LLOREDA & CIA. S. A.
ABOGADOS

BOGOTA - COLOMBIA
OFICINA FUNDADA EN 1941
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121 130

Señor
SUPERINTENDENTE DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES
E. S.

Re: P1.-**GLAXO GROUP LIMITED**.-Solicitud de Patente de Invención en Fase Nacional PCT para **"APARATO DE ABASTECIMIENTO DE FLUIDOS"**.-Clase **B65D 83/14**.-Expediente número **06-093.550**.-

1. Me refiero a mi memorial de 12 de Febrero de 2007.

2. De conformidad con lo dispuesto en el Artículo 5.2.12 de la Circular Externa No. 03 de 28 de Abril de 2003, y estando dentro del plazo de seis meses contados desde la fecha de la publicación de la solicitud en la Gaceta de la Propiedad Industrial número **583** de 18 de Diciembre de 2007, solicito a ese Despacho proceder a realizar el examen de patentabilidad de la presente invención.

3. Me permito recordar a usted, que tal como se informó en el Petitorio de la invención, la presente solicitud corresponde a Capítulo I.

4. Anexo me permito acompañar recibo número 08-20.136, expedido por la Superintendencia de Industria y Comercio, que acredita el pago de la tasa que dicho examen causa.

Señor Superintendente,

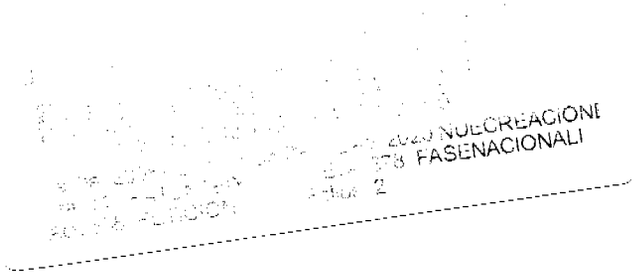
ALICIA LLOREDA RICAURTE
T.P. 53.215

132 131

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 08 - 20,136
FECHA : MARZO 7 DE 2008



***** C O N S I G N A C I O N *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
LLOREDA Y CIA S. A	CONSIGNACION	BANCO DE BOGOTA	062754307	1751413	07/03/2008	4,720,000.00

***** C O N C E P T O *****

CANT.	RENTISTICO	CONCEPTO		TOTAL CONCEPTO
1	50005-01-01 SOLICITUDES	112 PTC CAP-I EXAMEN DE PATENTIBILIDA		420,000.00
		TOTAL :	$	420,000.00

SON: CUATROCIENTOS VEINTE MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

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Industria y Comercio
SUPERINTENDENCIA

DIVISIÓN DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 06-93550

EL EXTRACTO DE LA PRESENTE SOLICITUD DE **PATENTE DE INVENCIÓN**

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No **583** DE

FECHA **18 DE DICIEMBRE DE 2007** EL TÉRMINO HÁBIL SEÑALADO POR LA

LEY EXPIRA EL **14 DE MARZO DE 2008**

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI _____ NO ____X____

1/33

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCIÓN DE NUEVAS CREACIONES

2020
Bogotá, D.C.,

Abogada
Alicia Lloreda R.
(Apoderada)

ASUNTO	Radicación	06 -93 550
	Trámite	002
	Evento	001
	Actuación	430
	Oficio	
	Folios	083

Patente de Invención	☑	Patente de Modelo de Utilidad	☐		
Vía Nacional	☐				
Vía PCT (fase nacional)	☐	Cap. I	☑	Cap. II	☐

Solicitud Internacional n.° _____
Fecha de Presentación Intrnl. _____

Como resultado del examen definitivo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le comunica.

- **Documentos estudiados**

Descripción:	Folios 56 a 86 como se radicó inicialmente
Reivindicaciones:	Folios 87 a 99 como se radicó inicialmente
Dibujos:	Folios 100 a 106 como se radicó inicialmente
Prioridad:	2004-03-11. GB. 0405477

2. Análisis de la Prioridad

De acuerdo con lo establecido en los folios 30 (en español) y 44 (en inglés), no se reconoce la validez de dicho derecho para la presente solicitud, por no haberse presentado la copia correspondiente dentro del plazo estipulado.

ver folio 219 vuelto

3. Objeto de la invención

Título de la solicitud: *Aparato de abastecimiento de fluido*, folio 1.

El objeto de la presente solicitud de patente de invención consiste en suministrar un aparato adecuado para albergar y operar un contenedor dosificador para fluidos especialmente para el tratamiento médico de afecciones en las vías respiratorias

El problema planteado en esta solicitud es satisfacer la necesidad de tener un aparato que le permita a cualquier usuario operar un dosificador mediante el empleo de un esfuerzo mínimo.

Para solucionar este problema técnico la solicitud en estudio proporciona un aparato dentro del cual se monta un dosificador. El aparato cuenta con un mecanismo de palanca y levas que operan el dosificador.

Clasificación Internacional de Patentes (IPC): A61M 15/08, B05B 11/00, B65D 83/14

4. De la solicitud de Patente

Antes de entrar en detalles específicos, se le dan al solicitante ciertas indicaciones generales, algunas de las cuales son aplicables a este caso y todas deberán ser tenidas en cuenta en las eventuales modificaciones:

El título o nombre de la invención debe concordar con lo que se reclama en el capítulo reivindicatorio. Esto es, si en las reivindicaciones se reclama un producto, tal producto debe ser mencionado en el título, y si en las reivindicaciones se reclama un procedimiento o un sistema o un método, también debe ser mencionado allí. Normalmente, el título debe contener máximo diez palabras aunque eventualmente pueden ser más. El título no debe contener palabras cuyo significado no esté reconocido dentro del sector de la técnica de que se trate. Preferiblemente, deben ser palabras cuyo significado se encuentre en el Diccionario de la Real Academia Española (DRAE).

En Colombia, la máxima autoridad en cuestiones del lenguaje es la Academia Colombiana de la Lengua. En caso de duda sobre el significado de las palabras, se debe acoger la definición que trae el Diccionario de la Real Academia Española (DRAE).

En Colombia, es de uso obligatorio el Sistema Internacional de unidades. Esto implica, también, que la coma decimal es de uso obligatorio. Cuando aparezca algún valor con unidades diferentes a las exigidas, deberá incluirse su correspondiente conversión al Sistema Internacional.

La parte técnica de la solicitud se divide en tres secciones, debidamente separadas, preferiblemente en este orden: El capítulo descriptivo, el capítulo reivindicatorio y el juego de dibujos o figuras. Ninguna de estas secciones podrá llevar membretes (encabezamientos o pies de página) ajenos al contenido técnico de la solicitud

Por lo menos el capítulo descriptivo debe estar debidamente paginado y estar escrito a doble espacio, con el fin de facilitar la referencia a los apartados del texto.

La terminología empleada en la descripción y en las reivindicaciones debe ser igual para designar las diferentes partes, piezas, elementos, detalles o aspectos de lo que se mencione en ellas, los cuales, a su vez, deben estar designados con números o signos de referencia.
Dentro del texto de la descripción y las reivindicaciones se aconseja encerrar entre paréntesis el número o signo de referencia cada vez que se mencione el detalle correspondiente con el fin de distinguirlo de otros tipos de números o signos que eventualmente aparezcan allí. Estos números o signos de referencia deben aparecer dentro del juego de dibujos (preferiblemente, sin paréntesis, aunque pueden estar encerrados dentro de un círculo) siempre acompañados de líneas o flechas que señalen o indiquen a qué parte, pieza, elemento o aspecto se encuentran asociados.

Las reivindicaciones deben estar numeradas individual y consecutivamente (1, 2, ... 5, 6, etc.) El capítulo reivindicatorio no debe tener subtítulos.
Normalmente se pueden encontrar dos categorías de reivindicaciones: una la de producto y la otra, de procedimiento.
En las reivindicaciones se deben definir los alcances de la protección que desea el solicitante. En consecuencia, las reivindicaciones forman un cuerpo aparte de la descripción y como tal debe ser redactado: la primera vez que se mencione un nombre dentro de las reivindicaciones debería estar acompañado de un artículo indeterminado; y, la inclusión -entre paréntesis- de un número de referencia no sustituye la definición del elemento o aspecto al que se refiere, simplemente sirve de información complementaria. Se debe entender que la descripción sirve para interpretar las reivindicaciones y, en consecuencia, si en una reivindicación se reclama un aparato, por ejemplo, no se deberían mencionar aspectos del funcionamiento del aparato dentro de la reivindicación, limitándose a definir únicamente los elementos que constituyen el aparato.

Cada una de las figuras debe estar debidamente identificada, preferiblemente con un número consecutivo: Figura 1, figura 2, ...
Las figuras deben ser realizadas siguiendo las reglas del dibujo técnico.
Se prefiere que dentro de las figuras no se incluya ningún texto. Cada uno de los detalles ilustrados en las figuras debera estar señalado con un número o signo de referencia, el cual será el mismo en todas las figuras en donde se encuentre el detalle en cuestión. Si en alguna figura no se encuentran números de referencia, se entiende que no se va a decir nada sobre ella dentro del texto de la descripción y, entonces, es preferible que se omita tal figura. Análogamente, si en una figura no se encuentra señalado algún detalle con el respectivo número de referencia, es preferible que se omita tal detalle.

La patente de **modelo de utilidad** no puede incluir los procedimientos, por definición. Si alguna de las reivindicaciones de una solicitud de patente de modelo de utilidad reclama un procedimiento, debe ser suprimida.

Descripción *(artículo 28 D. 486)*

- Durante el análisis del texto de la descripción y de las ilustraciones anexadas, se observaron los siguientes defectos:

1) En el título o nombre de la invención no se menciona ni el *abastecedor* ni el *conjunto de partes* que se reclaman en las reivindicaciones. Dicho título debera concordar con lo que se reclame en el capítulo reivindicatorio modificado por el solicitante

2) El capítulo descriptivo inicia la paginación en la página 2, folio 56, lo cual no es correcto.

3) En el folio 56 aparece por primera vez una expresión numérica (*Patente Norteamericana No. 4,946,069*) en la cual, en primer lugar, se debe sustituir la expresión *Norteamericana* porque no corresponde a ningún país; en segundo lugar, se sugiere sustituir la abreviación de número por n.°, de acuerdo con lo que aparece en el Apéndice 2 del *Diccionario panhispánico de dudas* de la Real Academia Española y de la Asociación de Academias de la Lengua Española, primera edición, octubre de 2005, página 729; y, en tercer lugar, se deben sustituir las comas por espacios en blanco, porque en Colombia se debe utilizar la coma decimal para las expresiones numéricas.

4) En el folio 57 aparecen las expresiones *cuello del contendor, ...las superficies... comprenden acciones...*, que carecen de sentido, según el contexto.

5) En el folio 58 aparece por primera vez la expresión *y/o*, Al respecto, el citado *Diccionario panhispánico de dudas*, página 681, dice:

> *y/o: Hoy es frecuente el empleo conjunto de las conjunciones copulativa y disyuntiva separadas por una barra oblicua, calco del inglés «and/or», con la intención de hacer explícita la posibilidad de elegir entre la suma o la alternativa de dos opciones: «Se necesitan traductores de inglés y/o francés».* ***Se olvida que la conjunción 'o' puede expresar en español ambos valores conjuntamente.***

El examinador ha subrayado la última frase porque es particularmente aplicable a este caso. -En el folio 69 aparece la expresión *y/u* que es equivalente a la objetada-

6) En el mismo folio 58 aparece la expresión *...la acción del dedo o del dedo pulgar* en la cual sobra la alternativa (*o del dedo pulgar*) porque el *dedo pulgar* también es un *dedo*. Un defecto similar ocurre hacia el final del mismo folio, donde aparece *la acción del dedo determinada (o dedo pulgar)* en donde además del defecto anotado se encuentra otro: la aclaración entre paréntesis debería ir antes del término *determinada*, no después. Se objeta, por una razón similar, la expresión *es girada hacia dentro por un dedo o el dedo pulgar del usuario* que aparece en el folio 62.

7) En el mismo folio 58 aparece por primera vez un intervalo (*un rango de 5 a 30N)* en el cual se ha omitido el símbolo de las unidades (*N*) para la primera cifra; la expresión objetada debería quedar: *un rango de 5 N a 30 N*. El mismo defecto se encuentra, por ejemplo, en las siguientes expresiones del folio 59: *8 a 50 ml , 25 a 150 µl , 50 a 100 µl* , que, corregidas, serían: *8 ml a 50 ml, 25 µl a 150 µl, 50 µl a 100 µl*. En el folio 84 hay otros intervalos con el mismo defecto.

8) En el folio 60 aparece la expresión *La figura 9 es una reenganche esquemática de un mecanismo...* que carece de sentido.

9) En el folio 65 aparece la expresión *el primer ángulo debe de ser menor de aproximadamente 20° y, convenientemente, en un rango de... 20° a 35°,... 20° a 26°,... 22° a 26°* en la cual el antecedente no concuerda con el consecuente.

10) En el folio 67 aparece la expresión *haciendo referencia a la figura 3,... el seguidor de leva 1452,... las superficies redondeadas 1493* pero, los números de referencia (*1452, 1493*) no se encuentran en la figura 3, folio 102. Incidentalmente, se le sugiere al solicitante que encierre entre paréntesis los números de referencia cuando aparezcan dentro del texto de la solicitud, con el objeto de distinguirlos de otros tipos de números que ocasionalmente aparecen allí.

11) En el folio 75 aparece -dos veces- la expresión *como se muestra en la figura 2.... lengüeta 1501* pero en la figura 2, folio 101, no se encuentra el número de referencia (*1501*).

12) En el folio 77 aparece por primera vez una sigla (*PDE4*) que no se encuentra acompañada por su correspondiente significado. El mismo defecto ocurre con las siglas *NSAIDs*, *iNOS* que aparecen en el folio 79.
13) En el folio 80 se encuentran varios números en los cuales no se emplea la coma decimal, por lo que deben ser corregidos.
14) En el folio 82 aparece la expresión *p/p* cuyo significado no está claro.
15) En los folios 85 y 86 aparece la expresión *Todo el uso de términos en la presente descripción, (¿?) tales "acerca", aproximadamente", "substancialmente" y similares en relación con un parámetro o propiedad significan que incluyen el parámetro exacto o propiedad, así como las desviaciones inmateriales de las mismas*, que, en primer lugar, al tratarse de fijar o establecer significados, debería encontrarse, como aclaración, en la primera ocasión en que se emplee uno de tales términos dentro del texto de la descripción; en segundo lugar, toda la expresión carece de sentido y, en consecuencia, no afecta el sentido natural de los términos mencionados expresamente en ella; y, en tercer lugar, si por *desviaciones inmateriales* el solicitante quería referirse a las *desviaciones insignificantes*, entonces, el término al que se refiera la expresión sobraría, sería superfluo, -se podría omitir sin que sufra la claridad de la exposición-.

- La descripción no cumple con los requisitos de claridad y divulgación completa, lo que dificulta o impide su comprensión y ejecución de acuerdo al Art. 28 de la Decisión 486 o al Art. 22 del Tratado PCT

Reivindicaciones *(artículo 30 D 486)*
- Durante el análisis del texto de las reivindicaciones se observaron los siguientes defectos:

1) En la reivindicación 1, folio 87, se reclama *un aparato de abastecimiento de fluidos para abastecer un producto fluido* expresión que resulta redundante y por tanto afecta negativamente la concisión.
2) En la misma reivindicación 1 aparecen las expresiones *se puede abastecer, se puede operar, se puede mover* que son ambiguas, porque así como *se puede....* se encuentra implícita la otra posibilidad: *se puede no abastecer, se puede no operar, se puede no mover*. En este caso, para evitar ambigüedades, el solicitante debería establecer las características físicas, tangibles, del aparato que está reclamando como propio, que le comunican esa factibilidad. Concretamente, ¿qué partes, piezas, aspectos, detalles,... del aparato son los que le dan la potencialidad que menciona? Si los puede definir, entonces podrá definir el aparato y, por el contrario, si no los puede definir, entonces no podrá definir el aparato y -como consecuencia- no podrá reclamar un aparato específico, concreto. Defectos similares a los anotados aquí se encuentran en las reivindicaciones 30, 31, 37, 39 -donde se encuentra una variante: *hace posible*- y, en la reivindicación 52.
3) En la reivindicación 2, folio 88, aparece por primera vez dentro del capítulo reivindicatorio el término *aproximadamente* que, como se vio arriba, con relación a la descripción, es indefinido; en otras palabras, es ambiguo, subjetivo, no contribuye a definir los alcances de la protección que desea el solicitante. El mismo término se encuentra en las reivindicaciones 4, 5, 7 y 14.
4) En la reivindicación 4, folio 88, aparece por primera vez dentro del capítulo reivindicatorio un intervalo o rango (*20 a 45 N*) en el cual se ha omitido el símbolo de las unidades de la primera cifra. En las reivindicaciones 7 y 14 se encuentra un defecto similar.
5) En la reivindicación 22 se reclama *el aparato tal y como se describe en la reivindicación 19 o cualquiera de las reivindicaciones dependientes de la misma* en la cual se ha subrayado la expresión objetable porque, por una parte, se está

autoreferenciando, y, por otra parte, se remite a reivindicaciones posteriores: la 23 y la 26, por ejemplo; lo cual no es admisible.

6) En la reivindicación 23 aparece la expresión *caracterizado porque el elemento accionador es el elemento accionador solo* que afecta negativamente la concisión, ya que no está definiendo nada que no haya sido definido antes.

7) En la reivindicación 26 aparece la expresión *aparato... caracterizado porque el producto fluido es un medicamento* lo cual no es admisible, porque no se puede definir un continente (un recipiente) por su contenido; ninguna de las características del fluido afecta al aparato que se reclama, éste sigue siendo el mismo aparato a pesar de que el fluido sea agua o sea aire o sea una medicina o un medicamento o cualquier otro fluido.

8) En la reivindicación 38, folio 96, se reclama *el abastecedor tal y como se describe en la reivindicación 37* pero, en la *reivindicación 37*, folios 94 a 96, se reclama un *aparato* no un *abastecedor*, por lo que la reivindicación 38 carece de definición. Una objeción similar es aplicable a la reivindicación 39, folio 96.

9) En la reivindicación 48, folio 98, se reclama *un conjunto de partes componentes* expresión que, en aras de la concisión, debería ser *un conjunto de componentes*.

10) En la misma reivindicación 48 aparece la expresión [conjunto de partes] *caracterizado porque cada boquilla es idéntica, cada alojamiento tiene una abertura para recibir una de las boquillas y cada alojamiento además tiene una característica diferente a las otras* con la cual, como se puede observar, no se está definiendo el *conjunto de partes*. Se ha subrayado una expresión que se debe omitir en aras de la concisión. Con esta reivindicación no se puede determinar cómo es el conjunto de partes que el solicitante desea proteger como propio.

