquide hors du récipient ne se produise tant que l'on ne comprime pas la paroi du récipient.

Afin de favoriser le passage de l'air à travers la membrane, l'invention prévoit alors qu'il soit possible de maintenir cette
30 membrane sèche entre deux délivrances de liquide, quand le récipient est en position reposée sur sa base, grâce à la présence d'une chambre intercalaire ménagée en interposition entre le tampon microporeux et la membrane. Une telle chambre intercalaire peut aussi être mise à profit pour constituer une chambre de
35 régularisation de la délivrance du liquide. A cet effet, on peut

avantageusement lui donner un volume suffisant pour collecter au moins une goutte de liquide à distribuer lors d'une opération de délivrance du liquide pour le faire sortir goutte à goutte de la tête de distribution.

- 5 Le volume de la chambre intercalaire constitue en outre et avantageusement une réserve d'air qui, quand la buse est obturée par le capuchon, conserve une pression qui tend à empêcher le liquide de passer à travers le tampon microporeux. On notera qu'en association avec la chambre intercalaire, le caractère hydrophobe
10 du tampon microporeux favorise un rôle d'obstacle s'opposant au passage du liquide à son travers.

- La chambre intercalaire constitue en outre et avantageusement une capacité pour accueillir le liquide n'ayant pas encore traversé la membrane quand on cesse d'exercer une pression
15 sur la paroi du récipient. Pour cela, il est avantageux de s'assurer que la chambre intercalaire s'étende sur toute la surface de la membrane et qu'elle soit située à une distance axiale d'elle suffisante pour favoriser l'assèchement de la membrane dès lors que la pression exercée sur la paroi du récipient cesse après une
20 délivrance de liquide, et que ce récipient est ramené dans sa position de repos, en appui sur sa base et la tête de distribution en haut. Il en résulte que tout reliquat de liquide qui, n'ayant pas été expulsé, reste contenu dans la chambre intercalaire, ne perdure pas à mouiller la membrane par capillarité. On notera que le caractère
25 hydrophobe du tampon microporeux favorise aussi l'assèchement de la membrane.

- Par ses différentes caractéristiques, telles qu'elles ont été évoquées ci-avant et qu'elles seront plus complètement définies et décrites ci-après, l'invention a l'avantage, dans la pratique
30 industrielle, de s'affranchir des systèmes complexes de fermeture dynamique que l'on utilisait antérieurement. Grâce aux dispositions prévues par l'invention, il n'est besoin ni d'un opercule ou autre cloison déchirable, ni d'un clapet d'autre forme, ni d'une procédure d'ouverture du flacon par translation ou rotation de la tête de
35 distribution par rapport au récipient réservoir de liquide à distribuer

goutte à goutte.

On relèvera en particulier la combinaison avantageuse de la présence du tampon microporeux à caractère hydrophobe, de celle de la membrane filtrante, et de celle de la chambre intercalaire
5 entre eux, qui confèrent conjointement à la tête de distribution à la fois une fonction de régularisation du flux de liquide lors de l'expulsion de ce dernier et une fonction d'obturation et d'assèchement de la membrane en combinaison avec la pression de l'air retenu dans la chambre intercalaire en raison de la fermeture
10 étanche du capuchon sur la tête de distribution.

Un tampon microporeux tout à fait approprié dans le cadre de l'invention présente, pour le passage du liquide dans la direction longitudinale, des microcanaux dont le diamètre de pores moyen est compris entre 0,3 et 10 microns.

15 Une telle fourchette de valeurs est notamment particulièrement appropriée dans le domaine d'application privilégié de l'invention, qui est la conservation et la distribution d'une solution pharmaceutique, notamment de collyre.

En outre, elle assure que le tampon produira une perte de
20 charge suffisante pour isoler la membrane du liquide contenu dans le récipient avant la première utilisation. On évite de ce fait avantageusement que la membrane se dégrade au contact du liquide lors de la phase de stockage du récipient avant la première utilisation.

25 En outre, il est tout à fait avantageux dans le cadre de l'invention d'associer un tel tampon microporeux avec une membrane partiellement hydrophile et partiellement hydrophobe dont le diamètre de pores est inférieur à celui du tampon, notamment compris entre 0,1 et 0,2 microns. On obtient de ce fait notamment
30 des propriétés d'étanchéité et de régulation de flux de la tête de distribution améliorées.

La membrane peut être réalisée en un matériau polymère, à base par exemple de résine de polyamide ou de polyéther sulfone,

qui lui donne un caractère hydrophile. Elle est alors rendue partiellement hydrophobe par modification de sa structure sur une partie de sa surface. Une telle modification peut être réalisée d'une façon classique en elle-même, par exemple par greffage en
5 présence d'un initiateur de réactions radicalaires. Le traitement est avantageusement réalisé de façon à rendre la membrane hydrophobe sur une bande médiane occupant 20 à 50 % de sa surface qui est mouillée lors de l'expulsion du liquide.

Préférentiellement, le corps est assemblé à l'intérieur du
10 col par emboîtement en contact étroit.

Le corps est de préférence élastiquement déformable pour son introduction en force à l'intérieur du col du récipient, un organe de centrage étant préférentiellement ménagé à la base du corps pour faciliter une telle introduction en force. Cet organe de centrage
15 est de préférence constitué d'ailes radiales de jonction par emboîtement du corps de la tête de distribution sur le col du récipient, les ailes délimitant entre elles des secteurs évidés.

Pour favoriser encore l'étanchéité du récipient et l'introduction en contact étroit du corps à l'intérieur du col du
20 récipient, la surface extérieure du corps de la tête de distribution est avantageusement équipée d'un jonc périphérique issu dudit corps avec lequel il constitue un ensemble monobloc, ce jonc étant de préférence en pluralité et axialement répété sur le corps.

On notera que le corps est avantageusement obtenu par
25 moulage, dans des conditions telles qu'un jonc, issu du plan de joint, soit radial à son axe général d'extension, et notamment le cas échéant parallèle au jonc périphérique précité. Ce jonc résultant du plan de joint est plus particulièrement situé à l'extrémité distale du corps, à la limite de jonction de l'organe de centrage, pour favoriser
30 au mieux l'étanchéité entre la tête de distribution et le récipient.

Le capuchon amovible quant à lui est rapporté préférentiellement sur le récipient par vissage pour favoriser le serrage du capuchon sur la tête de distribution, et donc l'étanchéité entre ces organes.

A cet effet, le capuchon comporte avantageusement une combinaison d'organes d'étanchéité associant un picot pénétrant à l'intérieur de la buse de la tête de distribution et une jupe coiffant cette buse. Le picot et la jupe sont avantageusement issus du
5 capuchon, lors de l'obtention de ce dernier d'une seule pièce, par moulage notamment.

La présente invention sera mieux comprise à la lecture de la description qui va en être faite en relation avec les figures de la planche annexée, dans laquelle :

10 La figure 1 et la figure 2 sont des schémas en coupe axiale qui illustrent un récipient pour le conditionnement d'un liquide selon des variantes respectives de réalisation de la présente invention.

La figure 3 est une vue en coupe du récipient illustré sur la figure 2, prise radialement dans la zone d'un organe de centrage
15 que celui-ci comporte.

Sur les figures 1 et 2, un récipient pour le conditionnement d'un liquide 1 est à déformation spontanément réversible, pour permettre une distribution du liquide 1 à partir d'une compression manuelle exercée par un utilisateur de sa paroi 2 et un retour
20 spontané à sa forme initiale par admission d'air. Ce récipient ménage une capacité 15 de stockage du liquide 1, et est équipé d'une tête de distribution 3 du liquide goutte à goutte. Cette tête de distribution 3 est principalement constituée d'un corps évidé 4 munie d'une buse 5, et d'un capuchon amovible 6 d'obturation de la buse
25 5. Une membrane filtrante 7 anti-bactérienne, partiellement hydrophile et partiellement hydrophobe, donc perméable à l'air mais aussi au liquide, est disposée en amont de la buse 5, pour protéger le liquide à l'encontre d'une introduction indésirable d'agents polluants éventuellement présents dans l'air ambiant, bactéries
30 notamment.

Le corps 4 de la tête de distribution 3 loge dans son évidement intérieur un tampon microporeux 8 qui est réalisé en une matière hydrophobe, notamment en polyéthylène, pour interdire le passage du liquide 1 vers la buse 5, en l'absence d'une compression

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sur la paroi 2 du récipient. Ce tampon microporeux 8 est disposé en amont et à distance de la membrane 7, de manière à ménager entre lui-même 8 et cette dernière 7 une chambre intercalaire 9.

La chambre 9 s'étend sur toute la surface du tampon de manière à constituer une réserve d'air qui exerce, quand la buse 5 est obturée par le capuchon 6, une pression sur toute la surface du tampon 8 empêchant le liquide 1 de passer à travers le tampon microporeux 8 lorsque la buse 5 est obturée par le capuchon 6. Plus précisément, le capuchon 6 fait obstacle à une évacuation de l'air hors du récipient, et plus particulièrement hors de la chambre intercalaire 9. L'air étant confiné en aval du tampon microporeux 8, ce dernier fait obstacle au passage du liquide 1 à son travers tant que la buse 5 est obturée par le capuchon 6. Inversement pour une délivrance du liquide 1, le tampon microporeux 8 ne fait pas obstacle à cette délivrance dès lors que l'air peut être évacué hors du récipient à travers la buse 5. La chambre intercalaire 9 est mise à profit pour permettre une régularisation spontanée du flux du liquide 1 traversant le tampon microporeux 8, préalablement à sa distribution à travers la buse 5.

La chambre intercalaire 9 s'étend sur toute la surface de la membrane de manière à constituer une capacité pour recueillir le liquide 1 à l'écart de la membrane 7 quand on cesse d'exercer une pression sur la paroi 2 du récipient et favoriser ainsi l'assèchement de la membrane entre deux délivrances de liquide.

Le corps 4 est assemblé à demeure à l'intérieur du col 10 du récipient, par emboîtement en force. Selon les diverses variantes illustrées sur la figure 1 et la figure 2, cet emboîtement est réalisé soit directement par contact étroit entre les surfaces extérieure du corps 4 et intérieure du col 10, tel qu'illustré sur la figure 1, soit et de préférence par l'intermédiaire de joncs toriques 11 ménagés à la périphérie du corps 4, comme il est illustré sur la figure 2. On remarquera sur ces exemples de réalisation la présence préférée d'un organe de centrage 12 ménagé à la base du corps 4 pour faciliter son introduction à l'intérieur du col 10 du récipient. L'organe de centrage 12 illustré pour exemple est globalement constitué

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d'ailes radiales de jonction 13 par emboîtement du corps 4 sur le col 10, les ailes 13 délimitant entre elles des secteurs évidés, plus particulièrement visibles sur la figure 3.

5 On relèvera enfin sur les variantes illustrées l'assemblage par vissage du capuchon 6 sur le col 10 du récipient, par l'intermédiaire de reliefs 14 coopérants. Pour faciliter le vissage du capuchon 6 sur le récipient et conforter l'étanchéité entre l'un et l'autre, le capuchon 6 comporte un picot 15 pénétrant à l'intérieur de la buse 5 de la tête de distribution et une jupe 16 coiffant la buse.

REVENDICATIONS

1. Récipient pour le conditionnement d'un liquide à distribuer goutte à goutte, caractérisé en ce qu'il comporte un réservoir à paroi (2) à déformation élastiquement réversible par admission d'air à l'intérieur du récipient, pour délivrer le liquide (1) sous l'effet d'une pression exercée contre cette paroi (2) et pour autoriser un retour spontané du récipient à sa conformation initiale après délivrance d'une dose de liquide (1), et une tête de distribution (3) comprenant un corps évidé (4) qui est muni d'une buse (5) de délivrance du liquide (1) et qui contient un tampon microporeux hydrophobe (8) placé en aval du réservoir, le corps (4) étant assemblé de manière irréversible à l'intérieur d'un col (10) du récipient, ce dernier étant en outre équipé d'un capuchon amovible (6) d'obturation étanche de la buse (5), qui associé au tampon microporeux hydrophobe (8) fait obstacle à l'écoulement spontané du liquide (1) hors de la capacité (15) du récipient réservé à son stockage vers la buse (5), de sorte qu'en premier lieu le passage spontané du liquide (1) à travers le tampon microporeux (8) soit interdit lorsque le capuchon (6) obture de manière étanche la buse (5), et qu'inversement en deuxième lieu le libre écoulement du liquide (1), hors de la capacité (15) du récipient réservée à son stockage et à travers le tampon microporeux hydrophobe (8), soit autorisé lorsque la buse (5) est dégagée en vue de la délivrance souhaitée d'une dose de liquide (1) par pression exercée contre la paroi (2) du récipient, et pour en troisième lieu autoriser le passage de l'air qui est aspiré à travers le tampon microporeux hydrophobe (8) vers la capacité de stockage (15) après délivrance d'une dose de liquide (1), par le retour élastique de la paroi (2) du récipient à sa conformation initiale.

2. Récipient pour le conditionnement d'un liquide à distribuer goutte à goutte selon la revendication 1, caractérisé en ce que le tampon microporeux (8) est réalisé en polyéthylène pour lui conférer son caractère hydrophobe, son caractère microporeux

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autorisant néanmoins le passage du liquide à travers lui sous l'effet d'un différentiel de pression induit par une pression exercée par un utilisateur contre la paroi du récipient.

5 3. Récipient pour le conditionnement d'un liquide à distribuer goutte à goutte selon la revendication 1 ou 2, caractérisé en ce que le tampon microporeux (8) présente des microcanaux dont le diamètre de pores moyen est compris entre 0,3 et 10 microns.

10 4. Récipient pour le conditionnement d'un liquide à distribuer goutte à goutte selon l'une quelconque des revendications précédentes, caractérisé en ce qu'une membrane filtrante (7) anti-bactérienne est disposée en amont de la buse (5).

15 5. Récipient pour le conditionnement d'un liquide à distribuer goutte à goutte selon la revendication 4, caractérisé en ce que ladite membrane filtrante (7) est une membrane partiellement hydrophile pour laisser passer le liquide à son travers sous l'effet de la surpression créée dans le récipient par pression de sa paroi, et partiellement hydrophobe pour autoriser le passage de l'air à son travers sous l'effet de la dépression
20 créée dans le récipient en relâchement de la pression exercée sur sa paroi.

 6. Récipient pour le conditionnement d'un liquide à distribuer goutte à goutte selon la revendication 4 ou 5, caractérisé en ce que ladite tête de distribution comporte une
25 chambre intercalaire (9) de régularisation de la délivrance du liquide, qui est ménagée en interposition entre le tampon microporeux (8) et la membrane (7).

 7. Récipient pour le conditionnement d'un liquide à distribuer goutte à goutte selon la revendication 6, caractérisé en

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ce que ladite chambre est de volume suffisant pour collecter au moins une goutte de liquide à distribuer lors d'une opération de délivrance.

5 8. Récipient pour le conditionnement d'un liquide à distribuer goutte à goutte selon la revendication 6 ou 7, caractérisé en ce que ladite chambre s'étend sur toute la surface du tampon sous un volume suffisant pour constituer une réserve d'air qui, quand la buse (5) est obturée par le capuchon (6), exerce une pression empêchant le liquide (1) de passer à travers
10 le tampon microporeux (8).

 9. Récipient pour le conditionnement d'un liquide à distribuer goutte à goutte selon l'une quelconque des revendications 6 à 8, caractérisé en ce que la chambre intercalaire (9) s'étend sur toute la surface de la membrane à une
15 distance axiale suffisante pour accueillir le liquide n'ayant pas encore traversé la membrane quand on cesse d'exercer une pression sur la paroi du récipient et favoriser ainsi l'assèchement de la membrane entre deux délivrances de liquide.

 10. Récipient pour le conditionnement d'un liquide à distribuer goutte à goutte selon l'une quelconque des revendications précédentes, caractérisé en ce que le corps (4) est
20 assemblé à l'intérieur du col (10) du récipient par emboîtement en contact étroit.

 11. Récipient pour le conditionnement d'un liquide à distribuer goutte à goutte selon la revendication 10, caractérisé
25 en ce que le corps (4) est élastiquement déformable pour son introduction en force à l'intérieur du col (10) du récipient, un organe de centrage (12) étant ménagé à la base du corps (4) pour faciliter une telle introduction en force.