11) Pero, las reivindicaciones 49 y 50, folio 98, no contribuyen a definir tal *conjunto de partes*, ambas contienen vaguedades sin trascendencia (... *de color diferente, de forma diferente,* en ninguno de los dos casos está clara la diferencia respecto a qué).

12) En la reivindicación 51, la cosa se agrava: esta reivindicación reclama: *el conjunto... comprende además una pluralidad de contenedores, uno por cada abastecedor, conteniendo cada contenedor una formulación de medicamento fluido idéntico o diferente.* Con esta reivindicación se está agregando otra *parte* al *conjunto de partes* pero no se le está añadiendo definición al *conjunto* que se reclama.

Las reivindicaciones no cumplen con los requisitos de definición, claridad, concisión o sustento por la descripción de acuerdo al Art. 30 de la Decisión 486 o el Art. 22 Tratado PCT. Debe entenderse que las reivindicaciones dependientes de las reivindicaciones objetadas son, asimismo, objetadas, por razones análogas.

Se deben presentar, entonces, nuevos capítulos descriptivo y reivindicatorio, ambos completos, junto con un nuevo juego de dibujos, donde se hayan corregido todas las objeciones que se han hecho arriba. Esto con el fin de evitar -cuando solo se presentan algunas páginas sueltas corregidas- que el lector tenga que desplazarse desde un sitio a otro de la solicitud y luego regresar a donde estaba antes sin perder la ilación de la lectura, porque esto produce confusión y afecta negativamente la claridad de dichos capítulos.

Se le advierte al solicitante que por lo menos parte de las modificaciones sugeridas arriba podrían resultar inconducentes si se mantienen las objeciones a la patentabilidad que se insinúan adelante.

5. **Unidad de concepto inventivo** *(artículo 25 D 486)*

En el capitulo reivindicatorio se encontraron seis (6) reivindicaciones independientes:
La reivindicación 1, folio 87, que reclama *un aparato de abastecimiento de fluidos*.
La reivindicación 30, folio 92, que, también, reclama *un aparato de abastecimiento de fluidos*.
La reivindicación 37, folio 94, que, de nuevo, reclama *un aparato de abastecimiento de fluidos*.
La reivindicación 42, folio 96, que reclama *un abastecedor de fluidos*.
La reivindicación 48, folio 98, que reclama *un conjunto de ~~partes~~ componentes para la fabricación*... [que comprende]: *una pluralidad de boquillas... y una pluralidad de alojamientos*...
Y, la reivindicación 52, folios 98 y 99 que reclama, otra vez, un *abastecedor de fluidos*.
Análisis previo:
Puede verse, sin entrar en mayores detalles, que lo reclamado en la reivindicación 48 -y sus dependientes- no tiene unidad de concepto inventivo con respecto a lo reclamado en las demás reivindicaciones.
En cuanto al aparato reclamado en las reivindicaciones 1, 30 y 37, sin entrar en detalles: El capítulo reivindicatorio, en este aspecto, o bien carece de concisión -debería ser una sola reivindicación independiente para reclamar el aparato- o bien carece de unidad de concepto inventivo -deberían ser dos o más solicitudes de patente para intentar proteger cada uno de ellos-.
Y, en cuanto al *abastecedor* reclamado en las reivindicaciones 42 y 52, de nuevo, sin profundizar en detalles: El capítulo reivindicatorio, en este aspecto, o bien carece de concisión -debería ser una sola reivindicación independiente para reclamar el *abastecedor*- o bien carece de unidad de concepto inventivo -deberían ser dos solicitudes de patente para intentar proteger cada uno de ellos-.

Para un análisis detallado respecto a la falta de unidad de concepto inventivo, nos remitimos -haciendo las correspondientes modificaciones respecto a las referencias sobre el sustento legal- a los folios 33 a 35, donde aparece la Opinión Escrita de la Autoridad de Búsqueda Internacional; opinión que, mutatis mutandis acogemos en general.

En cualquier caso, le corresponde al solicitante establecer claramente las reivindicaciones que no sean afectadas por la falta de concisión o la falta de unidad de concepto inventivo.

6. Determinación del Estado de la Técnica

La fecha que se ha tenido en cuenta para determinar el Estado de la Técnica es la

Fecha de presentación internacional 2005-03-10

Se realizó la búsqueda en el estado de la técnica de documentos relacionados con la solicitud teniendo en cuenta la fecha indicada; y durante la búsqueda de anterioridades se encontraron los siguientes documentos, que forman parte de la familia de patentes de la presente solicitud: publicación WO 2005/087615 del 05-09-22, citada por el solicitante, folio 1, cuya copia aparece en los folios 25 a 28; Publicación WO 2005/044354 A1 del 05-05-19; Publicación EP 1 699 512 A1 del 06-09-13; Publicación EP 1 723 052 A1 del 06-11-22;

Publicación uS 2007/0131717 A1 del 07-06-14; Publicación US 2007/0138207 A1 del 07-06-21. Se anexa la copia de las primeras páginas de estos documentos junto con la copia del Informe de Búsqueda Internacional para el segundo documento WO citado y la copia de las páginas 2 a 10 del rechazo (no definitivo) fechado 2009-08-06 por la USPTO. También se encontraron los siguientes documentos que forman parte del estado de la técnica más cercano al objeto de la solicitud:

n.°	Documento	Título	Fecha de publicación
D1	Patente US 4 860 738, cuyos inventores son Manfred K. Hegermann y Edward J. Drozd, Jr., quienes le cedieron sus derechos a la Schering Corporation	«Hand held metered spray dispenser»(Dispensador de rocio dosificado para sostener en la mano)	1989-08-29
D2	Publicación FR 2 671 294 A1, cuyos titulares son Jean-Louis Savona y Michel Tomassini	«Boîtier rechargeable pour support de bombe anti-agression à gaz paralysant coloré pour marquage et identification de l'agresseur»(Una caja recargable para soporte de una bomba antiagresiones con gas paralizante coloreado para marcar e identificar al agresor)	1992-07-10
D3	Patente US 5 899 365, cuyos inventores son Gerd Eichler, Dieter Hochrainer y Reiner Reeg , quienes le cedieron sus derechos a la Boehringer Ingelheim KG	«Device for assisting manual actuation of an aerosol dispenser»(Un dispositivo para asistir la operación manual de un dispensador de aerosol)	1999-05-04
D4	Publicación WO 99/49984 A1, cuyos inventores son Paul John Rennie, Eric Wilkinson, Julian Robert Pieters y Robert Andrew Lawson, quienes le cedieron sus derechos a The Procter & Gamble Company	«Nasal spray device with elastomeric valve»(Un dispositivo de rocío nasal con una válvula elastomérica)	1999-10-07
D5	Patente US 6 305 371 B1, cuyos inventores son Per Frid, Robert Jansen y Paul Wright, quienes le cedieron sus derechos a la AstraZeneca AB	«Inhalation for administering medicament by inhalation»(Inhalador para administrar medicinas por inhalación)	2001-10-23
D6	Publicación WO 02/20168 A1, cuyo inventor es Giuseppe Stradella	«Multiple-dose device for dispensing a fluid product»(Un dispositivo para dispensar un producto fluido)	2002-03-14
D7	Patente US 6 382 205 B1, cuyos inventores son Robert E. Weinstein y Allan M. Weinstein	«Method and device for organizing and coordinating the combined use of topical agents for the treatment of respiratory disorders»(Un método y un dispositivo para organizar y coordinar el empleo combinado de agentes tópicos para el tratamiento de desórdenes respiratorios)	2002-05-07
D8	Publicación US 2002/0170928 A1, cuyos inventores son Jerry Grychowski, Martin P. Foley, Robert Morton y Daniel K. Engelbreth	«Medicament applicator»(Un aplicador de medicinas)	2002-11-21

n.°	Documento	Título	Fecha de publicación
D9	Publicación WO 03/095007 A2, cuyo inventor es Michael Birsha Davies, quien le cedió sus derechos a la Glaxo Goup Limited	«A fluid dispensing device»(Un dispositivo dispensador de fluido)	2003-11-20
D10	Publicación WO 04/080606 A1, cuyos inventores son Michael Birsha Davies y James William Godfrey, quienes le cedieron sus derechos a la Glaxo Goup Limited	«A fluid dispensing device with stopper»(Un dispositivo dispensador de fluido con un tapón)	2004-09-23
D11 ‡	Publicacion US 2005/0211241 A1, cuyos inventores son Gregor John McLennan Anderson, Michael Birsha Davies y Paul Kenneth Rand	«A fluid dispensing device»(Un dispositivo dispensador de fluido)	2005-09-29‡

ver F. 226 vuelta

Se anexa la copia de las páginas pertinentes de estos documentos

‡: El documento D11 fue publicado después de la fecha de presentación de la solicitud original PCT (2005-03-10), esto es, no forma parte del estado de la técnica; se incluye aquí porque es citado -junto con los documentos D5 y D8- en el rechazo de la USPTO mencionado arriba.

NOTAS: No se realizaron las evaluaciones de los demás requisitos de patentabilidad, porque se hicieron algunas objeciones respecto a la definición, la claridad y la concisión de las reivindicaciones. Además, se hicieron objeciones respecto a la falta de unidad de concepto inventivo de lo reclamado en las reivindicaciones. En otras palabras, no hay materia sobre la cual realizar las comparaciones de rigor.

No obstante lo anterior, teniendo en cuenta las enseñanzas de los documentos mencionados arriba y los exámenes realizados por la autoridad PCT y por la USPTO, cuyos resultados se mencionan arriba como *Informe de Búsqueda Internacional*; y, *Rechazo no definitivo*, respectivamente, se prevén objeciones a la novedad y al nivel inventivo de la mayoría de -si no todas- las reivindicaciones.

7. Conclusión:

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados negativamente por la falta de claridad de la descripción y las reivindicaciones y por la falta de definición, de sustento y de concisión de estas últimas.

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a

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pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única n.° 10 de 2001.

ALIX CARMENZA CÉSPEDES DE VERGEL
Directora de Nuevas Creaciones (C)

El anterior requerimiento fue notificado por fijación en lista, de fecha _____ 14 MAR 2013

CONCEPTO TÉCNICO n.° 0545

EXAMINADOR TÉCNICO
Código n.° 202009

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 May 2005 (19.05.2005)

PCT

(10) International Publication Number
WO 2005/044354 A1

(51) International Patent Classification[7]: A61M 15/08, B05B 11/00, B65D 83/14

(21) International Application Number: PCT/GB2004/004626

(22) International Filing Date: 2 November 2004 (02.11.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

0325629.4	3 November 2003 (03.11.2003)	GB
0405477.1	11 March 2004 (11.03.2004)	GB
0420539.9	17 September 2004 (17.09.2004)	GB

(71) Applicant *(for all designated States except US)*: **GLAXO GROUP LIMITED** [GB/GB]; Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB).

(72) Inventors; and

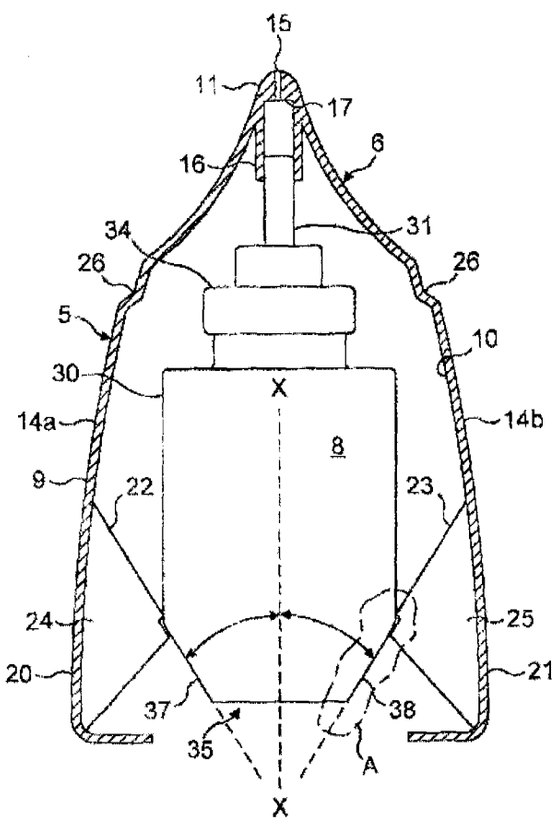
(75) Inventors/Applicants *(for US only)*: **DAVIES, Michael, Birsha** [GB/GB]; GlaxoSmithKline, Park Road, Ware Hertfordshire SG12 0DP (GB). **HEDLEY, Mark, Graham** [GB/GB]; GlaxoSmithKline, Park Road, Ware Hertfordshire SG12 0DP (GB). **JONES, Margot, Jean** [AU/GB]; GlaxoSmithKline, Park Road, Ware Hertfordshire SG12 0DP (GB).

(74) Agent: **GIDDINGS, Peter, John**; GlaxoSmithKline, Corporate Intellectual Property (CN925.1), 980 Great West Road, Brentford, Middlesex TW8 9GS (GB).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,

[Continued on next page]

(54) Title: A FLUID DISPENSING DEVICE



(57) Abstract: A fluid dispensing device (5, 105, 205, 305, 405, 505) for dispensing a fluid form medicament formulation having a viscosity of from 10 to 2000 mPa.s, is disclosed and comprises a housing (9, 109, 209, 309, 409, 509) and a fluid discharge device (8, 108, 208, 308, 408, 508) arranged to be actuated by one or more levers (20, 21; 120, 121; 170, 220, 221; 320, 321; 420, 421; 520) to cause actuation of a pump forming part of the fluid discharge device. A pre-load means (28; 27, 28; 39,40; 41, 42, 44; 144, 47a, 47b; 150, 152, 153, 224, 227; 342; 424x, 446; 425a; 427, 428; 560, 561) is used to prevent actuation of the pump until a pre-determined force is applied to each lever of sufficient magnitude to guarantee the production of a well developed efficient spray from the fluid dispensing device.

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB2004/004626

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M15/08 B05B11/00 B65D83/14

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 A61M B05B B65D

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, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	FR 2 812 826 A (VALOIS SA) 15 February 2002 (2002-02-15) the whole document	1-54
Y	EP 0 412 524 A (TOKO YAKUHIN KOGYO KABUSHIKI KAISHA) 13 February 1991 (1991-02-13) the whole document	1-54
P,X	WO 2004/080606 A (GLAXO GROUP LIMITED; DAVIES, MICHAEL, BIRSHA; GODFREY, JAMES, WILLIAM) 23 September 2004 (2004-09-23) page 12, line 22 - page 17, line 27 page 45, line 4 - page 46, line 19 page 49, lines 12-14 figures	1-54

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 February 2005	24/02/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Azaïzia, M

Form PCT/ISA/210 (second sheet) (January 2004)

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 55

Claims shall not, except where absolutely necessary, rely, in respect of the technical features of the invention, on references to the description or drawings (Rule 6.2 (a) PCT). In particular, they shall not rely on such references as: "as described in part ... of the description," or "as illustrated in figure ... of the drawings."

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

information on patent family members

Inte national Application No
PC T/GB2004/004626

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2812826 A	15-02-2002	FR 2812826 A1	15-02-2002
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Deutsches
Patent- und Markenamt

Hinweis des DPMA zu einer EuroPCT-Anmeldung

Information provided by the DPMA concerning a Euro-PCT application

Information du DPMA concernant une demande euro-PCT

(11) Veröffentlichungsnummer:
Publication number:
Numéro de publication:

EP 1 699 512 A1

(43) Veröffentlichungsdatum:
Publication date:
Date de publication:

13.09.2006

Internationale Anmeldung veröffentlicht durch die Weltorganisation für geistiges Eigentum,

International application published by the World Intellectual Property Organization,

Demande internationale publiée par l'Organisation Mondiale de la Propriété Intellectuelle,

siehe / see / voir:

(87) Internationale Veröffentlichungsnummer:
International publication number:
Numéro de publication internationale:

WO2005/044354

(19.05.2005 Gazette 2005/20)

Deutsches
Patent- und Markenamt

Hinweis des DPMA zu einer EuroPCT-Anmeldung

Information provided by the DPMA concerning a Euro-PCT application

Information du DPMA concernant une demande euro-PCT

(11) Veröffentlichungsnummer:
Publication number:
Numéro de publication:

EP 1 723 052 A1

(43) Veröffentlichungsdatum:
Publication date:
Date de publication:

22.11.2006

Internationale Anmeldung veröffentlicht durch die Weltorganisation für geistiges Eigentum,

International application published by the World Intellectual Property Organization,

Demande internationale publiée par l'Organisation Mondiale de la Propriété Intellectuelle,

siehe / see / voir:

(87) Internationale Veröffentlichungsnummer:
International publication number:
Numéro de publication internationale:

WO2005/087615

(22.09.2005 Gazette 2005/38)

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US 20070131717A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2007/0131717 A1**

Davies et al. (43) **Pub. Date: Jun. 14, 2007**

(54) **FLUID DISPENSING DEVICE**

(76) Inventors: **Michael Birsha Davies**, Hertfordshire (GB); **Mark Graham Hedley**, Hertfordshire (GB); **Margot Jean Jones**, Hertfordshire (GB)

Correspondence Address:
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CORPORATE INTELLECTUAL PROPERTY, MAI B475
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RESEARCH TRIANGLE PARK, NC 27709-3398 (US)

(21) Appl. No.: **10/577,977**

(22) PCT Filed: **Nov. 2, 2004**

(86) PCT No.: **PCT/GB04/04626**

§ 371(c)(1),
(2), (4) Date: **May 3, 2006**

(30) **Foreign Application Priority Data**

Nov. 3, 2003 (GB) 0325629.4
Mar. 11, 2004 (GB) 0405477.1
Sep. 17, 2004 (GB) 0420539.9

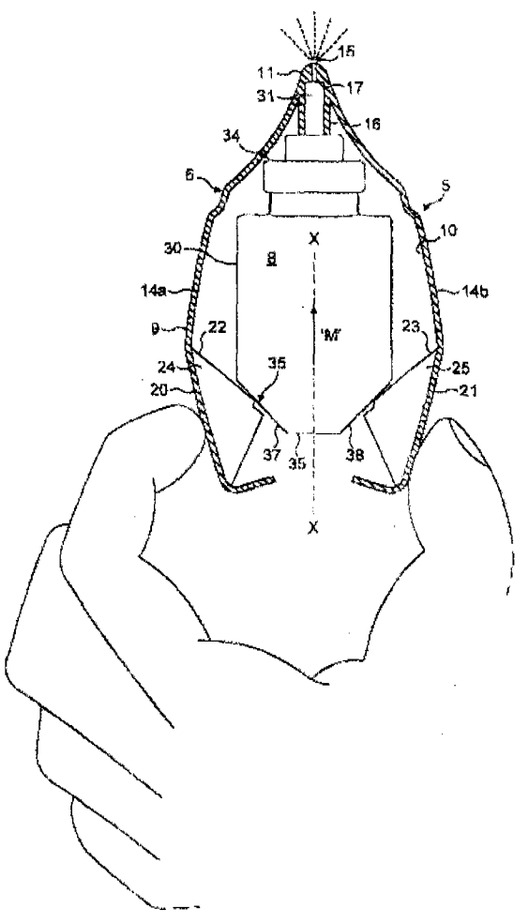
Publication Classification

(51) **Int. Cl.**
B67D 5/64 (2006.01)

(52) **U.S. Cl.** **222/162**; 128/200.23

(57) **ABSTRACT**

A fluid dispensing device for dispensing a fluid form medicament formulation having a viscosity of from 10 to 2000 mPa·s. is disclosed and comprises a housing and a fluid discharge device. The fluid discharge device is arranged to be actuated by one or more levers so as to apply a force to the fluid discharge device which is used to move a container forming part of the fluid discharge device along a longitudinal axis of the fluid discharge device to cause actuation of a pump forming part of the fluid discharge device. A pre-load means is used to prevent actuation of the pump until a pre-determined force is applied to each lever of sufficient magnitude to guarantee the production of a well developed efficient spray from the fluid dispensing device.



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US 20070138207A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2007/0138207 A1**

Bonney et al. (43) **Pub. Date: Jun. 21, 2007**

(54) **FLUID DISPENSING DEVICE**

(75) Inventors: **Stanley George Bonney**, Hertfordshire (GB); **Hugh Alexander Connell**, Worcestershire (GB); **Michael Birsha Davies**, Hertfordshire (GB); **James William Godfrey**, Hertfordshire (GB); **Mark Graham Hedley**, Hertfordshire (GB); **Robert William Tansley**, Warwickshire (GB)

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RESEARCH TRIANGLE PARK, NC 27709-3398 (US)

(73) Assignee: **Glaxo Group Limited**

(21) Appl. No.: **10/598,464**

(22) PCT Filed: **Mar. 10, 2005**

(86) PCT No.: **PCT/GB05/00944**

§ 371(c)(1),
(2), (4) Date: **Aug. 31, 2006**

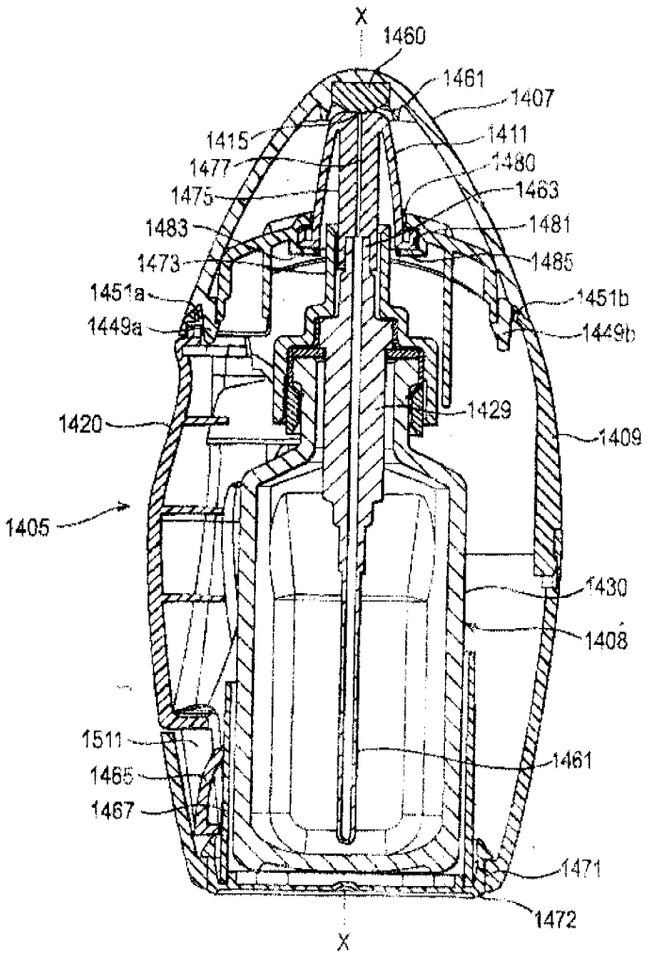
Publication Classification

(51) **Int. Cl.**
B67D 5/64 (2006.01)

(52) **U.S. Cl.** **222/162**; 128/200.23

(57) **ABSTRACT**

A fluid dispensing device for dispensing a fluid product having a dispensing outlet from which the fluid product is dispensable, a supply of the fluid product, a dispensing member mounted for movement in a dispensing direction along an axis X-X from a first position to a second position which causes a dose of the fluid product in the supply to be dispensed from the dispensing outlet and a finger-operable actuator member mounted for movement in an actuating direction which is generally transverse to the axis.



DETAILED ACTION

This is the initial Office Action based on the 10/598464 application filed August 31, 2006. Claims 1-53 as presented in the Preliminary Amendment are currently pending and considered below.

Information Disclosure Statement

1. The information disclosure statement filed August 31, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

3. Claim 14 is objected to because of the following informalities: the claim does not end in a period --.--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3, 6, 8, 10, 11, 13, 15-36, and 42-47 are rejected under 35 U.S.C. 102(e) as being anticipated by USPGPub 2007/0095853 A1 to Bonney et al.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) **might** be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claims 1, 3, 6, 8, 10, 11, 13, and 15-29, Bonney et al disclose a fluid dispensing device having: a dispensing outlet (27), a supply of fluid product (2), a dispensing member (56) mounted for movement in a dispensing direction along an axis, and a finger-operable actuator (101) mounted for movement in an actuating direction which is generally transverse to the axis (F), wherein the actuator member has at least one cam surface (129a, 129b) and the dispensing member has at least one cam

follower surface (135a, 135b), wherein the actuator is movable in the actuating direction (F) to cause the at least one cam surface to bear against the at least one cam follower surface to cam this dispensing member from a first position to a second position (Figs. 2A-2I), wherein the at least one cam surface has a commitment section at a first angle to the axis and an adjacent drive section at a second angle to the axis which is greater than the first angle (see figure reproduced below), wherein the device is configured such that the at least one cam follower surface successively rides over the commitment and drive sections (Figs. 2A-2I).

Furthermore, Bonney et al disclose that the commitment section is planar (each small portion of curvature is a plane), that the drive section has an arcuate transition portion contiguous with the commitment section, or is arcuate itself (Fig. 2A'), and that he commitment section is of a first length and the drive section is of a greater second length. Bonney et al also disclose that the at least one cam follower surface is arcuate (Fig. 2A'), that the actuator member is mounted in the device for movement on an arcuate path in the actuating direction (pivots about P1), that the first angle to the axis becomes steeper as the actuator member moves in the actuating direction, and that the second angle remains substantially constant as the actuator member moves in the actuating direction.

Bonney et al further disclose that the actuator member is mounted for pivotal movement about a first end (105) and the at least one cam surface is remote from the first end, wherein the dispensing direction is an upward direction and the first end of the actuator is at a lower end thereof and the cam follower is disposed toward an upper end

of the dispensing member (Fig. 2F). Further, Bonney et al disclose that the dispensing member is a dispensing container in which the supply of fluid product is contained (56, 2; Fig. 2A) and that the dispensing container has a pump (upper portion between the reservoir and the nozzle) and that the actuator member is the sole actuator (Fig. 1).

Additionally, Bonney et al disclose that the dispensing outlet is a nozzle sized and shaped for insertion into a nostril of a human or animal body (Paragraph [0065]) and that the fluid product is a medicament (Paragraph [0003]). Further, Bonney et al disclose that the dispensing member and housing have cooperating guide members for guiding movement of the dispensing member along the axis wherein the members prevent rotation of the dispensing member and comprise a runner and a track (inside of nozzle and outside of the pump portion of the dispensing unit).

Regarding claims 30-36, Bonney et al disclose a fluid dispensing device having a dispensing outlet (27), a supply of fluid product (2), a dispensing member (56) mounted for movement in a dispensing direction along an axis, a finger-operable actuator (101) mounted for movement in an actuating direction (F) which is generally transverse to the axis, wherein the actuator member has at least one cam surface (129a, 129b) and the dispensing member has at least one cam follower surface (135a, 135b), wherein the actuator member is movable in the actuating direction (F) to cause the at least one cam surface to bear against the at least one cam follower surface to cam this dispensing member in the dispensing direction (Figs. 2A-2I), and wherein the actuator member further has a stop to stop the dispensing member being movable along the axis in a direction opposite the dispensing direction beyond a predetermined

axial position to provide alignment of the at least one cam surface and the at least one cam follower surface (133a, 133b). Bonney et al further disclose that the stop comprises at least one stop surface engagable with a respective surface of the dispensing member (Fig. 2I), wherein the at least one stop surface extends generally transversely to the axis (Fig. 2I), wherein the at least one stop surface forms a continuation of the at least one cam surface (all a part of the drive system 109), wherein the at least one surface of the dispensing member forms a continuation of the at least one cam follower surface (135a, 135b), and wherein the at least one cam surface is provided by a nose of the actuator member (109) and the at least one stop surface is a tip portion of the nose section (Fig. 2I).

Regarding claims 42-47, Bonney et al disclose a fluid dispenser having a nozzle sized and shaped for insertion into a nostril (19, Paragraph [0063]), and a housing (3) in which the fluid product is containable, wherein the housing has an opening in which the nozzle is received (15) and a fastening mechanism which fastens the nozzle in the opening (lower and upper ridges (see Fig. 1). Bonney et al further disclose that the housing houses a dispensing container (56) having the fluid product (2) wherein the nozzle has an outlet passageway (27) and the dispensing member (pump portion) and outlet are in direct fluid communication and engaged (Fig. 2A). Bonney et al also disclose that the fastening mechanism has a clamp member which clamps the nozzle in the opening (housing half) wherein the nozzle has a flange (lower rim, see Fig. 1) abutting an inner surface of the housing (15), wherein the claim member fastens the flange to the inner surface and the clamp member is a collar structure (upper and lower

rings) being bent or folded over the flange (in formation) to claim the flange to the inner surface (Fig. 2A).

6. Claims 52 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by USPGPub 2002/0170928 A1 to Grychowski et al.

Regarding the above claims, Grychowski et al disclose a fluid dispenser having a nozzle (8) sized and shaped for insertion into a nostril and a housing in which the fluid product is containable (102) and an opening in which the nozzle is receivable wherein the nozzle is made of a different material (such as a different plastic) from the housing (Paragraph [0185]).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 2, 4, 5, 7, 9, 10, 12, and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Bonney et al.

Regarding the above claims, Bonney et al disclose the device of claims 1 and 8 as described above, but fail to teach or disclose specific values for the actuating force, first or second angles, or radius of curvature. At the time of invention, however, it would have been obvious to one having ordinary skill to choose the particular claimed values, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

11. Claims 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grychowski et al in view of USPGPub 2005/0211241 A1 to Anderson et al.

Regarding the above claims, Grychowski et al teach a fluid dispensing device having a housing (102) with a dispensing outlet (not labeled, end of nozzle) adapted to receive therein a container (6) for containing the fluid product for movement along an

axis from a rest position to a dispensing position (Figs. 15-16), the housing having an access opening (base of the device) through which the dispensing container is insertable during a rest position (at the time of manufacture) and at least one finger-operable actuator (120) mounted in the housing for movement inwardly with respect to the housing (Fig. 16) to cause the dispensing container to move, wherein the actuator member is movable from an outward position, enabling dispensing container insertion, to an inward position, which prevents insertion (Fig. 16). Grychowski et al fail to explicitly teach a releasable detent mechanism for holding the actuator in the inward and outward positions. However, Anderson et al teach use of a locking mechanism (Paragraph [0123]). At the time of invention, it would have been obvious to one having ordinary skill in the art to add a locking detent mechanism such as that disclosed by Anderson et al to the dispenser disclosed by Grychowski et al in order to prevent accidental discharge of the device (Paragraph [0123]).

12. Claims 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grychowski et al in view of USPN 6,305,371 B1 to Frid et al.

Regarding the above claims, Grychowski et al teach a set of component parts for manufacturing a plurality of fluid dispensers comprising a plurality of nozzles (8) sized and shaped for use in the nostril (Abstract), and a plurality of housings (102) wherein teach nozzle is identical, and each housing has an opening for a nozzle. Grychowski et al do not necessarily disclose different housings with different characteristics. However, Frid et al disclose device for administering medicament wherein the housings can have different characteristics, including but not limited to color, shape, or a different

medicament formulation (Col. 1, lines 43-57 and Col. 3, lines 15-55). At the time of invention it would have been obvious to one having ordinary skill in the art to combine the nasal applicator of Grychowski et al with the differing characteristics of Frid et al in order to easily distinguish applicators for different medications or for different users.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

United States Patent [19]

Hegemann et al.

[11] **Patent Number: 4,860,738**

[45] **Date of Patent: Aug. 29, 1989**

[54] **HAND HELD METERED SPRAY DISPENSER**

[75] Inventors: **Manfred K. Hegemann**, South Nyack, N.Y.; **Edward J. Drozd, Jr.**, Lake Hiawatha, N.J.

[73] Assignee: **Schering Corporation**, Kenilworth, N.J.

[21] Appl. No.: **212,847**

[22] Filed: **Jun. 29, 1988**

Related U.S. Application Data

[62] Division of Ser. No. 451,311, Dec. 20, 1982, Pat. No. 4,771,769.

[51] **Int. Cl.**[4] **A61M 11/00**

[52] **U.S. Cl.** **128/200.22**; 222/162

[58] **Field of Search** 128/200.23, 200.22, 128/203.15, 203.22, 203.23, 203.28, 200.14; 604/37, 38, 214, 212; 222/207, 162–164, 160, 211, 321

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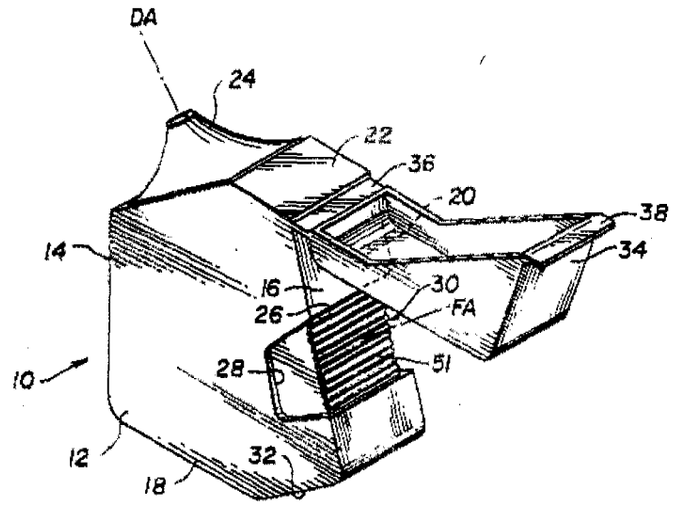
Primary Examiner—Max Hindenburg
Assistant Examiner—K. M. Reiche
Attorney, Agent, or Firm—Warrick E. Lee, Jr.

[57] **ABSTRACT**

A hand held metered spray dispenser including a housing, a nozzle on the housing, a fluid container in the housing, an orifice in the housing, and a converter pivotal to the housing for converting a manual force applied through the orifice along a manual force axis to a force moving the container along a pumping axis transverse to the manual force axis to dispense a metered amount of fluid through the nozzle along a dispensing axis substantially coincidental with the pumping axis.

13 Claims, 2 Drawing Sheets



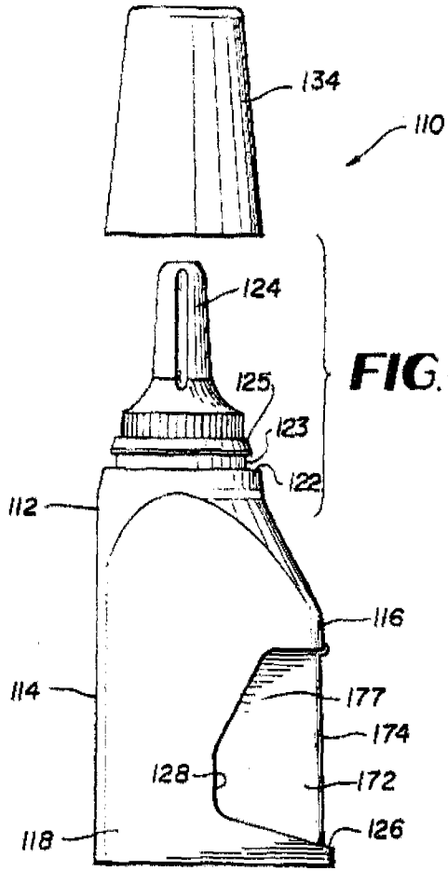


FIG.6

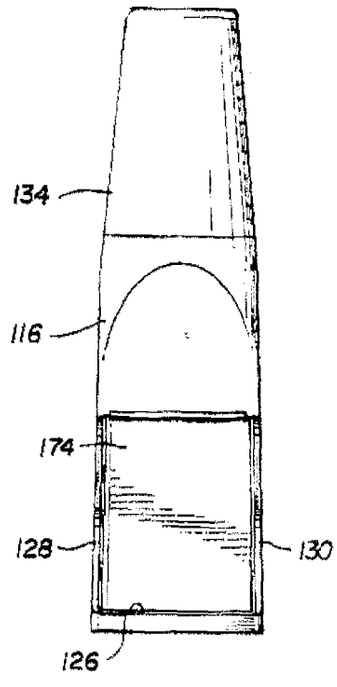


FIG.7

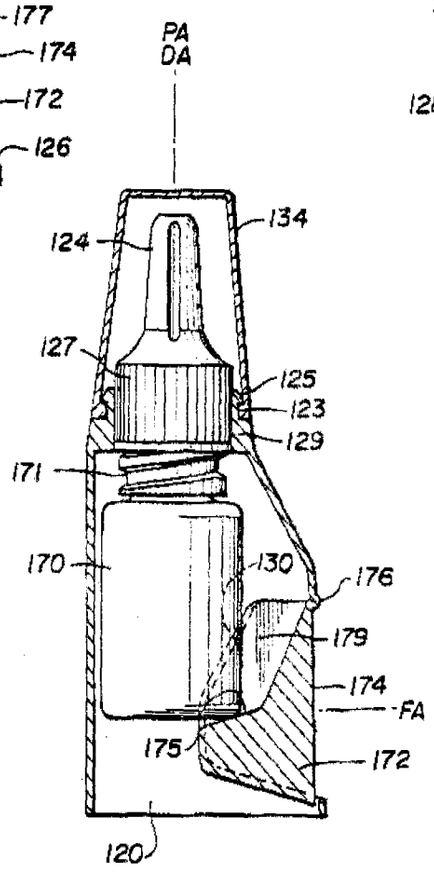


FIG.8

interior of the housing and contract. This contraction dispenses a metered portion of liquid from the container 50 through the nozzle 24, with the pumping axis PA aligned with the dispensing axis DA. Upon release of the manual force, the spring 62 of the pump returns the container 50 to its initial position illustrated in FIG. 2.