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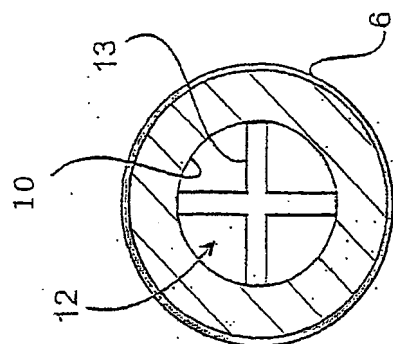
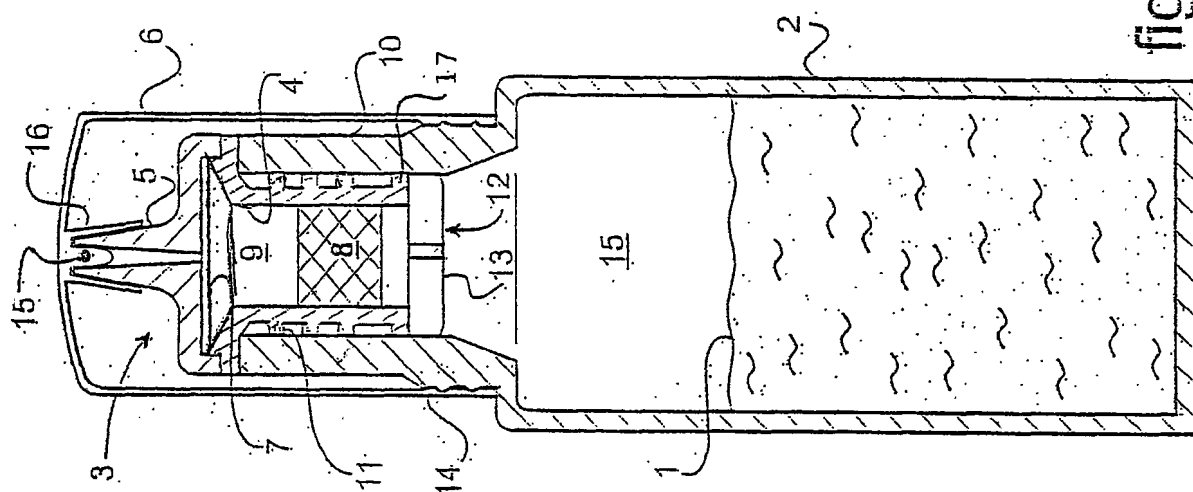
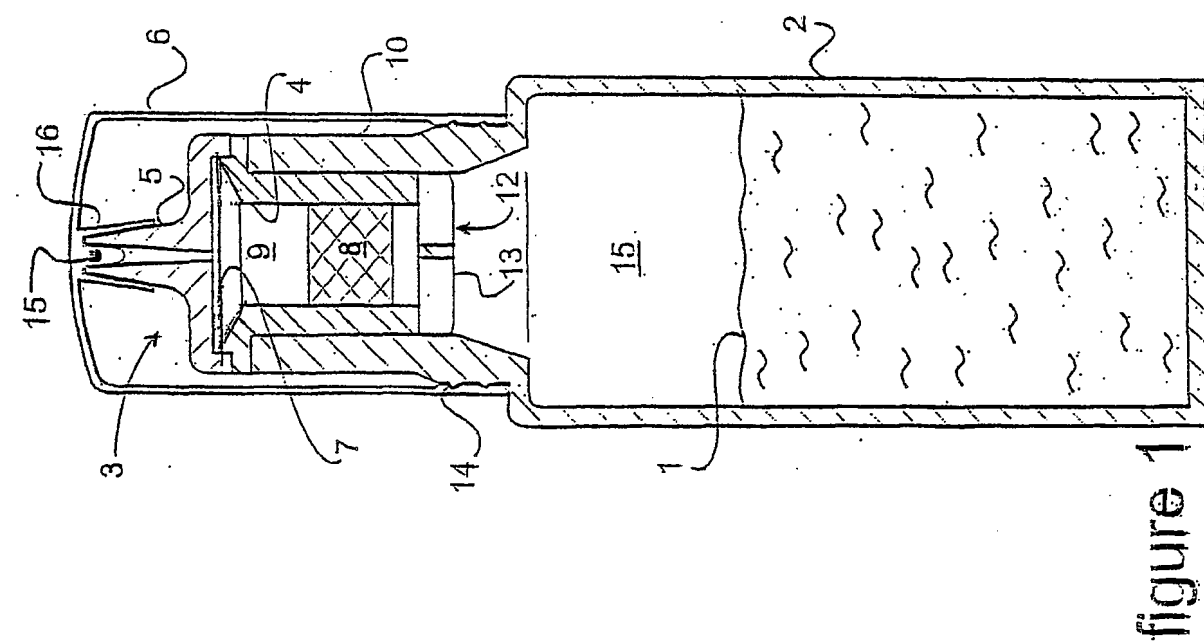
12. Récipient pour le conditionnement d'un liquide à distribuer goutte à goutte selon la revendication 11, caractérisé en ce que l'organe de centrage (12) est constitué d'ailes radiales de jonction (13) par emboîtement du corps (4) de la tête de distribution sur le col (10) du récipient, les ailes (13) délimitant entre elles des secteurs évidés.

13. Récipient pour le conditionnement d'un liquide à distribuer goutte à goutte selon l'une quelconque des revendications 10 à 12, caractérisé en ce que la surface extérieure du corps (4) de la tête de distribution est équipée d'au moins un jonc torique (11) issu dudit corps (4) avec lequel il constitue un ensemble monobloc, éventuellement une pluralité de joncs toriques axialement répartis.

14. Récipient pour le conditionnement d'un liquide à distribuer goutte à goutte selon l'une quelconque des revendications précédentes, caractérisé en ce que le corps (4) de la tête de distribution est obtenu par moulage dans des conditions telles qu'un jonc (17), résultant du plan de joint du moulage, est situé à l'extrémité distale du corps (4) à la limite de jonction de l'organe de centrage (12), ce qui favorise l'obtention d'une liaison étanche entre la tête de distribution et le récipient.

15. Récipient pour le conditionnement d'un liquide à distribuer goutte à goutte selon l'une quelconque des revendications précédentes, caractérisé en ce que le capuchon amovible (6) est rapporté sur le récipient par vissage.

16. Récipient pour le conditionnement d'un liquide à distribuer goutte à goutte selon la revendication 15, caractérisé en ce que le capuchon (6) comporte une combinaison d'organes d'étanchéité associant un picot (15) pénétrant à l'intérieur de la buse (5) de la tête de distribution et une jupe (16) coiffant cette buse (5).



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INTERNATIONAL SEARCH REPORT

International Application No

PCT/182005/001791

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 B05B11/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 B65D B05B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

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Date of the actual completion of the international search

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International Application No
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Demande Internationale No

PCT/IB2005/001791

A. CLASSEMENT DE L'OBJET DE LA DEMANDE
CIB 7 B05B11/04

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée (système de classification suivi des symboles de classement)

CIB 7 B05D B05B

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si réalisable, termes de recherche utilisés)

EPO-Internal

C. DOCUMENTS CONSIDERES COMME PERTINENTS

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(54) **DRIP LIQUID DISPENSER**

(52) U.S. Cl. 222/212; 222/420

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(57) **ABSTRACT**

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The invention relates to a packaging device for a liquid that is to be dispensed drop by drop, comprising a container (1) with manually elastically deformable walls, which ends in a rigid neck (3) in which a head (4) for dispensing the liquid is mounted. A membrane (31) which is both hydrophilic and hydrophobic, advantageously antibacterial, is arranged in the dispensing head (4) across the passage of the liquid towards a duct expelling it to the outside. This membrane allows external air to enter the container (1) once the liquid has passed through it in the expulsion phase, and the bottle reverts elastically to its initial shape after each dispensing operation. A frangible partition (7) isolates the membrane from the liquid contained in the bottle until the time of first use whereupon it is fractured by a striker secured to the said dispensing head (4).