As with the housing, the preferred embodiment for the container 50, the extension 52 and the hinge 54 is a unitary molded structure. Alternatively, as illustrated in FIGS. 4 and 5, the container 70 may be distinct and separate from the hinge element 72. The shape of the container 70 is substantially that of container 50, illustrated in FIG. 2, except for the extension 52 and the hinge element 54. The hinge 72 includes an extended portion 74 terminating in a cylindrical hinge element 76. An orifice 78 within the hinge member 72 is received on the neck of the container 70 and is held thereto by the pump 60 which is generally screwed onto the top of the container 70. Alternatively, the hinge can be attached to the bottom or other area of the container. The embodiment illustrated in FIG. 4 functions identical to that of the container 50 illustrated in FIGS. 2 and 3.

Another embodiment of the present invention is illustrated in FIGS. 6, 7 and 8. For ease of understanding, the embodiment of FIGS. 6, 7 and 8 will have 100 added to the numbers of the embodiment of FIGS. 1 through 5. The hand held metering dispenser 110 includes a housing having front walls 114, back wall 116, and side walls 118 and 120. A top wall 122 has a collar 123 therein through which extends a nozzle 124. The back wall 116 includes an orifice 126, the side wall 118 includes an indenture 128 contiguous with the orifice 126 and the side wall 120 includes an indenture 130 contiguous with the orifice 126. The orifice 126 and the indentures 128 and 130 form substantially a slot. A cap 134 engages and is held on the top wall 122 by a rim 125 on the collar 123.

The nozzle 124 is part of a base 127. The interior of the housing 110 includes a extended portion 129 which engages the circumference of the base 127 of the nozzle 124 and maintains the nozzle mounted to the housing. A container 170 has external threads 171 which are mounted to a pump means similar to that of FIGS. 1 through 5 which is not shown for sake of clarity in FIGS. 6 through 8. The pump means is provided between the container 170 and the nozzle 124 with the base 127 forming part of the pump. The container 170 moves along the coincident pumping and dispensing axis PA and DA, respectively.

The converter or the element which converts the manual force applied along force axis FA through the orifice 126 to move the container 170 along the pumping axis PA is shown in FIGS. 6 through 8 as a hinged element 172 having a generally [L-shaped cross-section as illustrated in FIG. 8 with portions 174 and 175. Portion 174 extends across the orifice 126 and follows the contour of the back wall 116. The portion 175 which is substantially orthogonal to the portion 174 f the converted hinge 172 provides a camming surface which engages the bottom of the container 170. The converter 172 is hinged at 176 to the back wall housing 116 by, for example, a living hinge. Thus, converter 172 is a unitary molded structure with the housing 112. Lateral walls 177 and 179 provide an enclosure around the sides of the container 170 and fill the void of indentures 128 and 130 of the housing.

Although the bottom edge of the converter 172 extends past the orifice 126 and engage the interior of back wall 116 to maintain the converter 172 within the housing, it should be noted that portion 174 may extend exterior the housing back wall 116 without departing from the present invention. The important thing is that it does not extend substantially behind the housing in order to prevent accidental operation of the device during transit. It should also be noted that although pivot 176 is shown as a living hinge and an integral part of the converter 172 and housing 112, the converter 172 may be a separate and distinct element and may be pivotally connected anyplace within the interior of the housing 112. Similarly, tee converter may be hinged at the corner of the L-shape instead of at the ends of one of the legs. It should also be noted that although housing 112 is illustrated as a closed molded device, it may be also formed as a unitary molded device with a living hinge along one of the walls such that it may be opened up to allow insertion of the container 170 other than along the pumping and dispensing axis PA and DA.

The operation of the embodiment of FIGS. 6 though 8 is the same as that of FIGS. 1 through 5 in that a manually applied force along force axis FA onto portion 174 of the converter 172 causes pivotal movement of the converter 172 about pivotal axis 176 to cause surface 175 to apply a force to move the container 170 along the pumping axis PA to actuate the pump to dispense fluid from the container along dispensing axis DA and out through nozzle 124. The hand of the user encompasses the housing 112 and a single finger is used to actuate converter 172. As in the previous embodiment, this minimizes the amount of motion of the housing 112 and the nozzle 124 thereby providing accurate placement of the dispensed fluid.

It is evident from the detailed description of the invention that the objects are attained in that a new and improved metered display dispenser is provided. This dispenser overcomes the problems of the prior art by applying the manual activation force of the metered pump on an axis transverse to the dispensing axis and transverse to the pumping axis. This minimizes lateral displacement of the nozzle. Since the majority of the hand encompasses the housing versus the container and the nozzle is integral to the housing, the lateral motion is minimized. In prior art devices, the hand engages a substantial portion of the container and applied the force in a substantially different direction relative to the dispensing axis and the pumping axis.

Although the invention has been described and illustrated in detail, it is clearly understood that the same is by way of illustration and example only and is not to be taken by way of limitation. The spirit and scope of the present invention is to be limited only by the terms of the appended claims.

What is claimed is:

1. A hand held metered spray dispenser comprising:

housing means;

nozzle means extending from the top of said housing means and shaped for insertion into an orifice for directing a spray along a dispensing axis;

container means movably mounted to the interior of said housing means for holding fluid to be dispensed;

manual pump means interconnecting said nozzle means and said container means and having a pumping axis substantially coincidental to said dispensing axis for pumping a metered amount of fluid from said container means to said nozzle means in a single pumping cycle;

(19) RÉPUBLIQUE FRANÇAISE

INSTITUT NATIONAL
DE LA PROPRIÉTÉ INDUSTRIELLE

PARIS

(11) N° de publication : **2 671 294**
(à n'utiliser que pour les commandes de reproduction)

(21) N° d'enregistrement national : **91 00461**

(51) Int Cl⁵ : B 05 B 9/04

(12) DEMANDE DE BREVET D'INVENTION A1

(22) Date de dépôt : 09.01.91.

(30) Priorité :

(43) Date de la mise à disposition du public de la demande : 10.07.92 Bulletin 92/28.

(56) Liste des documents cités dans le rapport de recherche : *Le rapport de recherche n'a pas été établi à la date de publication de la demande.*

(60) Références à d'autres documents nationaux apparentés :

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(74) Mandataire :

(54) Boîtier rechargeable pour support de bombe anti-agression à gaz paralysant coloré pour marquage et identification de l'agresseur.

(57) Boîtier pour support de bombe anti-agression caractérisé en ce qu'il est conçu pour contenir une cartouche rechargeable.

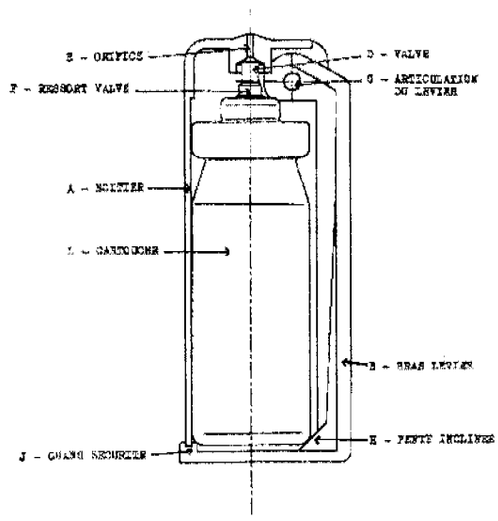
Boîtier pour support de bombe anti-agression caractérisé en ce que la cartouche contient, mélangé au gaz propulseur paralysant, un colorant non-toxique qui permet l'identification de l'agresseur.

Boîtier pour support de bombe anti-agression caractérisé en ce que son mécanisme permet, par une simple pression de la main, un jet direct dans le prolongement du bras vers l'agresseur sans être obligé de chercher un positionnement particulier, sans viser.

Boîtier pour support de bombe anti-agression caractérisé en ce qu'il est muni d'un véritable clip qui permet de l'avoir à disposition instantanément du fait qu'il peut être accroché sur soi, à portée de la main, à un revers de poche, à la ceinture, une anse de sac, etc.

Boîtier pour support de bombe anti-agression caractérisé en ce qu'il est miniaturisé de sorte qu'il tient dans la main sans être visible de l'extérieur.

Boîtier pour support de bombe anti-agression caractérisé en ce qu'il est doté d'une sécurité évitant son fonctionnement en position de repos.



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La présente invention concerne un boîtier rechargeable pour support de bombe aérosol anti-agression à gaz paralysant coloré pour marquage et identification de l'agresseur.

Les bombes auto-défense existantes se présentent sous forme de bombe aérosol de type courant(cosmétique,ménager,etc).Elles sont assez volumineuses,non rechargeables,et la valve d'extraction est positionnée de sorte qu'il est nécessaire,pour bien viser l'agresseur, de tenir la bombe en position perpendiculaire au bras et à bien veiller à ce que l'orifice d'extraction soit dans la bonne direction. Elles ne contiennent que du gaz paralysant et pas de colorant. Leur volume et leur système d'attache en font un objet encombrant à porter sur soi.Il en existe aussi de toutes petites genre porte-clés, ce sont alors des gadgets : leur faible contenance et l'étroitesse de la valve font qu'elles ne peuvent être efficaces.

La présente invention vise à supprimer ces inconvénients.

Le boîtier pour support de bombe anti-agression,selon l'invention, se caractérise en ce que son mécanisme permet,par une simple pression de la main,un jet direct dans le prolongement du bras vers l'agresseur, sans avoir à viser (voir description de la fig.2).

Quelle que soit,donc,la position de la personne agressée et quelque soit la position du boîtier dans la main,il suffit d'une pression des doigts ou de la paume pour faire jaillir le gaz paralysant.

Le boîtier pour support de bombe anti-agression,selon l'invention, se caracterise en ce qu'il est conçu pour contenir une cartouche rechargeable de gaz paralysant ou de toute autre matière anti-agression (gel,liquide,etc).Le fait que le boîtier soit rechargeable présente deux avantages : une personne qui a utilisé une fois une bombe auto-défense normale ne sait pas s'il reste assez de gaz pour parer à une éventuelle deuxième agression,alors que dans notre cas, il met une cartouche neuve dans le boîtier.Avantage économique aussi, la cartouche coûte beaucoup moins cher qu'une bombe.Ce qui est valable également dans le cas où la date de validité de la bombe est périmée et qu'il faut la changer.

Le boîtier pour support de bombe anti-agression,selon l'invention, se caractérise en ce que la bombe (cartouche) contient,mélangé

au gaz paralysant un colorant non toxique.Dans la majorité des cas,les agressions s'effectuent de façon ultra-rapide,les agresseurs prenant la fuite à toute vitesse.La victime,dans notre cas,a pu soit se défendre au moment de l'agression,soit"tirer" la gaz colorant sur l'agresseur, de face ou de dos; Dans ce cas,l'agresseur est "marqué" et peut être plus facilement intercepté et identifié par la victime,un témoin ou les Services de Police.

Le boîtier pour support de bombe anti-agression,selon l'invention, se caractérise en ce qu'il est muni d'un véritable clip qui permet de l'avoir à disposition instantanément du fait qu'il peut être accroché sur soi,à portée de la main,à un revers de poche,à la ceinture, à une anse de sac,etc.Prêt immédiatement à l'emploi.

Le boîtier pour support de bombe anti-agression,selon l'invention, se caractérise en ce qu'il est doté d'une sécurité évitant son fonctionnement en position de repos,et donc de tacher ses vêtements ou son sac.

Le boîtier pour support de bombe anti-agression,selon l'invention, se caractérise en ce qu'il peut être utilisé comme support de toutes les variétés d'aérosols (parfumerie,entretien,pharmacie,etc).Il présente dans ce cas les avantages d'être rechargeable et d'une manipulation plus aisée,plus directe que celle des aérosols conventionnels.

Le boîtier pour support de bombe anti-agression,selon l'invention, se caractérise en ce qu'il peut être conçu soit en plastique soit en métal.

Le boîtier pour support de bombe anti-agression,selon l'invention, se caractérise en ce que son mécanisme peut être adapté à d'autres modèles que le boîtier. Exemple d'autre application : le pistolet (figure VIII).

Le boîtier pour support de bombe anti-agression,selon l'invention, se caractérise en ce que son mécanisme de pression sur la cartouche peut être différent : bouton-pressoir,clip pressoir,pression par le couvercle ou le fond,dispositif à ressorts ou électronique.

Le boîtier pour support de bombe anti-agression,selon l'invention se caractérise en ce qu'il peut être aussi fermé hermétiquement et non rechargeable.

PLANS ET DESSINS.

Feuille I - Boîtier chargé en position de repos.
Feuil.II - Boîtier chargé en position de marche.
Feuil.III - Boîtier vide ouvert.
Feuil.IV - Introduction de la cartouche.
Feuil.V - Cartouche positionnée dans le boîtier.
Feuil.VI - Détail du clip.
Feuil.VII - Vues diverses,droit,gauche,face,dessus.
Feuil.VIII- Exemple d'autre application : le pistolet.

DESCRIPTION DU BOITIER. (FIG.I)

Il se présente sous forme d'un étui en forme de U dont une extrémité est fermée et perforée en son centre par un orifice (E) d'un diamètre correspondant à l'orifice de la valve (D) de la cartouche de gaz (L).

Un bras-levier (B) articulé (G),au bas duquel se trouve ,appuyée sur le socle,une pente inclinée (H) permet,quand on le serre dans la main,de faire pression sur le ressort(F) de la valve (D) qui expulse de ce fait le gaz contenu dans la cartouche par l'orifice (E).

Deux crans de sécurité (J) empêchent qu'une seule pression de la main libère le gaz.

Un clip (Figure VI) est fixé sur un des côtés perpendiculaires au bras levier.

FONCTIONNEMENT.

On introduit la cartouche en ouvrant le boîtier (en levant le bras-levier (Fig.III,IV et V).

Il suffit alors de faire une pression assez forte sur le bras levier (B) pour passer le premier cran de sécurité (J).La pente inclinée (H) du bras levier fait monter la cartouche de gaz (L). Le ressort (F) de la valve (D) se contracte et libère le gaz contenu dans la cartouche.Dès que l'on relache la pression de la main,le bras-levier (B) revient automatiquement à sa position de repos ainsi que le ressort de la valve qui arrête ainsi l'expulsion du gaz

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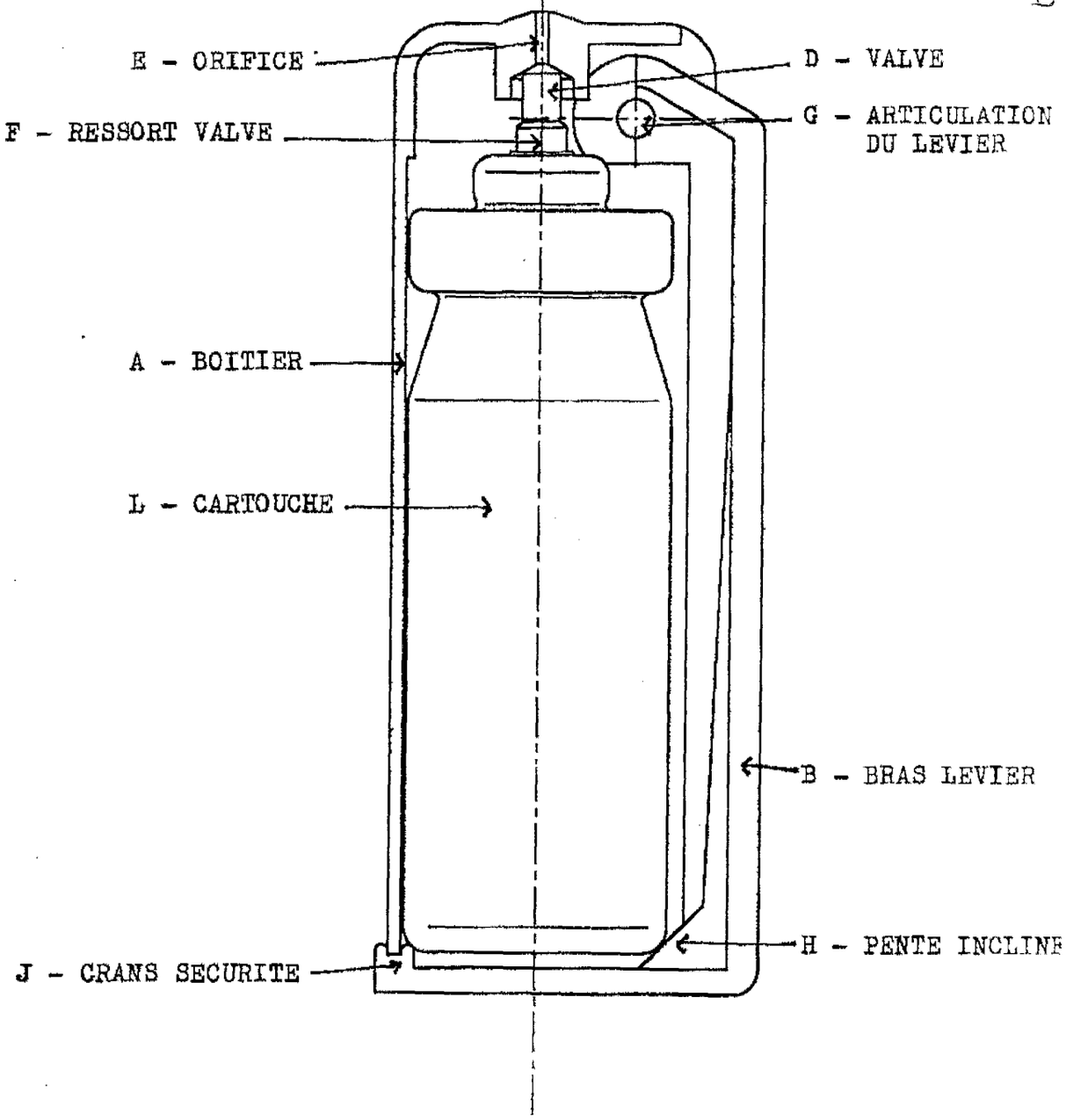
BOITIER CHARGE EN POSITION REPOS FIG.1

2671294 D2



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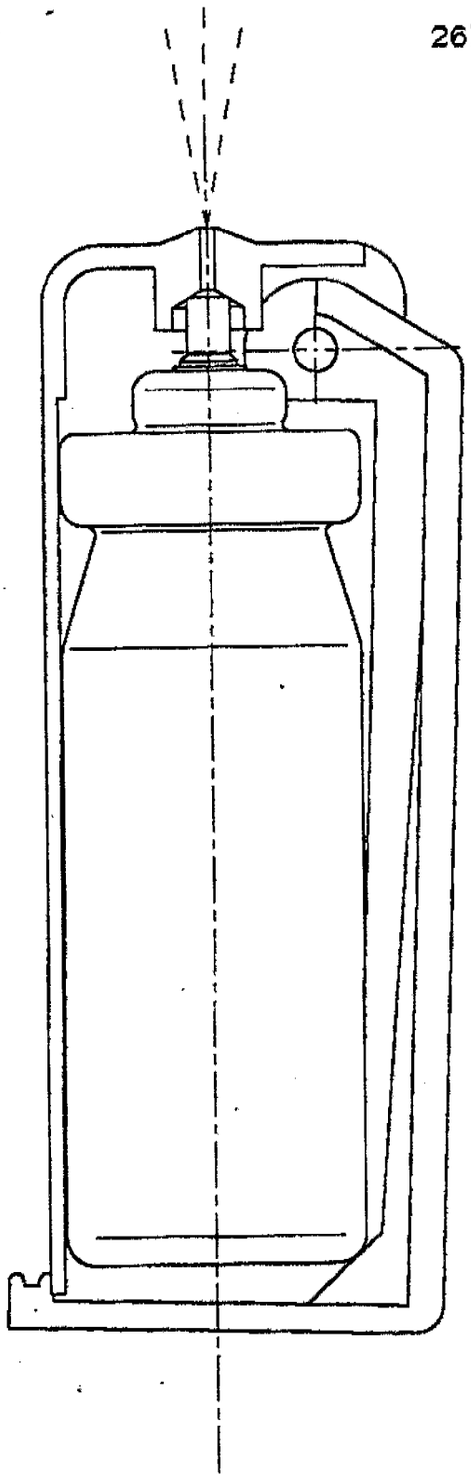

US005899365A

United States Patent [19]

Eichler et al.

[11] Patent Number: 5,899,365

[45] Date of Patent: May 4, 1999

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[54] **DEVICE FOR ASSISTING MANUAL ACTUATION OF AN AEROSOL DISPENSER**

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[73] Assignee: **Boehringer Ingelheim KG**, Ingelheim am Rhein, Germany

[21] Appl. No.: **08/817,355**

[22] PCT Filed: **Oct. 6, 1995**

[86] PCT No.: **PCT/EP95/03951**

§ 371 Date: **Sep. 20, 1997**

§ 102(e) Date: **Sep. 20, 1997**

[87] PCT Pub. No.: **WO96/11152**

PCT Pub. Date: **Apr. 18, 1996**

[30] **Foreign Application Priority Data**

Oct. 10, 1994 [DE] Germany 44 36 051

[51] **Int. Cl.**[6] **B67D 5/64**

[52] **U.S. Cl.** **222/162**; 222/509

[58] **Field of Search** 222/173, 162, 222/509

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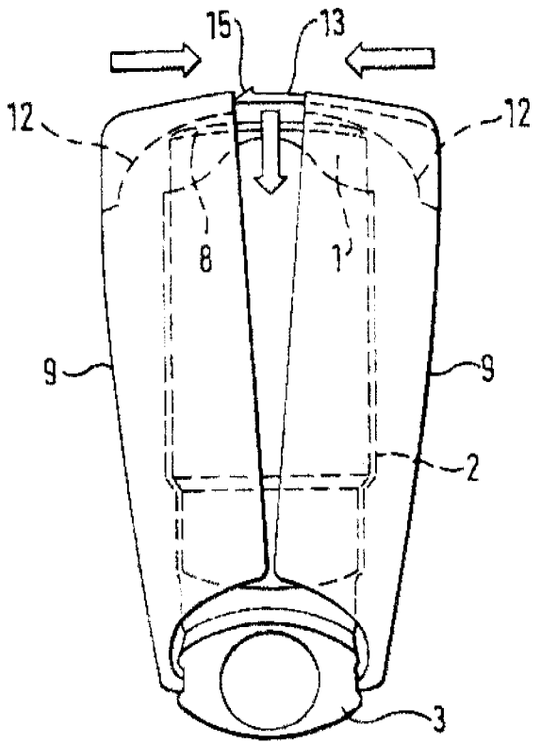
Primary Examiner—Gregory L. Huson
Attorney, Agent, or Firm—Robert P. Raymond; Alan R. Stempel; Mary-Ellen Devlin

[57] **ABSTRACT**

A device for assisting the manual actuation of aerosol dispensers, especially dispensers of the sort used to dispense metered doses of phamaceuticals. Dispensers to be used with the device of the invention are of known per se design and comprise a container, a nozzle and a valve with an axially movable valve stem which releases material from the container when the valve stem is urged toward the container. Such dispensers are normally actuated by exerting compressive force along the axis of the dispenser, by squeezing the nozzle and one end of the container between the thumb and forefinger. The device of the invention works with such dispensers so that they may instead be actuated by exerting compressive force in a direction that is orthogonal to the axis of the dispenser, by squeezing the device between the fingers and the palm, a motion that is easier for certain individuals.

2 Claims, 2 Drawing Sheets



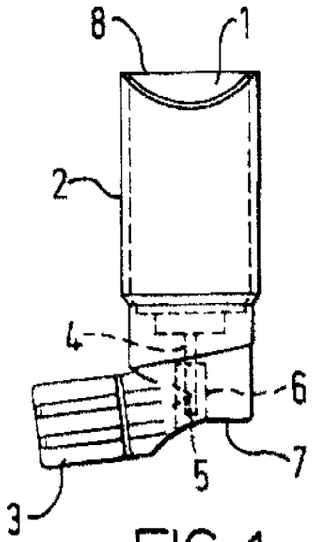


FIG. 1
Prior Art

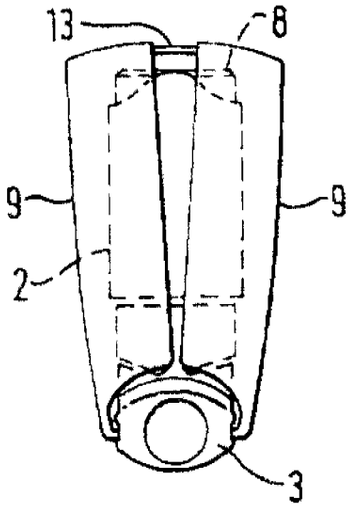


FIG. 3

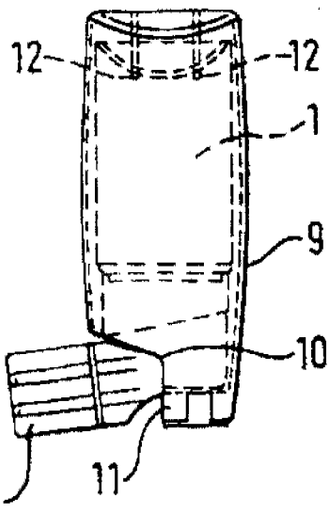


FIG. 2

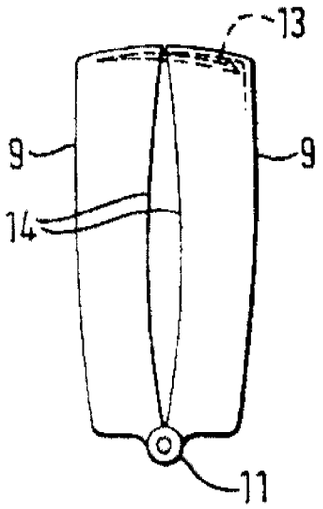


FIG. 4

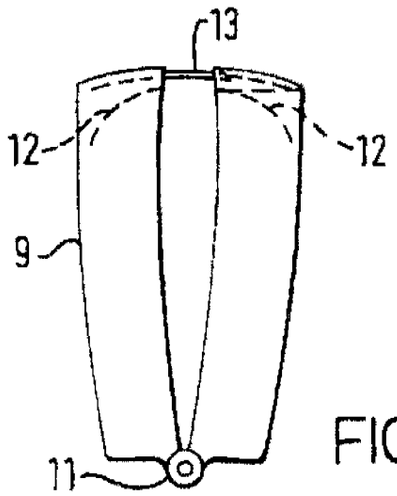


FIG. 5

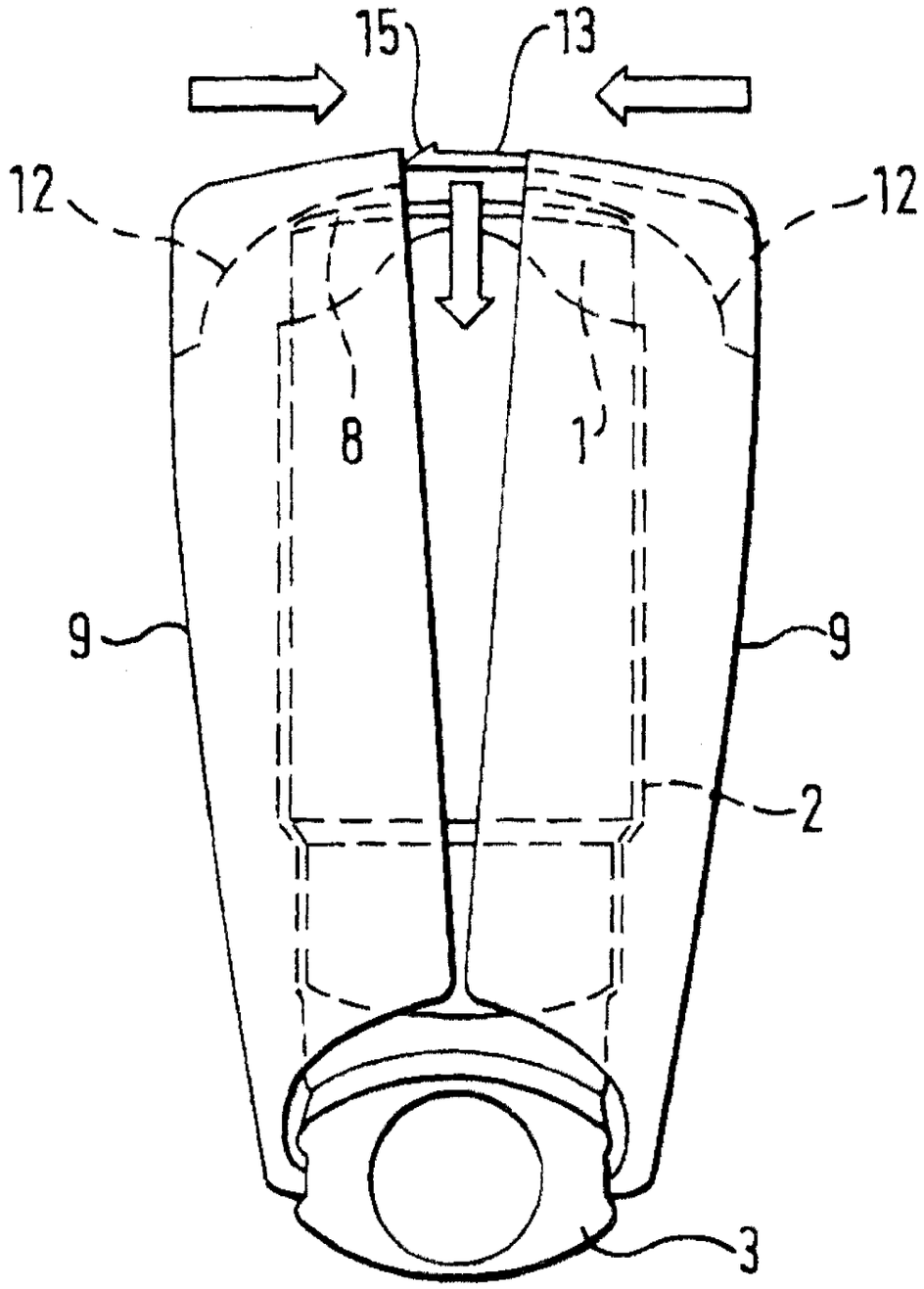


FIG. 6

DEVICE FOR ASSISTING MANUAL ACTUATION OF AN AEROSOL DISPENSER

The invention relates to a device which makes it easier to dispense an aerosol dose from conventional aerosol containers.

Conventional containers comprising pharmaceutical preparations which dispense an aerosol upon use are generally known as "aerosol containers". These containers are filled with a fluid preparation pressurised at a pressure of several bar, of which a certain amount is released as a spray which, together with the air, forms the aerosol. The preparations themselves comprise a liquefied fuel gas or fuel gas mixture in which at least one active substance and, optionally, auxiliary agents may be dissolved or suspended.

Conventional aerosol containers are provided with metering valves which dispense a fixed amount of the preparation during each operation. The release of the dose takes place when the axially movable valve stem of the metering valve is pressed in. In conventional equipment the valve stem is placed into a corresponding receiving means of a nozzle which simultaneously forms a support surface for the thumb or finger by means of which the valve stem is depressed. A typical aerosol container of this kind is shown in FIG. **1**.

The aerosol container **1**, while forming a lateral or cylindrical cavity, is positioned in a sleeve **2** open at the top, which is fixedly connected to the nozzle **3**. The valve stem **4** with the lateral outlet orifice **5** is secured in the recess **6** of the nozzle. By means of the inner pressure of the container and a spring, the valve stem is pushed outwards. The forces acting thereon must be overcome to initiate an aerosol spray.

In order to actuate the container, the patient normally presses his thumb and one finger onto the grip surface **7** of the nozzle and onto the base **8** of the aerosol container. The initiation of the aerosol spray must be coordinated with the breathing of the patient so that the aerosol administration takes place at the right time during breathing in. It has been shown that many patients find this coordination difficult, for example, if there is a need for a particularly speedy administration in the event of an asthma attack. Here, it may happen that the patient administers too low a dose of active substance. If he himself has the feeling of having received an insufficient amount of active substance, he may possibly administer a further dose which could result in exceeding the proper dosage.

The device according to the invention described below is an accessory for conventional aerosol containers. It achieves the object of making release of the aerosol spray easier, thus also avoiding any problems of coordination.

The device of the invention largely comprises two elongate, shell-like members, whose open sides face one another. They are jointly able to receive a conventional aerosol dispenser with a nozzle and are, on one narrow side, pivotally connected by a hinge, the nozzle projecting through an opening close to the hinge, substantially perpendicular to the plane in which the pivotal movement takes place, and means being provided on the narrow side of the shell-like members positioned opposite the hinge. These means press onto the base of the aerosol container upon actuation of the device (thereby initiating an aerosol spray) and, upon non-actuation, under the pressure of the valve stem, cause the shell-like members to pivot away from one another in such a way that the valve stem reaches its starting position. The new device is surrounded by the whole hand and may therefore be triggered off in a particularly easy manner.

The invention is described in greater detail by means of a typical embodiment shown in FIGS. **2** to **6**.

FIG. **2** is a lateral view of the device of the invention. Here, in the inside of the aerosol device, aerosol container **1**, sleeve **2** and nozzle **3** are visible. The shell-like member **9**, which is to the right in the operational position, faces the viewer. Hinge **11** is visible below opening **10** for nozzle **3**. The means **12** are shaped in such a way that they increasingly push base **8** of the aerosol container downwards, while the shell-like members **9** are compressed. If the shell-like members **9** are then released, the forces acting upon the valve stem result in the valve stem being pushed out again into its starting position and the base **8** thus being pressed upwards. In this way, the shell-like members **9** are pivoted outwards so that the device may again be started.

FIG. **3** illustrates the embodiment shown in FIG. **2**, during use. The shell-like members **9** are in their starting position. A tongue **13** ensures that the movable members **9** cannot be pivoted any further to the outside when the starting position is reached.

FIG. **4** shows the back of the device, in the end position upon actuation. The two shell-like members **9** come into contact on the side facing the hinge **11**. Between the two members **9**, there is a recess **14** limited by flat curved portions. They ensure that the skin of the patient's hand is not caught upon actuation. The recess may also be of another shape and may have a correspondingly shaped front.

FIG. **5** is also a view of the back of the device. However, it shows the starting position before actuation. The means **12** pressing onto the base **8** of the aerosol container are curved so that, upon compression of the two shell-like members **9**, they slide over the edge of the base **8** and increasingly press it further downwards, thereby pushing the valve stem into the aerosol container until it reaches its end position.

FIG. **6** is a view of the front of the device, showing the frontal view of the nozzle **3** in the starting position before actuation. The tongue **13** with the barb **15** prevents the two shell-like members **9** from being opened out unintentionally. In this Figure, the tongue **13** is in the open position, i.e. before it engages in the shell part **9** positioned opposite. The Figure shows the coordinated action of the means **12** on the base **8** of the aerosol container **1** upon the pressing together of the two shell-like members **9**.

The lateral arrangement of these two members **9** has proved to be particularly advantageous during use, because the hand is able to adopt a natural and relaxed position.

The shape of the individual members may be modified in various ways. The shell-like members **9** may, for example, be provided with overlapping parts so that there is no cavity even in the starting position (i.e. when the members **9** are pivoted apart). On the other hand, the shell-like members **9** may also be replaced by narrower members, provided there is sufficient rigidity, and/or they may have grip indentations. Furthermore, the skilled man has various possibilities of locking the device in the initial position so that it cannot be operated unintentionally.

The means **12** may also have other forms. In the Figures shown, they are shaped like narrow ribs with an arched boundary face which frictionally slides past the edge of the base of the aerosol container. Instead of being arched the sliding surface may also be of another suitable curved shape or, for example, be wedge-like. Furthermore, the hinge may be replaced by a connecting member made of flexible material. In order to illustrate the actuation process more clearly, the construction of the device may be such that a pressure point needs to be overcome before the aerosol spray is released. Finally, it is also possible to construct the device

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PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
B05B 11/00, 5/025, 5/16

A1

(11) International Publication Number: **WO 99/49984**

(43) International Publication Date: 7 October 1999 (07.10.99)

(21) International Application Number: PCT/IB99/00474

(22) International Filing Date: 22 March 1999 (22.03.99)

(30) Priority Data:
9806937.0 31 March 1998 (31.03.98) GB

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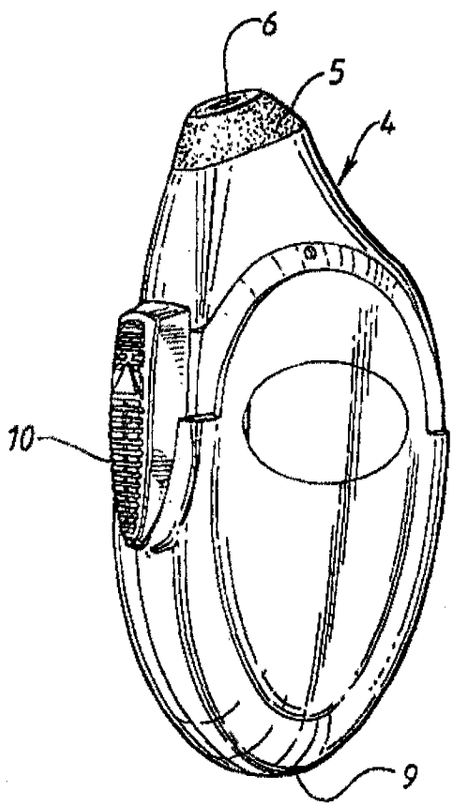
(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: NASAL SPRAY DEVICE WITH ELASTOMERIC VALVE

(57) Abstract

The invention relates to a spray device adapted to provide multiple, unit doses of a fluid, each dose having a volume in the range from about 1 to about 100 $\mu\lambda$, the device comprising an elastomeric, self–sealing valve having a fluid side and a delivery side, the valve opening to allow passage of the fluid when pressure is applied to fluid on the fluid side and sealing when the pressure is removed. The valve achieves a clean stop–start flow of the fluid at low fluid volumes. The device is particulary suitable for low volume medical applications such as nasal spraying.



adjusted by varying the viscosity or surface tension of the fluid, by varying the fluid flow rate or exit velocity, or by varying the electrical field strength through applied voltage, potential gradient or by use of a field intensifying electrode.