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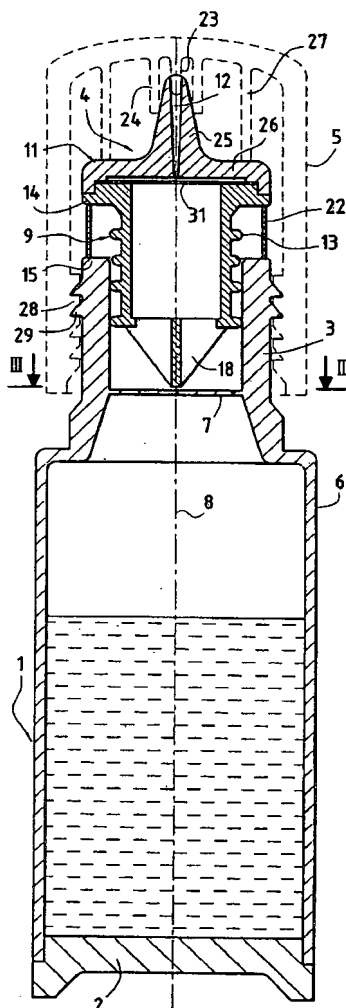
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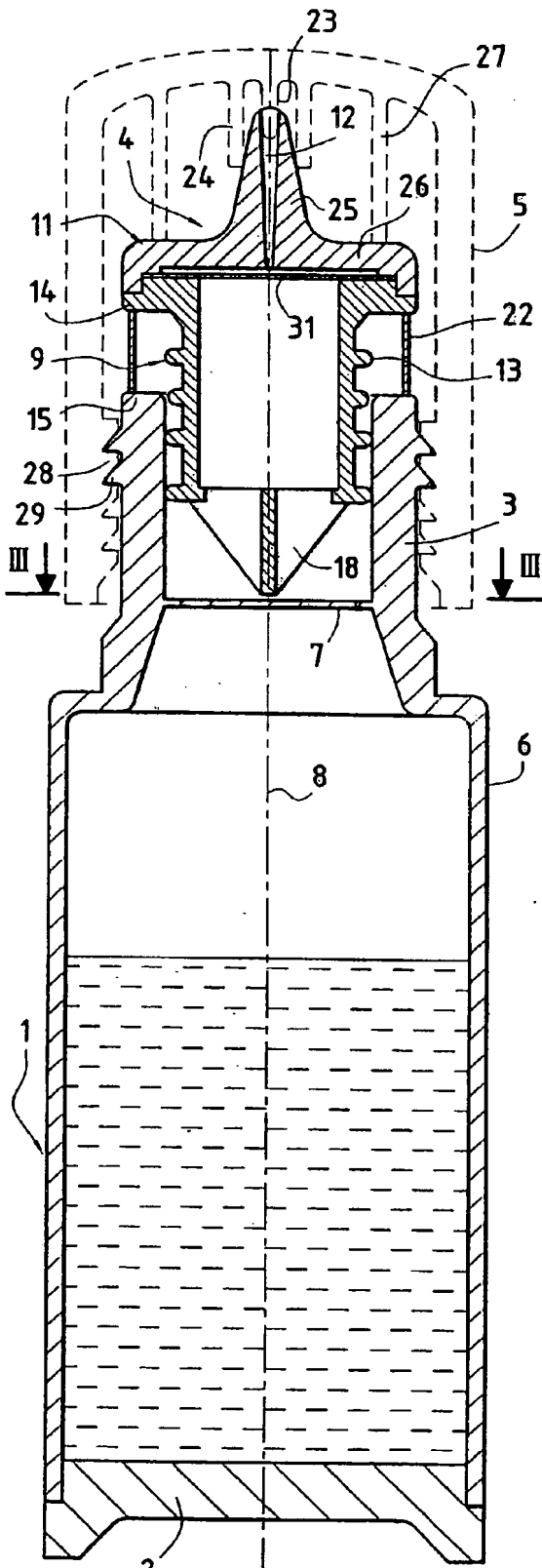


FIG.1

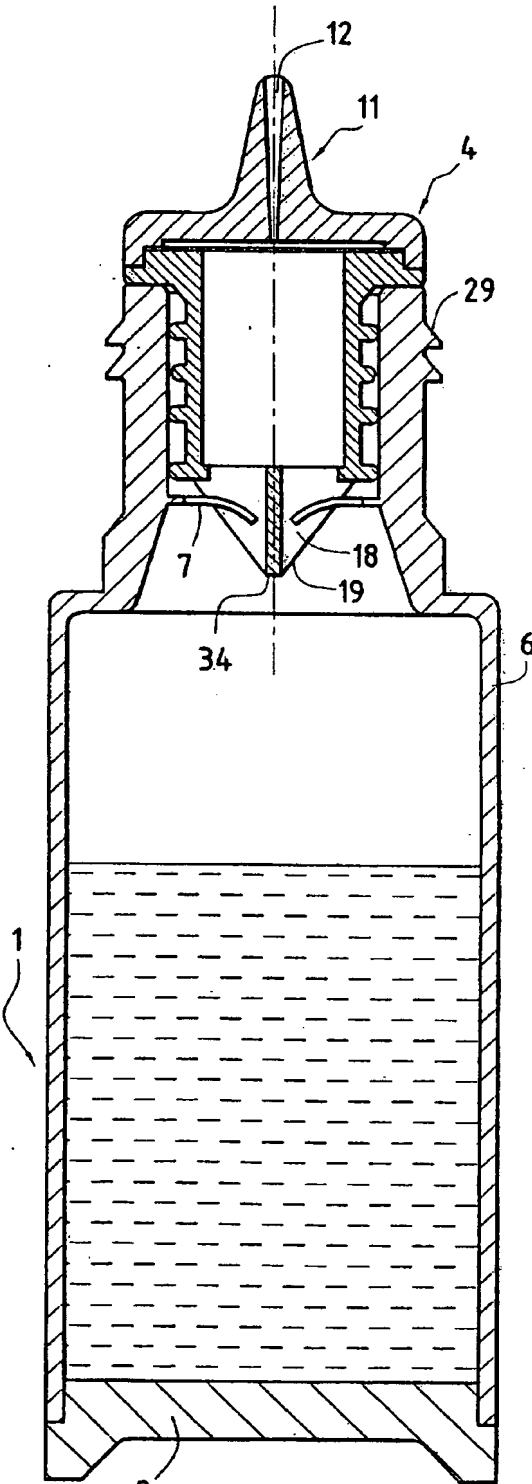


FIG.2

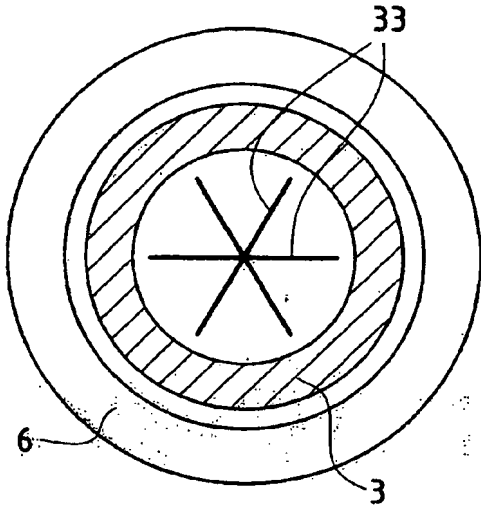


FIG. 3

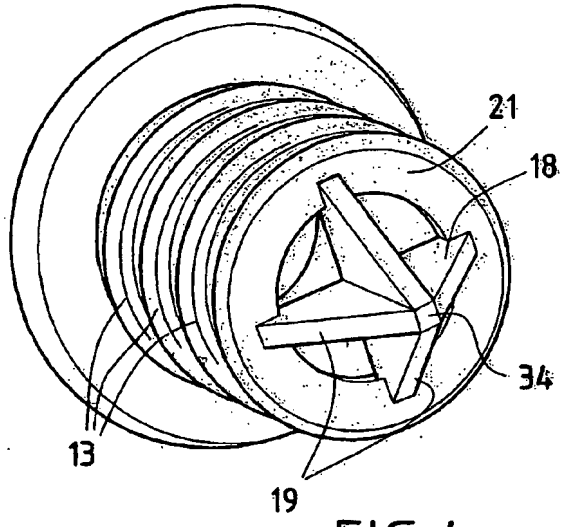


FIG. 4

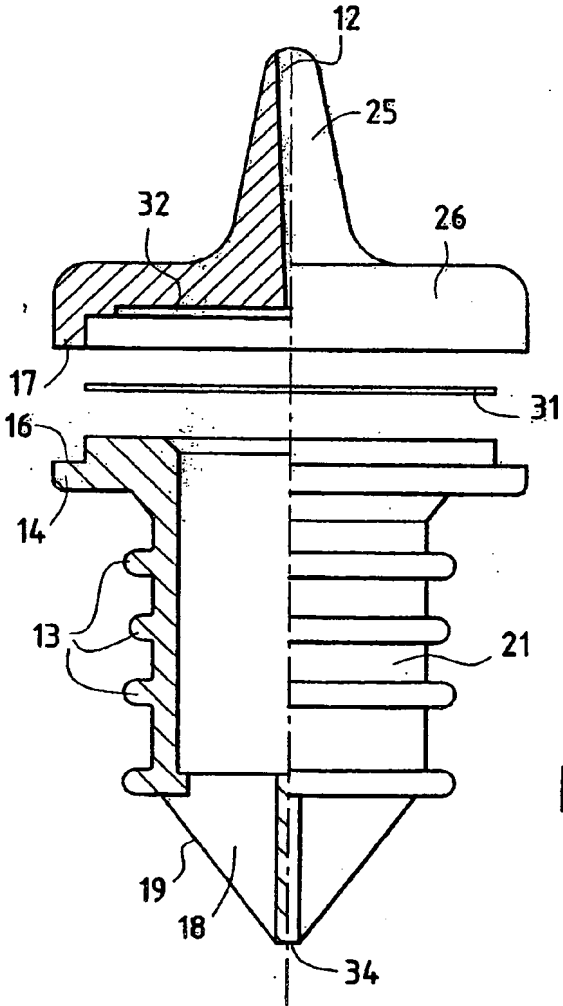


FIG. 5

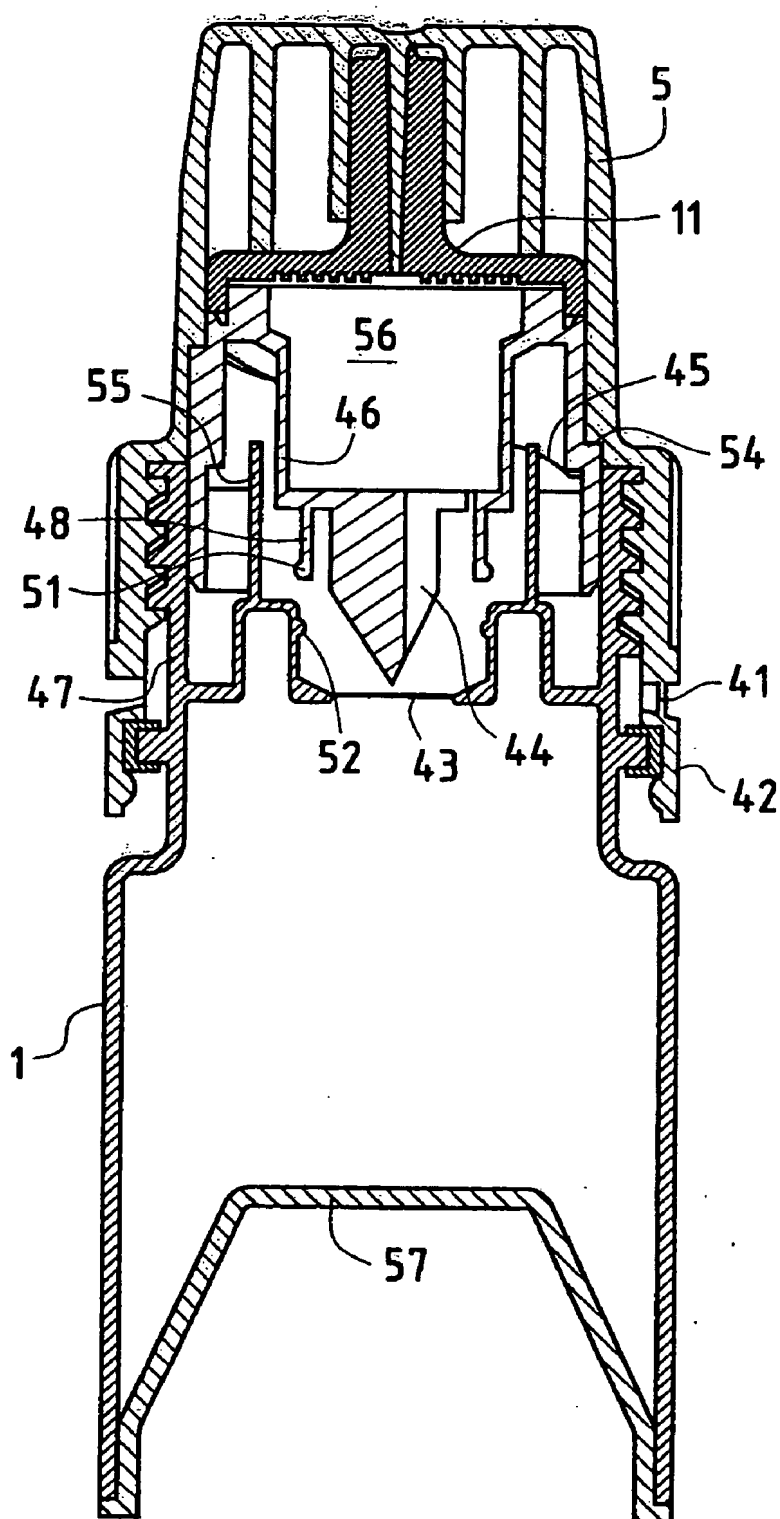


FIG. 6

DRIP LIQUID DISPENSER

[0001] The present invention relates to the liquid product packaging industry, particularly to the design and manufacture of bottles comprising a built-in dropping dispensing head such as those that can be used for packaging liquids that are to be dispensed drop by drop.

[0002] Such bottles are used in numerous fields of application, particularly for packaging pharmaceutical or cosmetic products in the form of liquid, particularly in the form of aqueous solutions, but also for lubricants, colourings, solutions of additive used in the food industry, etc. These are liquid products that are used in small doses, each time expelling just a few drops from the bottle containing the liquid, while the remainder needs to be kept for a long period of time. Quite often, the product kept in the bottle has in addition to be kept away from any possibility of contamination by bacterial or other agents from the outside. This is the case, in particular, of pharmaceutical compositions, including, in particular, ophthalmic solutions, which are here going to be taken as an example of a particularly relevant industrial application of the invention.

[0003] The conditions of purity required from the product prevent from allowing ambient air to enter the bottle freely to replace, by volume, the fraction of liquid which has been expelled therefrom during each dispensing operation. It is common practice to demand that this kind of bottle be equipped with a tamperproofing means which constitutes a visual indicator that guarantees that they have not been open during the time they are in storage at the shop before being sold to an end user. However, this tamperproofing security operates only up to the time of first use of the bottle, so that it remains an entire need for a technological solution to preserve the purity during the use of the bottle by expulsion of successive doses of product.

[0004] In order to answer the problems encountered in industrial practice in the field in question, the invention essentially proposes to combine two means for the sealed closure of a part of the bottle which forms the container containing the liquid that is to be dispensed and the outside of the bottle, one being of a mechanical kind and the other being of a physicochemical kind, in a form such that air is taken in during each step of dispensing some product while at the same time avoiding the risk of contamination by agents present in the outside air. The contaminating agents to be taken into consideration are commonly of the kind including bacteria, viruses and other biological agents, especially in the context of pharmaceutical and cosmetic products, but may also involve other kinds of harmful agents, particularly those which could result in destruction or denaturing of the product that is to be dispensed.

[0005] The bottle according to the invention represents significant technological progress by comparison with the currently known devices for packaging liquids that are to be dispensed drop by drop, which envisage manual deformation of the container containing the liquid that is to be dispensed which is of the plastic kind, by virtue of a cylindrical bellows configuration, something which allows the interior volume to be reduced gradually as the liquid is expelled therefrom during each dispensing step. Such a bellows-shape container needs to be protected by a rigid shell to which a dispensing head is attached, this closing the neck of the container and ending outside the latter in a duct

for expelling drops, protection against contamination being obtained by means of an antibacterial filter which is arranged in the dispensing head upstream of the duct for expelling drops.

[0006] It will be readily understood that it would be advantageous to be able to dispense with the additional envelope of the container that the rigid shell represents. In fact, this scenario results in complex and expensive manufacture, both from the point of view of producing each constituent part of the assembly and from the point of view of assembling them. In addition, if, in the context of industrial manufacture, there is a desire to alter the product capacity of the bottle, this cannot be achieved without this leading to significant modifications to the production plant, and therefore a not insignificant additional cost.

[0007] Furthermore, the structure of the known bottles of this type entails that the bottles be filled at the factory before the dispensing head is fitted, that is to say while the bottle is being assembled. The industrial party producing the liquid that is to be dispensed packaged in these bottles therefore has to send to the place of manufacture all the constituent elements of the bottle to then receive the bottles ready for sale and get hold of a special machine for the filling and final assembly of the bottle, the cost of which is such that it becomes economically viable only for very high rates of use. It is therefore desirable for the operation of filling the bottle to be able to be performed outside of the factory at which the bottle is manufactured by the company who prepares the liquid that is to be dispensed, for example using a customary bottle filling machine.

[0008] The invention aims to meet the expectation of Industry in the field of the packaging of liquids that are to be dispensed in drops, including those which have just been emphasized. Its object is therefore particularly to propose a new bottle for the packaging of liquids to be dispensed drop by drop, the structure of which is simplified, and which lends itself to filling at an automated site which is autonomous from the manufacture of the bottle, and which makes it possible to obtain different capacities without huge modifications to the manufacture.