The total length of the ligament can be, and preferably is, longer than the length from the nosepiece end to the delivery end since the ligament preferably originates from a point on the device side of the nosepiece plane, such as from an elastomeric, self-sealing valve as disclosed herein, and passes through a passage in the nosepiece. Suitably the distance from the point of origin of the ligament to the nosepiece plane is in the range from about 2 mm to about 15 mm, preferably from about 3 to about 10 mm and more preferably from about 5 to about 9 mm. In this way the nosepiece can be employed as a field intensifier which helps to control the ligament length. For this purpose the nosepiece is preferably a non-conducting material such as a plastic which can be e.g. polypropylene but is preferably a soft thermoplastic elastomer which provides for greater comfort if held against the nose. Elastomers described herein for the self-sealing valve are also suitable for the nosepiece.

Electrostatic devices suitable for ligament mode spraying are described in WO 96/40441, in EP-A-501,725 and in co-pending application PCT/GB97/02746. Preferably the present device is a device according to embodiments of EP-A-501,725 or PCT/GB97/02746 in which a jet is created by mechanical means and an applied high voltage leads to the jet or ligament breaking up into a spray cone. The jet can be generated by, for example, a syringe pump. Suitable jet velocities are from about 0.5 to about 8, preferably from about 1 to about 3 ms^{-1}.

A suitable high voltage is in the range from about 1 kV up to about 15 kV, preferably from about 2kV to about 10kV and more preferably from about 2kV to about 5kV. The voltage can conveniently be applied, even within the constraints of a small hand-held device, from a low voltage (1.5V is sufficient) battery coupled to a step-up transformer. The battery is preferably of the long-life type and can be rechargeable. If a metal syringe pump is used, the voltage can be applied to the fluid through the pump which is preferably encased in an insulating plastic housing. Alternatively, the fluid can be charged by an electrode inserted into the fluid. The generator can be activated by the user by means of an external switch which can also be used to mechanically prime the pump. Preferably the switch includes a metal portion by means of which the user completes an earth return path to the high voltage circuit. A suitable arrangement for the overall device construction is described in PCT/GB97/02746. In this way the user does not acquire a net charge. Alternate

The invention will now be described by way of example only, with reference to the accompanying drawings in which:

Fig. 1 is a sectional view through a human nose.

Fig. 2 is a perspective view of a spray device according to the invention.

Fig. 3 is a greatly simplified sectional view of the spray device of Figure 2 showing the relationship of the elastomeric nozzle to the nosepiece and dosing means.

Fig. 4 is a schematic part section showing a spray issuing from a device according to the invention.

Fig. 5 is a enlarged sectional view of an elastomeric exit valve according to the invention.

Referring to Fig. 1, the nose comprises a nasal cavity 1 in which are located the turbinates 2, convoluted finger-like structures covered with epithelium and which are susceptible to inflammation. The exterior opening to the nasal cavity is through two nostrils 3. Since the turbinates are located in the posterior part of the nasal cavity it has generally been difficult to spray them effectively without inserting a spray device into the nostrils.

Referring to Figures 2 and 3, there is shown a spray device 4 fitted with a soft elastomeric nosepiece 5 which is designed to fit against a user's nostril opening without being inserted into the nostril. The nosepiece is provided with a passage 6 which connects to a syringe pump 7, the interior detail of which is not shown, which is used to generate the ligament of the spray through elastomeric exit valve 8. The insulating casing 9 of the device further encloses (not shown) a replaceable fluid reservoir, battery, transformer and electronic circuitry for supplying a high voltage from the transformer to the fluid. The device is supplied with an actuating mechanism 10 which mechanically primes the pump and triggers its release to deliver a pre-set unit dose of the fluid. The actuating mechanism includes a metal portion to provide an earth return from the user to the high voltage circuitry.

Referring now to Figure 4, a spray comprises ligament 11 and spray cone 12 having a cone angle θ. In practice the cone angle can be measured by spraying from a fixed distance onto disclosing paper and then measuring the diameter of the spray pattern or by direct viewing of the spray using high speed video photography with back lighting. The ligament has a delivery end 13 where the ligament breaks up into the spray cone and a nosepiece end 14 defined as the point where plane A-A intersects

ligament 11. Plane A-A is drawn perpendicular to the axis of the ligament, just touching the tip of nosepiece 5.

Figure 5 illustrates an elastomeric exit valve 8 according to the invention. The nozzle, which is circularly symmetrical, comprises a flange 15 for securing the nozzle to the spray device, a domed head 16, a recess 17 and a slit 18 extending from the recess to the top of the dome. The nozzle is formed by injection moulding a seal of essentially the same construction and then piercing the dome with a sharpened pin, of round cross-section and 200 μm diameter, from the inside of the recess.

Examples

The following examples further describe and demonstrate embodiments within the scope of the present invention. The examples are given solely for the purpose of illustration and are not to be construed as limitations of the present invention.

Example I

A fluid of the present invention is prepared by combining the following components utilising conventional mixing techniques similar to that described below.

Component	Wt %
oxymetazoline hydrochloride	0.31
sodium citrate dihydrate	1.75
citric acid	0.35
Tyloxapol	0.70
chlorhexidine digluconate	0.054
benzalkonium chloride	0.02
camphor	0.04
eucalyptol	0.02
disodium EDTA dihydrate	0.01
distilled water	q.s. 100ml

In an appropriately sized vessel, the above listed ingredients are added one at a time to water with mixing, allowing each to dissolve before adding the next. After all the ingredients have been added, purified water is used to bring the batch to the appropriate weight. The solution has a bulk resistivity of 120 ohm.cm. The solution

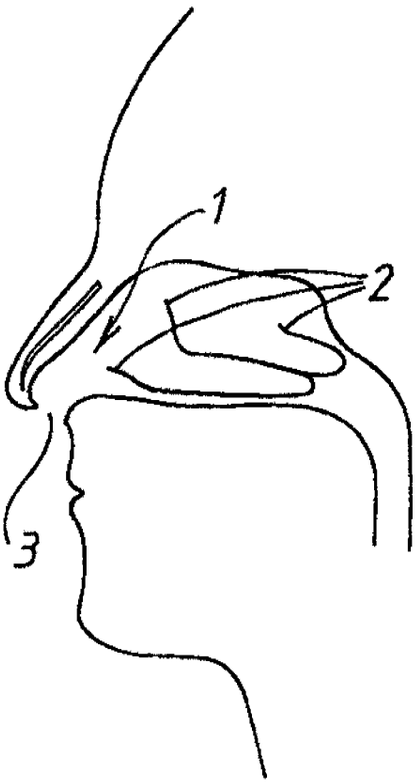


FIG. 1

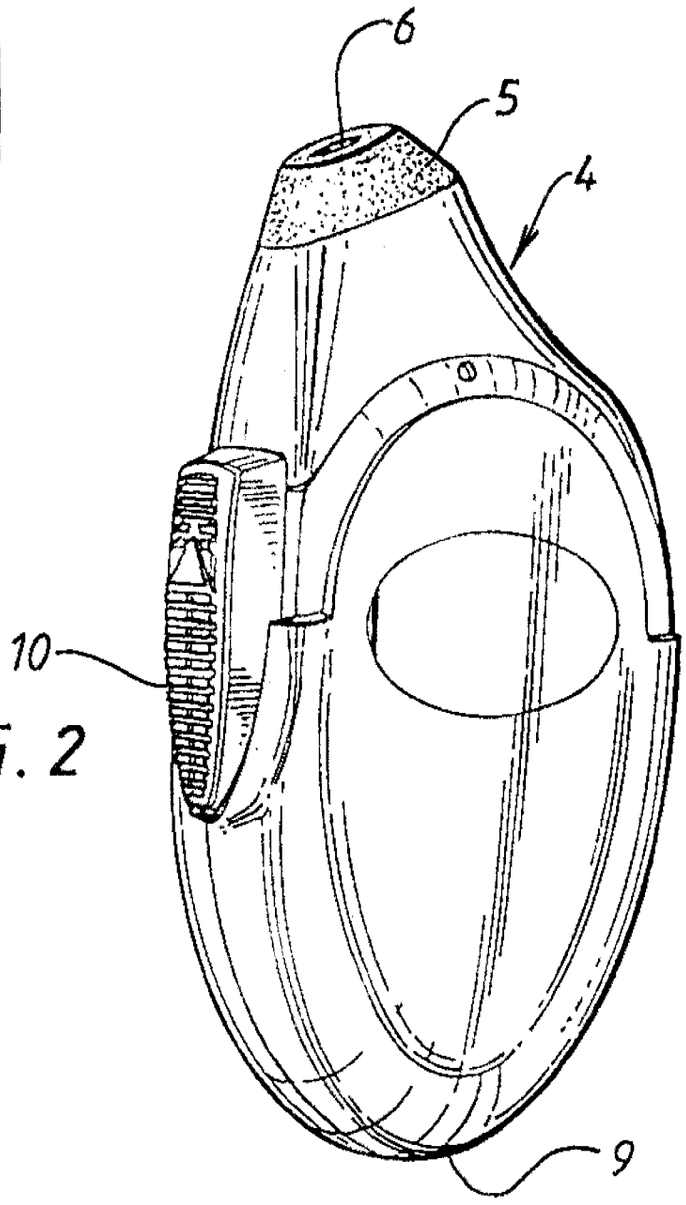


FIG. 2

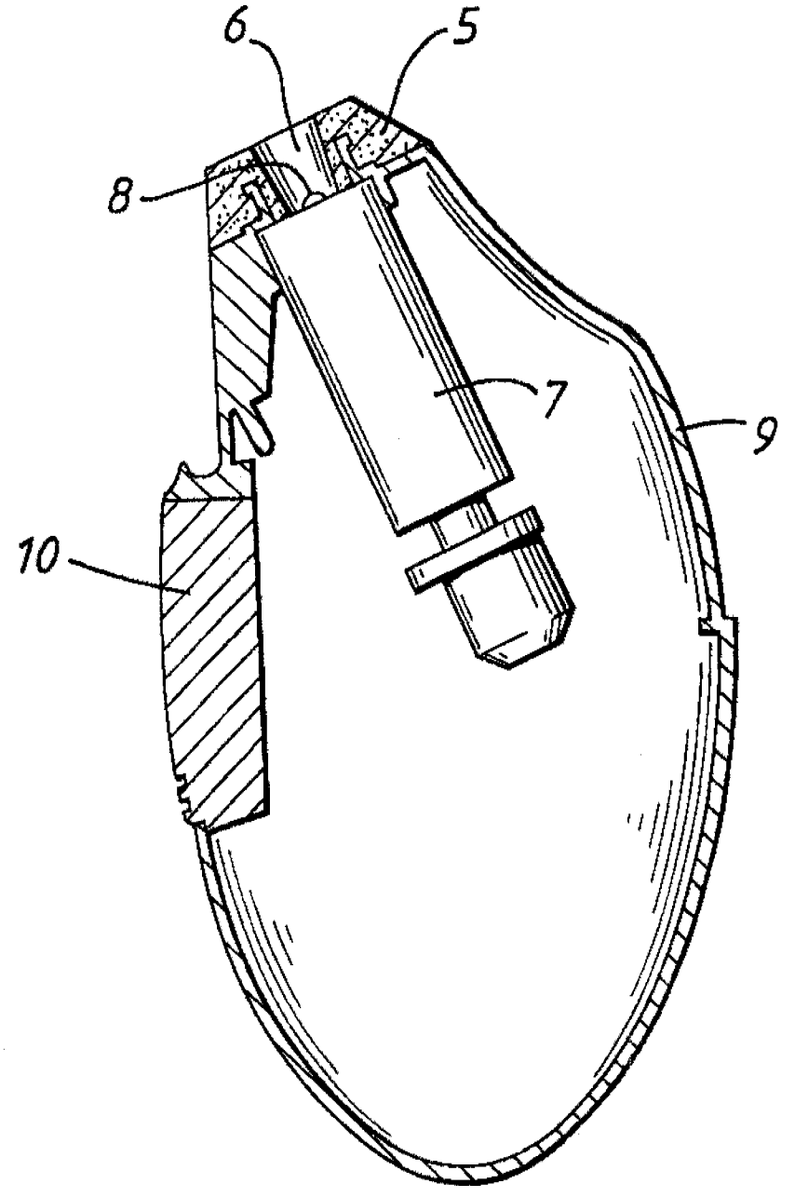


FIG. 3

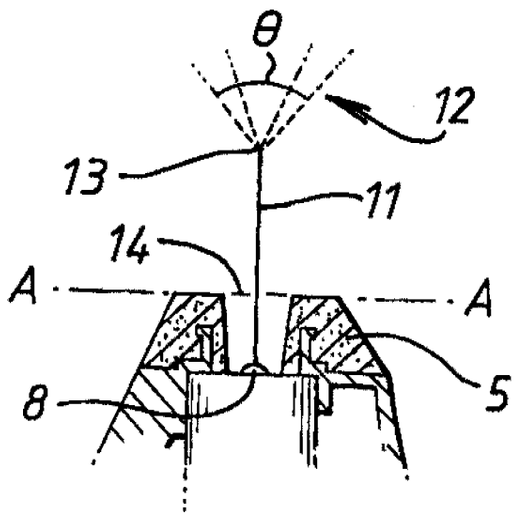


FIG. 4

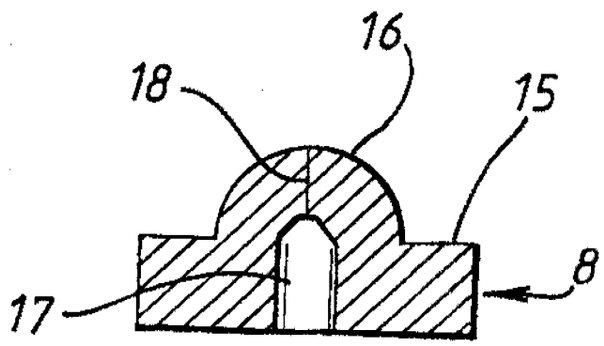


FIG. 5

181 180


US006305371B1

(12) **United States Patent**
Frid et al.

(10) **Patent No.: US 6,305,371 B1**
(45) **Date of Patent: Oct. 23, 2001**

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(54) **INHALATION FOR ADMINISTERING MEDICAMENT BY INHALATION**

(75) Inventors: **Per Frid**, Lund (SE); **Robert Jansen**; **Paul Wright**, both of Leics (GB)

(73) Assignee: **AstraZeneca AB**, Sodertalje (SE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/117,229**

(22) PCT Filed: **May 8, 1998**

(86) PCT No.: **PCT/SE98/00846**

§ 371 Date: **Jul. 24, 1998**

§ 102(e) Date: **Jul. 24, 1998**

(87) PCT Pub. No.: **WO98/51360**

PCT Pub. Date: **Nov. 19, 1998**

(30) **Foreign Application Priority Data**

May 12, 1997 (SE) 9701750

(51) **Int. Cl.**[7] **A61M 15/00**; A61M 16/00

(52) **U.S. Cl.** **128/203.12**; 128/200.14; 128/200.23

(58) **Field of Search** 128/200.14, 200.19, 128/200.23, 203.12, 203.13

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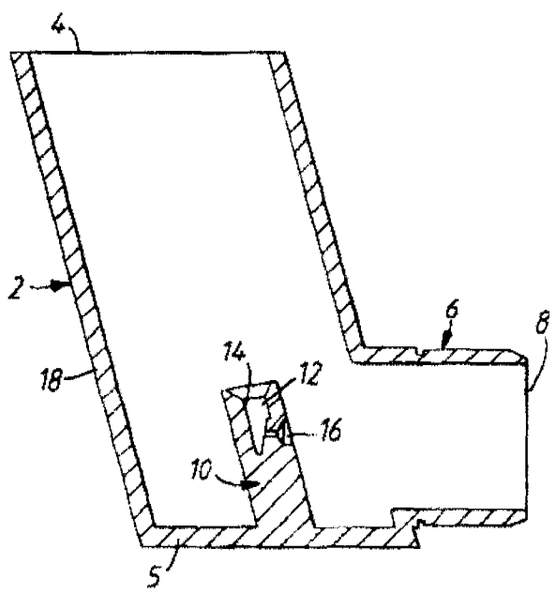
Primary Examiner—John G. Weiss
Assistant Examiner—Joseph F. Weiss, Jr.
(74) *Attorney, Agent, or Firm*—Nixon & Vanderhye

(57) **ABSTRACT**

An inhaler for administering medicament by inhalation and a method of manufacturing a housing of the same, the inhaler including a housing formed as a single-piece moulding having a first portion (**18**) which, in normal use, comes into contact with medicament and the mouth or nose of a user through which medicament is inhaled and a second portion (**20**) which defines at least part of the outer surface of the housing and, in normal use, does not come into contact with medicament or the mouth or nose of a user through which medicament is inhaled, wherein the material constitution of at least part of the second portion **(20)** defining at least part of the outer surface of the housing is different to the material constitution of the first portion (**18**).