[0009] To this end, the subject of the invention is a packaging bottle for a liquid that is to be dispensed drop by drop, of the type comprising a container ending in a rigid neck in which is mounted a dispensing head forming an external endpiece pierced with a duct for expelling the liquid from the said container, which is characterized in that the said container has an elastically deformable boundary wall for expelling a fraction of the liquid contained in the reservoir during each dispensing operation, in that the said dispensing head comprises, mounted across the path of the liquid thus expelled from the container, a membrane which is partially hydrophilic, to allow the liquid to pass under the effect of a raised pressure exerted in the container by the deformation of the wall, and partially hydrophobic so that the membrane wetted by the expelled liquid nonetheless allows air from the outside to enter the container when the container elastically reverts to its initial shape, after each operation of dispensing by manual compression, and in that it additionally comprises a frangible partition secured to the container for isolating the said membrane from the liquid contained in the container up to the time of first use, the said partition being torn by the passage of the said dispensing head from a security position into an availability position.

[0010] In the preferred embodiments of the bottle according to the invention, particularly those which are particularly intended for the packaging of aqueous liquids in the pharmaceutical and cosmetics spheres, and more especially for the packaging of ophthalmic solutions, the both hydrophilic and hydrophobic membrane is also capable of preventing contaminants present in the outside air from entering the bottle. This then is an antimicrobial membrane which, depending on its pore size, can hold back microbes of greater or lesser mobility.

[0011] According to other features of the invention, the bottle has a cylindrical overall shape, or one which is at least essentially so (namely, in general, a circular or oblong cross section), and its cylindrical side wall is elastically deformable by manual compression along all or part of its surface, so as to provide the raised pressure needed to expel liquid during each dispensing operation. In conjunction with the cylindrical overall shape, provision is advantageously made for the bottom closing off the container at its lower part, longitudinally at the opposite end from the frangible partition, to consist of a rigid cap which is sealed onto the cylindrical wall after the container has been filled.

[0012] We shall now place ourselves in the context of such embodiments of the invention that are suitable as ophthalmic dropping bottles, in order to complete the description of the characteristics of the invention and of their advantages. It shall be emphasized, considering such a bottle in its usual operating conditions, that the presence of a buffer chamber between the frangible partition and the hydrophilic/hydrophobic membrane plays a significant part in the preservation of the product purity.

[0013] The use of a membrane with hydrophilic/hydrophobic properties makes it possible to use a compressible container which reverts to its initial shape after each dispensing operation by allowing in air to replace the liquid dispensed, because this air is rendered sterile by the antimicrobial properties of the membrane and because the liquid contained in the container is thus preserved from any contamination. This then makes it possible to dispense with bellows, the container being made as a single piece, which in addition has the benefit of being able to be cylindrical overall so that it can bear any useful wording.

[0014] The invention makes it possible to reduce the number of constituent parts in the bottle and this results in an appreciable reduction in the cost of manufacture. In addition, this structure makes it possible to vary the capacity of the bottle to adapt it to suit the various uses, with a very small additional investment cost.

[0015] The fact of providing a frangible partition which is secured to the container makes it possible to use a dispensing head which, at the time of manufacture of the bottle, will be fitted into the neck at the top of the container, independently of the filling, which will take place, on the other hand, from the bottom. In this way also, manufacture of the container itself will be made easier, and will advantageously be performed by moulding the assembly as a single piece comprising its cylindrical wall, its neck and its frangible partition, because this intermediate transverse partition will be accessible from both sides. It also results in a reduction in the number of parts which make up the bottle because the double envelope of the container that was formed by the assembly comprising the bellows, the volume of which

varied gradually through plastic deformation of its wall, and the rigid external shell constituted in bottles of the prior art has been done away with.

[0016] Another advantage of the bottle according to the invention lies in the fact that, with the exception of the bottom cap, its parts can be fully assembled in the factory before the assembly is sent to a packaging industry which will be able to use a filling machine of the customary type in an automated filling shop. For filling, the bottles are then arranged head down, the liquid being isolated from the membrane in complete safety by the frangible partition. All that will then be needed will be the bottom of the bottle to be closed while the latter is still head down. This closure is effected by attaching the bottom cap already mentioned, the sealed attachment being performed by any technique known per se, for example involving welding, bonding and/or snap-fastening. As an alternative, it may also be performed by bonding the flexible wall of the container edge to edge along a diameter of its cross section.

[0017] According to another feature of the invention, the said dispensing head is mounted so that it can move in axial translation by sliding in the rigid neck of the container with elastically deformable walls between two different longitudinal positions inside the said neck, comprising the said security position in which communication between the container and the said expulsion duct via the said membrane is sealed off and the said availability position in which the said communication is allowed through the destruction of the frangible partition. In combination with this arrangement, the dispensing head is advantageously equipped, at its lower part, with a striker capable of fracturing or tearing the said partition the first time the container is used, entailing a movement of driving the said head into the said neck of the container, in longitudinal translation. According to some secondary features of the invention, the translational movement or driving of the dispensing head may advantageously be performed, in a way known per se, by means of a stopper which screws onto the rigid neck of the container.

[0018] Furthermore, the frangible partition is preferably constructed in such a way that it plays a part in controlling the conditions under which liquid is dispensed from the container, for example once pierced, freeing a passage cross section for the liquid which corresponds at least to one quarter of the active area of the hydrophilic/hydrophobic partition.

[0019] In order to be frangible, the partition advantageously has a number of lines of weakness, or precut lines, each of which is oriented radially and which are arranged in a star configuration, in a regular circular arrangement, at roughly equal angular spacings. Advantageously, in combination with this arrangement, but possibly separately, the striker for its part is preferably constructed with geometry that exhibits symmetry of revolution. Thus, in particular, it may be produced in the form of a number of triangular radial fins which are uniformly distributed about the longitudinal axis of the bottle. The number of precut lines of the partition is then advantageously different from the number of fins of the striker. This arrangement avoids the fins and the precut lines all being able to correspond with one another, which guarantees that the container will be opened by parting of the torn walls of the partition.

[0020] According to yet another feature of the invention, the bottle comprises a tamperproofing ring arranged between

the interior body of the dispensing head and the upper part of the neck of the container when the dispensing head is in its secure position. The fact of arranging this tamperproofing ring between the dispensing head and the neck of the container makes it possible to obtain good positioning of the dispensing head in the neck in the security position while at the same time eliminating any risk of the frangible partition being perforated when the bottle is being assembled. The height of the ring covers the travel of the dispensing head when it is driven in for first use. Once this ring has been removed, the dispensing head is then displaced very precisely as far as the availability position in which the partition becomes open to the passage of the liquid.

[0021] In another embodiment, the tamperproofing ring is mounted by breakable strips secured to a stopper that is screwed in protection of the dispensing head. Such a ring can then stay fixed on the body of the bottle after breaking of the said strips when, for the first use, the user forces on the stopper in order to unscrew it.

[0022] This solution for the tamperproofing rings is particularly advantageous in combination with other features of a preferred embodiment of the device of the invention which consists in particular in means commanding the movement of the dispensing head in axial translation in the neck of the bottle by the rotation of the protecting stopper during its unscrewing, this translation inducing automatically the opening of the frangible partition to connect the internal volume of the bottle with the expulsion duct of the dispensing head through a buffer chamber set inside the pod forming the interior body of the dispensing head.

[0023] The invention will now be described more fully in the context of some preferred characteristics and of their advantages, making reference to FIGS. 1 to 6 in which:

[0024] FIG. 1 is a view in axial section of a bottle according to the invention, in which the dispensing head is in the security position;

[0025] FIG. 2 is a view in axial section depicting the container and the interior body of the dispensing head in the availability position;

[0026] FIG. 3 is a view in section on III-III of FIG. 1;

[0027] FIG. 4 is perspective view showing the lower part of the interior body of the dispensing head with the striker;

[0028] FIG. 5 is a part view in axial section depicting the dispensing head before it is assembled;

[0029] and FIG. 6 illustrates in axial section another preferred embodiment of the invention.

[0030] The figures depict an exemplary embodiment of a bottle according to the invention as intended, as a particularly advantageous example of the implementation of the invention, for packaging pharmaceutical liquids which are to be dispensed drop by drop, particularly aqueous ophthalmic solutions.

[0031] To contain the liquid, the bottle comprises a container 1 of cylindrical overall shape, with a longitudinal axis that is vertical in FIGS. 1 and 2, which is closed at its lower part by a bottom cap 2 and is extended at its upper part by a neck 3 in which is housed a dispensing head 4 which is mounted therein so that it can be moved in translation along

the longitudinal axis. The assembly is supplemented by a stopper 5 which is screwed onto the neck 3 of the container.

[0032] In its entire cylindrical lateral part, the boundary wall 6 of the container 1 is flexible, in elastic deformation, so as to allow a temporary reduction in the interior volume of the container when pressure is applied to this wall, the release of manual compressive force having the tendency to return the interior volume of the container to its resting value by elastic return of its wall to the original cylindrical shape. By contrast, the cap 2 and the neck 3 are rigid.

[0033] The container 1 also comprises a radial transverse partition 7 perpendicular to its longitudinal axis 8 and which is arranged at the lower part of the neck 3. This intermediate partition is designed, as will be described later on, to tear automatically at the time of first use of the bottle as a dropper and thereby to create an opening in the container 1 upstream of the neck 3.

[0034] The dispensing head 4 is made in two parts joined together, namely an interior body or pod 9, which is of hollow annular shape and mounted so that it can move in axial travel in the neck 3, and an endpiece 11 which is fixed to the upper face of the pod 9 and is pierced with a duct 12 through which liquid is expelled out of the bottle. Sealing of the pod 9 against the interior wall of the neck 3 is provided by means of three exterior annular bulges 13 so that there always two of them actively sealing the connection between the pod and the neck of the container. At its upper part, the pod 9 comprises a shoulder 14 which is intended to come to bear against the upper face 15 of the neck 3 when the dispensing head 4 is in its availability position as depicted in FIG. 2. Formed on the upper face of the shoulder 14 is an annular recess 16 in which a lower collar 17 of the endpiece 11 can be housed (FIG. 5).

[0035] At its lower part, the pod 9 comprises a striker 18 (see FIGS. 4 and 5), the function of which is to open the partition 7 by definitively fracturing it at the time of first use. This striker is produced in the form of four radial fins 19 of triangular shape arranged at right angles to one another and which meet at the axis of the bottle and each meet at the lower part 21 of the pod 9. In the security position depicted in FIG. 1, an annular ring 22 is inserted between the upper face 15 of the neck 3 and the underside of the shoulder 14 of the pod 9. This ring performs a conventional tamperproofing function. It is secured to one of the two parts, in this instance the neck 3, in such a way that it is easy to remove it by tearing it or breaking it at the time of the first use of the bottle. In practice, it is moulded integrally with the container 1 and its neck 3.

[0036] The stopper 5 has a central pip 23 which fits quite easily into the flared end of the expulsion duct 12, an annular hoop 24 which guides it, centring it on the external face of a conical extension 25 of the base 26 of the endpiece 11, and another annular hoop 27, of larger diameter, which bears against the external face of the base 26. The stopper 5 has an internal screw thread 28 which collaborates with an external screw thread 29 of the neck 3.

[0037] According to the invention, and as can be seen in particular in FIG. 5, a membrane 31 is inserted in the path of the liquid expelled from the container 1, across the dropping head 4. It is arranged, held around its periphery between the pod 9 and the endpiece 11, more specifically

between the upper face of the shoulder 14 and the underside of the base 26 of the endpiece 11.

[0038] The underside of the base 26 of the endpiece 11 has a central circular dish 32, the diameter of which exceeds the inside diameter of the pod 9 and into which the lower part of the expulsion duct 12 opens. In this way, the membrane 31 is fixed only at its periphery between the pod 9 and the endpiece 11, and the vast majority of its area is free and accessible to the passage of the liquid through the space corresponding to the interior of the pod 9.

[0039] According to the invention, this membrane 31 first of all has antimicrobial properties which make it possible to filter out bacteria and therefore make sure that the liquid contained in the container is kept sterile. This membrane is also both hydrophilic and hydrophobic which means that it both allows ophthalmic liquid to leave the container and allows any liquid expelled in excess when the drops have been dispensed to be sucked back in and air to be taken into the container to compensate for the volume of liquid dispensed in the form of drops.

[0040] The dispensing head is manufactured as follows. First of all, the endpiece 11 and the pod 9 are produced separately. The membrane 31 is fixed into the lower part of the endpiece 11, making a peripheral weld using ultrasound or high frequency welding. The membrane 31 is then protected by the collar 17 to prevent it from becoming damaged when the endpiece 11 is being handled. The assembly comprising the endpiece 11 and the membrane 31 is then fixed, the collar 17 of the endpiece 11 being housed in the recess 16 of the pod 9. This connection is sealed for example by ultrasound welding or heat sealing. This then yields the complete dispensing head 4 which will subsequently be inserted, from the top, into the neck 3 of the container 1.

[0041] As can be seen in FIG. 3, which shows the upper part of the wall 6, the neck 3 and the partition 7, the latter is weakened in its central part by six lines of weakness or precut lines 33, which are arranged radially and configured uniformly with an angular spacing of 60 degrees. In this way, when pressure is exerted on the centre of the partition 7, it tears along the lines 33, and thus forms, at its centre, a passageway for the liquid contained in the container 1.

[0042] To this effect, the pod 9 comprises, at its lower part, a striker which consists of the four triangular radial fins 19, the lower ends of which make a point 34 which will strike the centre of the partition 7 when the dispensing head 4 is moved downward. As can be seen in the figures, the striker 18 of the example described has four fins while the partition 7 has six tear lines. This difference in number, resulting in a different spacing in the configuration which exhibits symmetry of revolution, makes sure that the fins cannot ever all coincide with the tear lines and that, as a result, there is no risk of the fins becoming lodged in the space left by the tears and blocking the passageway for the liquid.

[0043] The bottle according to the invention is far easier to manufacture because the entirety of the container, namely its side wall 6, the neck 3 with also the tamperproofing ring 22 and the partition 7 are made as a single piece by an injection-moulding or extrusion operation using synthetic material. This is, for example, high-pressure or low-pressure polyethylene, but use may be made of any other polymer or

composite material which exhibits a sufficient barrier to water vapour and sufficient flexibility (suited to an appropriate thickness) to perform the compression function that the cylindrical wall is to perform. This manufacturing by moulding as a single piece is made easier by the fact that the frangible transverse partition at the cylindrical wall is accessible from both sides when the bottom is absent.

[0044] The endpiece and the pod of the dispensing head are manufactured separately then the membrane is fixed into the dish 32 by ultrasound or high frequency welding. The assembly comprising the endpiece and the membrane is then placed on the pod, the collar 17 becoming housed in the recess 16 of the pod. The endpiece and the pod are then secured in a sealed manner, for example by welding, to form the dispensing head 4.

[0045] The dispensing head 4 is then engaged in the neck 3 until it comes into abutment with the tamperproofing ring in the security position in which the striker 18 is slightly above the partition 7, as can be seen in FIG. 1. The stopper 5 can then be screwed onto the neck 3 until it comes into abutment with the base 26 of the endpiece 11.

[0046] The assembly thus obtained and the closure cap 2 may be sent to a manufacturer of pharmaceutical products marketing the liquid that is to be dispensed, who will be able to place the bottles in the head down position in a filling machine of known type in which the container will be filled, without risk of contact with the membrane 31 because of the presence of the partition 7. When the bottle has been filled, the cap for closing the bottom 2 is fixed onto the bottom of the wall 6, in a sealed manner, for example by welding, and the bottle filled with liquid is then ready to be marketed.

[0047] At the time of first use, all that is required is to unscrew the stopper 5, remove the tamperproofing ring 22 and screw the stopper 5 back onto the neck 3. This screwing-on movement allows the dispensing head 4 to be driven in until it reaches the availability position which is depicted in FIG. 2 once the striker 18 has caused the partition 7 to tear along the precut lines 33. The cut triangular sections of the partition 7 are parted by the fins of the striker 18 so as to obtain a cross section for the passage of the liquid contained in the container 1 that corresponds at least to three quarters of the free area of the membrane 31. The central part 34 of the striker 18 makes it possible to avoid there being a direct jet of liquid onto the membrane 31.

[0048] At the time of each use, the wall 6 of the container 1 is pressed with the bottle held head down so as to cause one or more drops to be ejected through the duct 12. When the pressure on the wall 6 is released, the excess liquid which has been expelled from the membrane 31 is sucked back into the bottle by virtue of the pores with hydrophilic properties of the membrane 31. In addition, because this membrane is wetted with the liquid, its pores with hydrophobic properties allow air to pass and this air replaces the liquid which has been expelled in the form of drops. Because the membrane 31 has antimicrobial properties, this ingress of liquid and of air into the container 1 occurs in a sterile manner which means that the liquid contained in this container can be used over a long period of time without becoming contaminated.