13 Claims, 3 Drawing Sheets



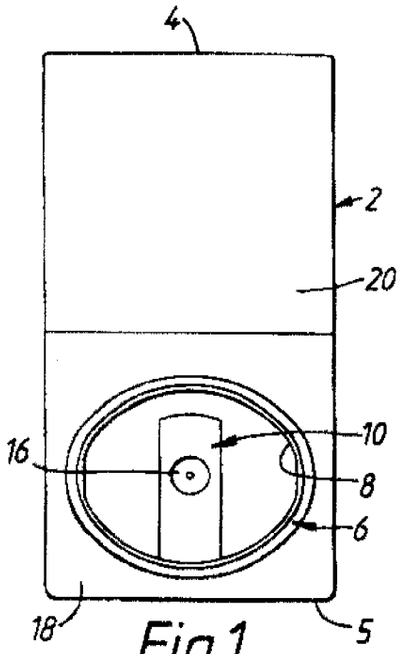


Fig.1

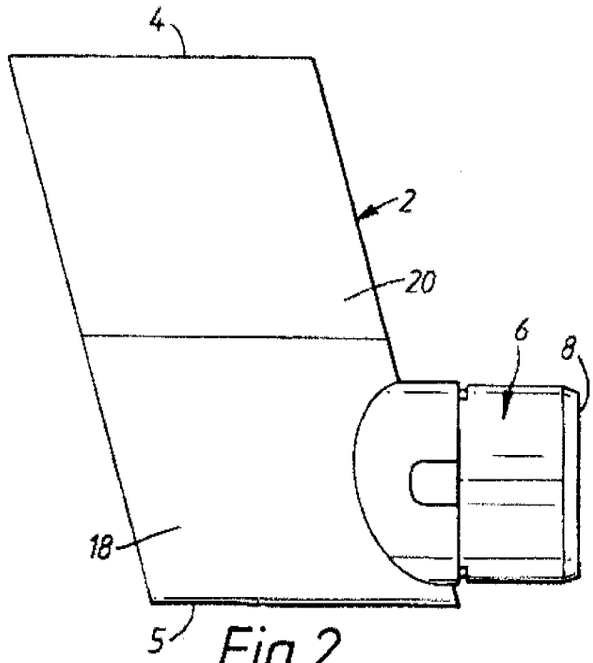


Fig.2

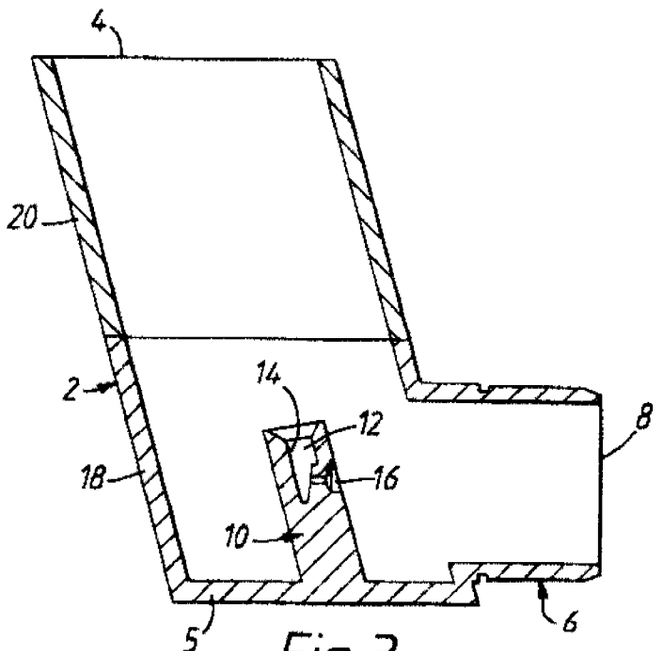


Fig.3

INHALATION FOR ADMINISTERING MEDICAMENT BY INHALATION

The present invention relates to an inhaler for administering medicament by inhalation and a method of manufacturing a housing of the same.

BACKGROUND OF THE INVENTION

Various kinds of inhaler are known for delivering metered doses of medicament for inhalation. Typically, pressurized liquid systems and dry powder systems are used to deliver medicament to a patient. In one pressurized liquid system a liquid containing medicament is stored in a pressurized container and a metered dose is delivered as an aerosol by a pressurized metered dose inhaler. In dry powder systems powder containing medicament is stored in individual blisters, on tape or in bulk in a chamber and a metered dose is provided by a dry powder inhaler.

All such inhalers include parts which come into contact with medicament and parts, some in common with the parts which come into contact with medicament, which come into contact with the mouth or nose of a user. It will be appreciated that it is important to ensure that those parts do not have any adverse effect on either the medicament or the user.

It is an aim of the present invention to provide an improved inhaler and a method of manufacturing a housing of the same in view of this requirement.

SUMMARY OF THE INVENTION

Accordingly, the present invention provides an inhaler for administering medicament by inhalation, including a housing formed as a single-piece molding having a first portion which, in normal use, comes into contact with medicament and the mouth or nose of a user through which medicament is inhaled and a second portion which defines at least part of the outer surface of the housing and, in normal use, does not come into contact with medicament or the mouth or nose of a user through which medicament is inhaled, wherein the material constitution of at least part of the second portion defining at least part of the outer surface of the housing is different to the material constitution of the first portion.

The at least part of the second portion can have many different material constitutions, for instance in including a coloring pigment for identifying the medicament to be administered and/or being formed of a rubberized material to provide for improved grip.

In this way, a range of housings having a single basic design can be developed for use with different medicaments. This approach has the particular advantage that, because the second portion of each of the housings does not come into contact with medicament or the mouth or nose of a user and the first portion of each of the housings is formed of the same material, in many countries throughout the world it is only be necessary to obtain regulatory approval for one housing in the entire range.

Preferably, other than a coloring pigment in the at least part of the second portion, the first and second portions have generally the same material constitution. Where the first and second portions are formed of polymeric materials, those portions are in a preferred embodiment formed of the same polymeric material even if of a different grade. In this way, the molding of the housing is simplified, since the first and second portions of the housing will bond together more readily and the problems associated with using materials having different thermal expansion characteristics are avoided. In practice, the coloring pigment in the at least part of the second portion is conveniently provided from a master batch which includes pigment, a polymer base or carrier (which may be different to the basic polymeric material of the first and second portions) and processing aids such as lubricants and dispersion agents.

Preferably, the first portion has a relatively simple material constitution, in particular without a coloring pigment. In this way, the risk of chemical leaching from the first portion is minimized.

The present invention also provides a method of manufacturing a housing of an inhaler for administering medicament by inhalation having a first portion which, in normal use, comes into contact with medicament and the mouth or nose of a user through which medicament is inhaled and a second portion which defines at least part of the outer surface of the housing and, in normal use, does not come into contact with medicament or the mouth or nose of a user through which medicament is inhaled, the method comprising the step of molding the first and second portions as a single piece, wherein at least part of the second portion defining at least part of the outer surface of the housing is formed of a material of different constitution to that of the first portion.

Preferably, the material for the at least part of the second portion is successively introduced into a mold with respect to the material for the first portion and the remainder of the second portion.

Alternatively, the housing may be moulded by insert molding. That is, material is introduced into a first mold to form part of the housing and then that part is transferred to another mold into which another material is introduced to complete the housing. In this way, the first portion of the housing which comes into contact both with medicament and the mouth or nose of a user is formed of a material suited for the medical purpose and for which regulatory approval has already been obtained, whilst the at least part of the second portion is formed from another material of different constitution.

By providing the housing as a single-piece molding the housing is more robust than a housing formed of separate components. Moreover, it is impossible for a user to tamper with the housing. If the first and second portions of the housing were to be provided by separate components it would be open to a user to interchange parts from one housing for use with one medicament with parts from another housing for use with another medicament which would lead to cross-contamination. Furthermore, the housing is less expensive to manufacture as a single-piece molding than as separate moldings which would have to be assembled.

The present invention recognises for the first time that multi-part molding techniques may be applied in this field with particular advantages, specifically relating to the conflicting demands of material contact with medicament and the mouth or nose of a user in some parts of the housing and desired variation in other parts of the housing.

It will be appreciated that the method of manufacture of the present invention is not limited to two-stage molding and the housing may have many parts formed integrally from different material constitutions.

In a preferred embodiment the inhaler is a pressurized metered dose inhaler and the housing is the actuator of the pressurized metered dose inhaler.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the present invention will now be described hereinbelow by way of example only with reference to the accompanying drawings, in which:

FIGS. **1** to **3** illustrate front, side and vertical sectional views of an actuator of a pressurized metered dose inhaler in accordance with a first embodiment of the present invention;

FIGS. **4** to **6** illustrate front, side and vertical sectional views of an actuator of a pressurized metered dose inhaler in accordance with a second embodiment of the present invention; and

FIGS. **7** to **9** illustrate front, side and vertical sectional views of an actuator of a pressurized metered dose inhaler in accordance with a third embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

FIGS. **1** to **3** illustrate an housing of a pressurized metered dose inhaler in accordance with a first embodiment of the present invention. The housing comprises a first, main tubular section **2**, one, the upper, end of which is open and provides an opening **4** into which a container (not illustrated), in this embodiment an aerosol canister having a valve stem, is in use inserted and the other, lower, end of which is closed by a wall member **5**.

The housing further comprises a second tubular section **6** which extends substantially laterally from the other, that is, the lower, end of the main tubular section **2**; the second tubular section **6** acting as a mouthpiece which is in use gripped in the lips of a user and having an opening **8** at the distal end thereof through which medicament is in use inhaled. The housing still further comprises a nozzle block **10** which extends upwardly from the wall member **5** into the main tubular section **2**. The nozzle block **10** includes a tubular bore **12** which is located on the longitudinal axis of the main tubular section **2**. One, the upper, end of the tubular bore **12** is open and provides an opening **14** into which is received the valve stem of a container. The other, lower, end of the tubular bore **12** includes a laterally-directed spray orifice **16** which is configured to direct a spray into the second tubular section **6**. The housing is integrally formed as a single-piece molding, first and second portions **18**, **20**, in this embodiment essentially lower and upper halves, of which are formed of polymeric materials of different constitution. Typically, the material of the second portion **20** includes a coloring pigment representative of the medicament with which the housing is to be used. In coloring a part of the housing with a pigment specific to the medicament with which it is to be used cross-contamination of medicaments can be avoided.

In use, with an aerosol canister fitted in the housing, a user grips the mouthpiece provided by the second tubular section **6** in his/her lips. The user then depresses the base of the canister which extends out of or is at least close to the opening **4** in the main tubular section **2** so as to release a dose of medicament from the aerosol canister and at the same time inhales so as to inhale the dose of medicament.

FIGS. **4** to **6** illustrate an housing of a pressurized metered dose inhaler in accordance with a second embodiment of the present invention. This housing is almost identical in construction to the actuator of the inhaler of the above-described first embodiment. For this reason, and in order to avoid unnecessary duplication of description, only the constructional differences will be mentioned and reference should be made to the preceding description. The housing of this embodiment differs from the actuator of the above-described first embodiment only in that the first and second portions **18**, **20** are differently configured. In this embodiment the second portion **20** is formed as a panel in the main tubular section **2**. In a preferred embodiment the panel provided by the second portion **20** includes printed information, for instance as a transparent decal with opaque lettering.

FIGS. **7** to **9** illustrate an actuator of a pressurized metered dose inhaler in accordance with a third embodiment of the present invention. This housing is almost identical in construction to the housing of the inhaler of the above-described first embodiment. For this reason, and in order to avoid unnecessary duplication of description, only the constructional differences will be mentioned and reference should be made to the preceding description. The housing of this embodiment differs from the actuator of the above-described first embodiment only in that the first and second portions **18**, **20** are differently configured. In this embodiment the second portion **20** is formed as a series of substantially axially-directed strips in the main tubular section **2**. In a preferred embodiment the strips provided by the second portion **20** are formed of a rubberized material to assist the user in gripping the actuator.

Finally, it will be understood by a person skilled in the art that the present invention has been described in its preferred embodiments and can be modified in many different ways without departing from the scope of the present invention as defined by the appended claims.

What is claimed is:

1. An inhaler for administering medicament by inhalation, including a housing formed as a single-piece molding having a first portion which, in normal use, is contactable with medicament and a mouth or nose of a user through which medicament is inhaled and a second portion which defines at least part of an outer surface of the housing and, in normal use, is not contactable with medicament or a mouth or nose of a user through which medicament is inhaled, at least part of the second portion defining at least part of the outer surface of the housing having a material constitution which is different to the material constitution of the first portion to allow identification of the medicament to be administered.

2. The inhaler according to claim **1**, wherein the at least part of the second portion includes a coloring pigment for identifying the medicament to be administered.

3. The inhaler according to claim **2**, wherein, other than including a coloring pigment, the at least part of the second portion has generally the same material constitution as the first portion

4. The inhaler according to any of claim **1**, wherein the inhaler is a pressurized metered dose inhaler and the housing includes means for releasing a dose of medicament.

5. The inhaler according to claim **4**, wherein said means comprises a nozzle block having a spray orifice configured to direct a spray into said first portion.

6. An inhaler for administering medicament by inhalation, comprising:

a housing formed as a single-piece molding having a first portion which, in use, is contactable with medicament and a mouth or nose of a user;

a second portion which defines at least part of an outer surface of said housing and, in use, is not contactable with medicament or a mouth or nose of a user through which medicament is inhaled;

at least part of the second portion defining at least part of the outer surface of the housing having a material constitution which is different to the material constitution of the first portion to allow identification of the medicament to be administered.

7. A method of manufacturing a housing of an inhaler for administering medicament by inhalation having a first por-

(12) DEMANDE INTERNATIONALE PUBLIÉE EN VERTU DU TRAITÉ DE COOPÉRATION EN MATIÈRE DE BREVETS (PCT)

(19) Organisation Mondiale de la Propriété Intellectuelle
Bureau international

(43) Date de la publication internationale
14 mars 2002 (14.03.2002)

PCT

(10) Numéro de publication internationale
WO 02/20168 A1

(51) Classification internationale des brevets⁷ :
B05B 11/00, A61M 15/00

(21) Numéro de la demande internationale :
PCT/FR01/02684

(22) Date de dépôt international : 28 août 2001 (28.08.2001)

(25) Langue de dépôt : français

(26) Langue de publication : français

(30) Données relatives à la priorité :
00/11429 7 septembre 2000 (07.09.2000) FR

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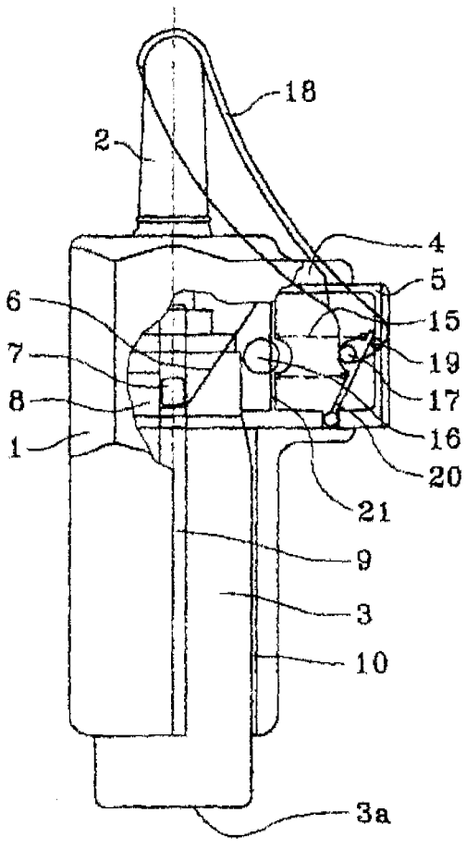
(81) États désignés *(national)* : CN, IN, JP, US.

(84) États désignés *(régional)* : brevet européen (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

[Suite sur la page suivante]

(54) Title: MULTIPLE-DOSE DEVICE FOR DISPENSING A FLUID PRODUCT

(54) Titre : DISPOSITIF DE DISTRIBUTION DE PRODUIT FLUIDE DE TYPE MULTIDOSE



(57) Abstract: The invention concerns a device for dispensing fluid product, comprising a body (1), a product reservoir (3) a dispensing member, such as a pump or a metering valve comprising an axially mobile piston or valve, mounted on the reservoir (3), and an actuating element (5) mobile between a neutral position and an actuating position, to actuate the dispensing member and thereby selectively dispense the product contained in the reservoir (3). The invention is characterised in that the direction of displacement of said actuating element (5) is different, in particular about perpendicular, to the axial displacement direction of the piston or metering valve of the dispensing member, the device comprising force-controlling means for predetermining the force to be exerted on the actuating element (5) to actuate the dispensing member, said force being constant each time the device is actuated, independently of the amount of product contained in the reservoir (3) and/or the resistance of the piston or the metering valve of the dispensing member.

(57) Abrégé : Dispositif de distribution de produit fluide, comprenant un corps (1), un réservoir de produit (3), un organe de distribution, tel qu'une pompe ou une valve doseuse comportant un piston ou une coupape déplaçable axialement, monté sur le réservoir (3), et un élément d'actionnement (5), déplaçable entre une position de repos et une position d'actionnement, pour actionner l'organe de distribution et ainsi distribuer sélectivement le produit contenu dans le réservoir (3), caractérisé en ce que la direction de déplacement dudit élément d'actionnement (5) est différente, notamment environ perpendiculaire, à la direction de déplacement axiale du piston ou de la soupape de l'organe de distribution, le dispositif comportant des moyens de régulation de force pour prédéterminer la force à exercer sur l'élément d'actionnement (5) pour actionner l'organe de distribution, cette force étant constante à chaque actionnement du dispositif, indépendamment de la quantité de produit contenu dans le réservoir (3) et/ou de la résistance ou piston ou de la soupape de l'organe de distribution.

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l'intérieur de l'élément d'actionnement 5. Dans cette position, l'élément d'actionnement 5 est maintenue dans sa position de repos par la paire de boutons 16. De préférence, ces boutons 16 sont formés sur des bras flexibles (non représentés) solidaires de l'élément d'actionnement 5, et qui en position de repos de l'élément d'actionnement 5 sont sollicités élastiquement dans des trous 22 du corps 1. Une pression latérale appliquée par l'utilisateur sur les boutons 16 qui sont formés de manière appropriée, leur permet de sortir des trous de retenue 22 et par conséquent de libérer l'élément d'actionnement 5, qui sous la poussée du ressort 15 glisse à l'intérieur du manchon 4 du corps 1 pour actionner la pompe. Il est à noter que pendant ce déplacement de l'élément d'actionnement, l'axe de pivotement 17 du capot 18 sur le corps 1 n'empêche pas le déplacement de l'élément d'actionnement 5 puisque ledit capot est pourvu de deux fentes appropriées (non représentées) sur ces côtés pour empêcher toute interférence avec lesdites chevilles formant l'axe de pivotement 17.

Eventuellement, l'élément d'actionnement peut comporter en outre des moyens de rappel élastiques, qui ramènent l'élément d'actionnement dans sa position de repos après chaque actionnement du dispositif. Généralement, toutefois, la force du ressort de rappel du piston de la pompe suffit pour ramener l'élément d'actionnement 5 vers sa position de repos, par l'intermédiaire des projections 7 poussant sur le plan incliné 6. De préférence, lorsque l'élément d'actionnement 5 revient vers sa position de repos, les boutons 16 reviennent automatiquement dans les trous 22 du corps, et le dispositif est prêt pour être réutilisé.

Si souhaité, ces moyens de rappel de l'élément d'actionnement 5 vers sa position de repos peuvent être actionnés uniquement lorsque le capot 18 est ramené vers sa position d'obturation de l'orifice de distribution représenté sur la figure 1. Dans ce cas, on garantit que l'utilisateur est obligé de refermer le capot, et ainsi de protéger l'orifice de distribution du dispositif après chaque utilisation.