[0049] The membrane may be made in the known way of a polymer material (with, for example, as its base, resins of polyamide, polyvinyl fluoride, polyether sulphone, etc) to

which its composition gives a hydrophilic nature and which is rendered hydrophobic by modification of its structure over part of its free area only. The modification in question is performed in the conventional way by grafting in the presence of an initiator of radical reactions. The treatment is advantageously performed in order to render the membrane hydrophobic across a diametral band covering from 20 to 50% of its area that can be wetted by the liquid that is to be expelled. By way of example, use was thus made of a membrane based on polyamide resins with a pore diameter of 0.2 microns. In another example, use was made, for the same passage flow rate of the aqueous solution considered, of a membrane based on polyether sulphone resins with a pore diameter reduced to 0.1 microns, which allows better antimicrobial filtration by holding back the most mobile and deformable bacteria.

[0050] We will now refer to FIG. 6 which illustrates another embodiment of the device according to the invention which has the advantage with regard to the former to facilitate the use of the bottle by the consumer. Indeed, the components at the head of the bottle are constituted in such a way that, when at the time of first use, the consumer unscrews the cap or stopper 5, the first induces the breaking of the strips 41 which hold the tamperproofing ring 42, then he induces the perforation of the intermediate partition 43 by the striker 44. When he goes on unscrewing the stopper 5, he frees this one completely from the dispensing endpiece 11.

[0051] It can be seen on the figure a ramp 45 which is arranged to this effect inside the dispensing head and which makes the pod which constitutes its interior body 46 cooperate with internal components of the neck 47 of the bottle. This ramp has an inverse thread and a much steeper slope with respect to the screw thread of the stopper 5. It operates when the pod is driven in rotation by the stopper during the unscrewing of the latter.

[0052] In the position illustrated on the figure, the pod 46 is still in a high position. It forms around the striker 44 a hoop 48 which presents protusions 51 engaging a bulge 52 protruding from the body of the bottle, on the internal wall of a small cup 49 that it forms around the partition 43.

[0053] In its part cooperating on one hand with the thread of the stopper 5 on the external side, on the other hand with the interior pod 46 through the ramp 45 on the internal side, the body of the flask forms two annular hoops between which is placed an external skirt 54 of the pod, meanwhile an internal skirt of that one ending with the hoop 48 is placed inside the internal hoop 55. The internal hoop is thus inserted between the two co-axial skirts of the pod. It is at this place that is provided the ramp 45. This ramp runs on a half-turn of the bottle, which allows the cooperating part of the pod to come in mesh with it whatever its original rotation position is.

[0054] FIG. 6 shows other details of construction, in particular concerning a cam formed on the skirt 54 in abutment cooperation with a shoulder of the stopper 5 and the fact that the rotation of the pod with respect to the neck of the bottle is restricted to a small sector by the presence of grooves coming in overthickness on the skirt 54.

[0055] It can also be seen on the figure the buffer chamber 56 that, as in the exemplary embodiment illustrated by

FIGS. 1 and 2, is arranged inside the pod between the entry zone formed by sectors widely open around the striker 44 and the hydrophilic/hydrophobic membrane at the entrance of the dispensing duct of the endpiece. The striker 44 is constituted a little differently from the striker 18 of FIG. 1. It forms a peak of triangular section which is borne in excentric position by the internal skirt of the pod 46.

[0056] FIG. 6 is interesting in that it illustrates the use of the same dispensing head and of the same base body of the bottle to obtain a global bottle of smaller capacity by virtue of a bulging bottom 57. In this case as in the other, this bottom is fixed on the bottle for having been welded to it during its filling.

[0057] It can also be pointed that in the case of FIG. 6, unlike that of FIG. 1, the tamperproofing ring keeps in place on the fixed ring of the body of the bottle on which it is mounted, but it is freed from the breakable strips that maintained it fixed to the terminal shoulder of the stopper 5.

[0058] It is apparent from the foregoing that the invention is not restricted to the embodiments which have been specifically described during the examples hereinabove and that it extends, on the contrary, to any alternative form using equivalent means. In particular, it is possible, by way of a striker, to use a central cannula fixed to the lower part of the pod 9.

[0059] Moreover, the bottom cap may be fixed by any means providing sufficient sealing; for example it is possible to envisage snap-fastening. It is also possible to dispense with this cap, closing the bottom by pinching together the cylindrical wall of the container.

[0060] The invention as described and illustrated hereinabove is also not restricted in its applications. In particular, it is obvious that a device equipped with a membrane which, through its hydrophilic nature, is intended to allow aqueous liquid to pass through it may just as easily be used for the drop-by-drop dispensing of solutions in a polar solvent rather than in water.

1. Packaging bottle for a liquid that is to be dispensed drop by drop, comprising a container (1) having a rigid neck (3) in which is mounted a dispensing head (4) forming an external endpiece (11) pierced with a duct for expelling the liquid from the said container (1), characterized in that the said container consists of a deformable cylindrical wall closed, at its lower part, by a rigid cap (2) which is fixed on after the container (1) has been filled, and in that the said container has an elastically deformable boundary wall (6) for expelling a fraction of the liquid contained in the reservoir during each dispensing operation, in that the said dispensing head comprises, mounted across the path of the liquid thus expelled from the container, a membrane (31) which is partially hydrophilic, to allow the liquid to pass under the effect of a raised pressure exerted in the container by the deformation of the wall, and partially hydrophobic so that the membrane wetted by the expelled liquid nonetheless allows air from the outside to enter the container when the container elastically reverts to its initial shape, and in that it comprises a frangible partition (7) secured to the container for isolating the said membrane (31) from the liquid contained in the container (1) up to the time of first use, the said partition being torn by the passage of the said dispensing head from a security position into an availability position.

2. Bottle according to claim 1, characterized in that the said membrane is made of a hydrophilic polymer, particularly one based on polyamide or polyether sulphone, which is made hydrophobic over a zone covering from 20 to 50% of its area and which has a pore diameter advantageously of the order of 0.1 or 0.2 microns, capable of preventing contaminants present in the outside air from entering the bottle.

3. Bottle according to claim 1 or 2, characterized in that the said wall of the container is of cylindrical shape and is elastically deformable by manual compression so as to create a raised pressure in the container to cause liquid to be expelled during each dispensing operation, the elastic return of the container to its initial shape causing unexpelled liquid to be sucked back out of the endpiece and external air allowed in to compensate for the liquid expelled.

4. Bottle according to claim 3, characterized in that the said container is closed at the bottom, at the opposite end to the said dispensing head, by a rigid bottom cap to be fixed to its cylindrical wall equipped with the dispensing head after the bottle has been filled.

5. Bottle according to any one of claims 1 to 4, characterized in that the said dispensing head (4) is mounted so that it can move between two different longitudinal positions inside the said neck (3), comprising the said security position in which communication between the container (1) and the said expulsion duct (12) via the said membrane (31) is sealed off and the said availability position in which the said communication is allowed through the destruction of the frangible partition (7) and in that the said dispensing head (4) is equipped, at its lower part, with a striker (18) capable of fracturing the said partition (7) the first time the container is used, entailing a movement of driving the said dispensing head (4) into the said neck (3) of the container.

6. Bottle according to claim 5, characterized in that the said partition (1) is constructed in such a way that it

therefore frees a passage cross section for the liquid that corresponds at least to one quarter of the area of the said partition.

7. Bottle according to claim 5 or 6, characterized in that the said partition (7) is made as a single piece of a material that can be moulded with the said container (1) and the said neck (3).

8. Bottle according to any one of claims 5 to 7, characterized in that the partition (7) comprises precut radial lines (33) arranged in a star configuration and in that the striker (18) comprises radial fins (19), also arranged in a uniform distribution about the longitudinal axis, the number of precut lines (33) in the membrane being different from the number of fins (19) on the striker (18).

9. Bottle according to any one of claims 5 to 8, characterized in that it comprises a tamperproofing ring (22) inserted between a shoulder (14) of the dispensing head (4) and an upper face (15) of the neck (33) of the container (1) when the dispensing head (4) is in its security position, the said shoulder (14) coming to bear on the said upper face (15) after removal of the tamperproofing ring by the driving of the body (9) of the dispensing head (4) as far as the availability position.

10. Bottle according to any one of claims 5 to 8, characterized in that it comprises a tamperproofing ring (42) mounted permanently on the neck (3) of the container (1) which is linked by breakable strips to an unscrewable stopper (5) protecting the dispensing head until the time of first use of the bottle.

11. Bottle according to any one of claims 5 to 10, characterized in that it comprises means with a ramp (45) to induce the said driving of the dispensing head (4) towards the availability position during the unscrewing of a stopper (5) protecting the said head until the first use.

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