Dans les figures 3 à 6, il est représenté un second mode de réalisation de l'invention qui diffère de celui représenté sur les figures 1 et 2 en ce que le dispositif ne comporte pas les moyens élastiques précomprimables pour exercer une force sur l'élément d'actionnement 5 lors de l'actionnement du dispositif. Dans l'exemple représenté sur les figures 3 à 6, la force exercée par l'utilisateur sur l'élément

d'actionnement latéral 5 est directement transformé en force de déplacement axial du piston de la pompe par la pente inclinée 6 formant la surface de came et coopérant avec la cheville 7 solidaire de la bague de fixation 8. Dans ce mode de réalisation, les moyens de régulation de force sont réalisés sous la forme d'une pente variable dudit plan incliné 6. En effet, les pompes changent généralement leur résistance, et par conséquent la force requise pour l'actionnement, pendant la course d'actionnement. Ces augmentations de résistance pendant la course se produisent parfois de manière constante, parfois très rapidement. Une inclinaison de la surface de came 6 avec une variation appropriée peut totalement compenser ces augmentations de résistance et ainsi permettrent un actionnement sûr, avec la conséquence d'un dosage parfait et d'une pulvérisation parfaite, tout en exerçant une force constante sur l'élément d'actionnement 5.

Le dispositif selon l'invention présente donc les avantages suivants :

- la dose et la qualité du spray sont indépendantes de la pompe et de l'utilisateur puisqu'ils sont déterminés par les caractéristiques du ressort 15 dans le premier mode de réalisation, et par la pente variable du plan incliné 6 dans le second mode de réalisation ;
- l'actionnement est latéral, et par conséquent souvent plus facile et plus confortable pour l'utilisateur ;
- la manipulation est simplifiée puisque le capot de protection de l'embout nasal, qui est toujours présent dans ce type de dispositif, et qui doit toujours être retiré après utilisation puis revenir en place après utilisation, est dans le cas de la présente invention solidaire du dispositif et ne peut donc pas être perdu, de sorte que tous risques de problèmes hygiéniques de contamination au niveau de l'orifice de distribution sont éliminés ;
- l'ensemble du système d'actionnement latéral est assemblé sur le corps 1, à proximité de l'embout nasal 2 du dispositif, de sorte que le fond du réservoir 3 est librement accessible. Ceci permet un actionnement traditionnel standard par appui axial sur le fond du réservoir si nécessaire. Ceci peut être déterminant en cas de crise, par exemple de crise d'asthme, lorsque l'utilisateur, dans sa panique, essaie d'actionner le dispositif dans la manière dont il en a l'habitude

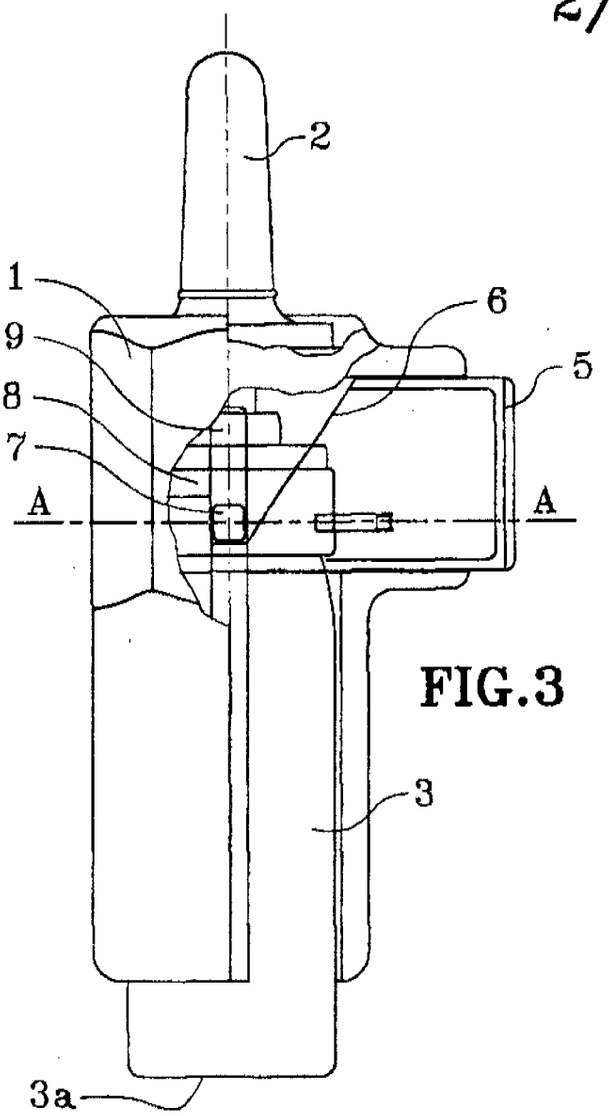

FIG.3

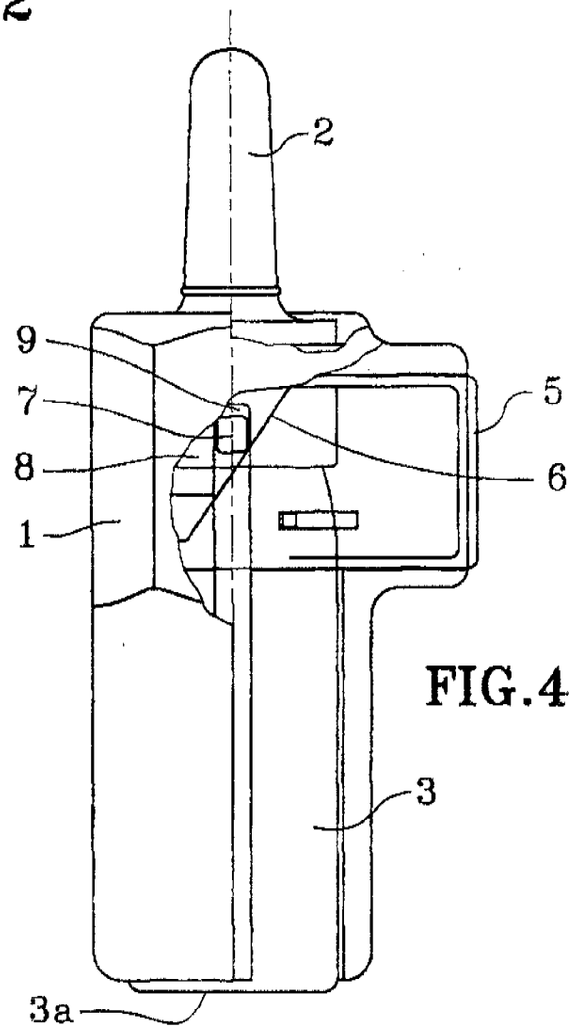

FIG.4

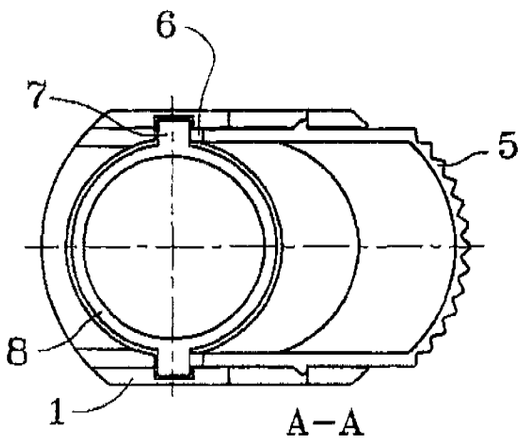

FIG.5

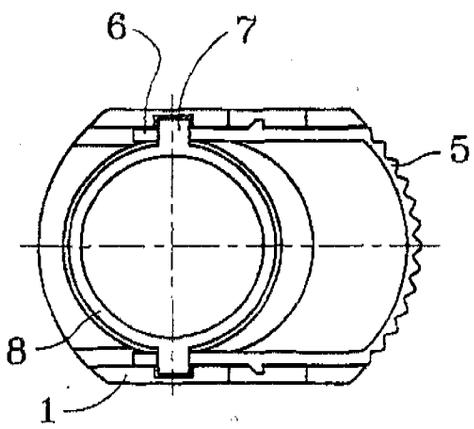

FIG.6

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D7

(12) **United States Patent**
Weinstein et al.

(10) **Patent No.: US 6,382,205 B1**
(45) **Date of Patent: *May 7, 2002**

(54) **METHOD AND DEVICE FOR ORGANIZING AND COORDINATING THE COMBINED USE OF TOPICAL AGENTS FOR THE TREATMENT OF RESPIRATORY DISORDERS**

(76) Inventors: **Robert E. Weinstein**, 177 Commonwealth Ave., Boston, MA (US) 02116; **Allan M. Weinstein**, 9205 Pegasus Ct., Potomac, MD (US) 20854

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/432,133**

(22) Filed: **Nov. 2, 1999**

(51) **Int. Cl.**[7] **A61M 11/00**

(52) **U.S. Cl.** **128/200.23**; 128/200.14; 128/203.12; 128/203.14; 206/534; 206/538; 206/828

(58) **Field of Search** 128/200.23, 200.14, 128/203.14, 203.12; 206/534, 538, 828

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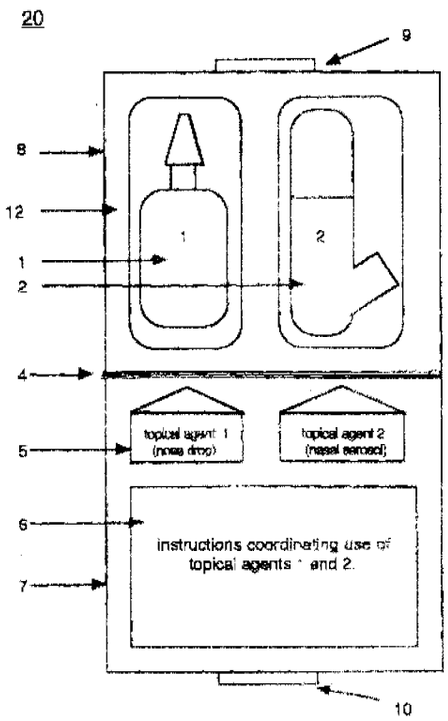
(57) **ABSTRACT**

A method and device for organizing, storing, instructing, and coordinating the combined use of topical therapeutic agents, including moisturizing agents, for the treatment of respiratory tract disorders.

13 Claims, 1 Drawing Sheet



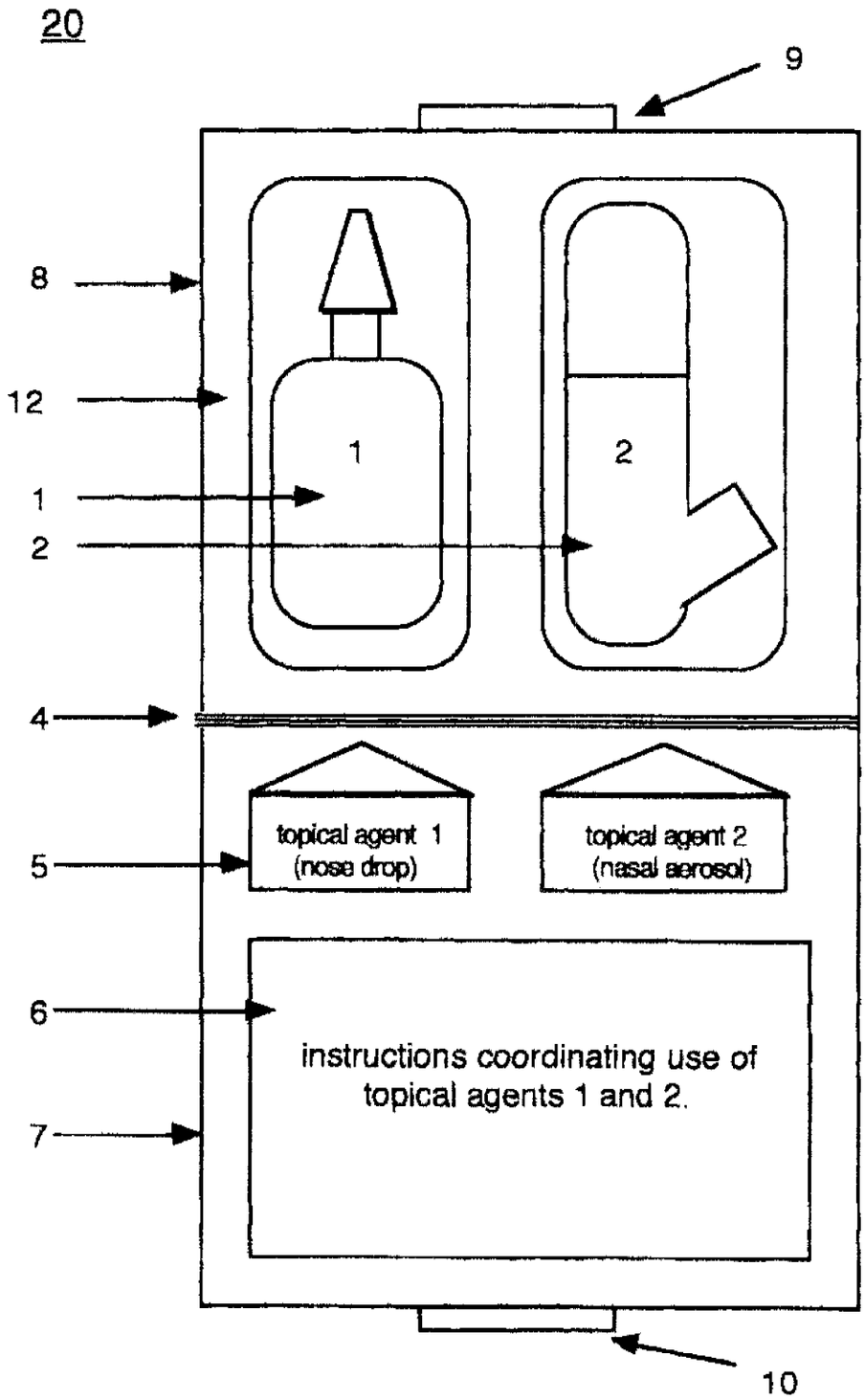

20
9
8
12
1
2
1
2
4
topical agent 1
(nose drop)
topical agent 2
(nasal aerosol)
5
6
instructions coordinating use of
topical agents 1 and 2.
7
10

Fig. 1

method includes obtaining a prepackaged, unifying container of the present invention and utilizing the topical agents according to the administration instructions incorporated within the prepackaged container.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a plan view of a container in accordance with the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The following detailed description of the invention is provided to aid those skilled in the art in practicing the present invention, however, it should not be construed to unduly limit the present invention. Variations and modifications in the disclosed embodiments may be made by those of ordinary skill in the art without departing from the scope of the present invention. With regard to the drawings, it will be understood that while preferred embodiments of the invention have been illustrated and described, the invention is not limited to such embodiments. Changes and additions may be made without departing from the spirit of the invention.

The present invention provides a unifying dispensing container for therapeutic agents for treatment of respiratory disorders which require a combined topical agent regimen and a method for reducing medication error and enhancing therapeutic compliance of combined topical agents for treatment of such disorders. The unifying container holds at least two topical agents in multi-dosage units, indicia for distinguishing these agents, and instructions for their coordinated use together as a single therapeutic regimen. Spacer devices and apparatus to measure outcomes of using the topical agents may also be included. It is to be understood that by multi-dosage unit it is meant that more than one dosage of the contained agent is available within the unit. Such multi-dosage units may contain and facilitate the application of multiple doses of the therapeutic agent preferably by aerosolization, and/or by other means of topically applying therapeutic agents as is known in the art, such as in liquid form as exemplified by drops or lavages, or in semi-solid form as exemplified by creams, and ointments. The word aerosolization encompasses its ordinary dictionary meaning of a providing a suspension of fine solid or liquid particles in air or gas.

Detailed embodiments of the invention have been described in the aforementioned U.S. Pat. No. 5,941,241 which disclosure is incorporated herein by reference in its entirety. An additional embodiment is depicted in FIG. 1.

FIG. 1 depicts a topical respiratory treatment system **20** in a support package **12**. Support package **12** has a first portion **7** and a second portion **8**. Second portion **8** houses dosages of a first topical agent **1** and a second topical agent **2**. A fold **4** in the package is provided in the center between first portion **7** and second portion **8**. Identifying indicia **5** is provided with respect to first topical agent **1** and second topical agent **2**. Identifying indicia **5** may be provided on first portion **7** or second portion **8**, or on the immediate package of the agents, or on the agents themselves such as by color, shape, size, etc. First portion **7** houses an instruction-bearing portion **6** that provides instructions coordinating use of first topical agent **1** and second topical agent **2** as a regimen. The first portion **7** and the second portion **8** of the support package each contain respective clasp portions **9** and **10** which can be secured together when support package **12** is folded along fold **4**. Other containers, such as a conventional folding paper box, and other closures are within the scope of the invention.

Topical agents that are presently used in combination for the treatment of respiratory disorders have been previously disclosed in U.S. Pat. No. 5,830,490. These include corticosteroids, decongestants, antihistamines, cell stabilizers, broncho-dilating adrenergic agents, and anticholinergic agents. What has not previously been disclosed is the inclusion of topical moisturizers. Topical moisturizers are utilized to moisten dry nasal membranes, loosen or thin nasal secretion and lavage the nasal cavity to remove mucous and inflammatory secretions from the nasal passages and/or sinuses.

Topical nasal moisturizers and washes may be formulated so as to be isotonic, hypotonic, or hypertonic with respect to saline. Examples of marketed topical nasal moisturizers include NaSal™ Moisturizer which contains sodium chloride 0.65%, benzalkonium chloride and thimerosal 0.001% as preservatives, mono- and dibasic sodium phosphates as buffers and purified water, and AYR Saline Nasal Mist and Drops which contain buffered isotonic saline adjusted to pH and topicity with monobasic potassium phosphate/sodium hydroxide buffer, and similarly preserved. It may be considered desirable to modify or eliminate the inclusion of preservatives. Other examples of agents used to moisten membranes are the wetting agents propylene glycol and polyethylene glycol.

The invention will be further clarified by a consideration of the following examples, which are intended to be purely exemplary of the invention.

EXAMPLE 1

Topical Intranasal Agents including a Moisturizing Agent and a Corticosteroid

One beneficial treatment regime includes the use of topical nasal saline aerosol or drops to relieve nasal dryness and help moisten and remove thick secretions, followed by a topical intranasal corticosteroid aerosol to reduce inflammation. One advantage of using the saline moisturizer first is to clear the nasal passages for improved dispersion of the anti-inflammatory corticosteroid. A medication regimen exemplifying this includes: Ocean Mist™ Buffered Saline, two sprays in each nostril four times a day, followed by Flonase® Nasal Spray, one spray in each nostril twice a day.

EXAMPLE 2

Topical Intranasal Agents including a Decongestant and a Moisturizing Agent.

Another beneficial treatment regime includes the use of a topical nasal decongestant in the form of aerosol or drops to shrink the nasal membranes and open the nasal and sinus passages, followed by a topical intranasal moisturizing agent to moisten and remove thick secretions and relieve nasal dryness. A medication regimen exemplifying this includes: Neo-Synepherine Nasal Spray® (phenylephrine hydrochloride) decongestant two sprays in each nostril four times a day followed by Ocean Mist™ Buffered Saline, two sprays in each nostril four times a day. Examples of other topical decongestants include oxymetazoline and ephedrine solutions. Topical nasal decongestants are preferably utilized for a five-day period or less.

Examples of more complex regimens that limit the use of decongestant are:

(a) a five day course of decongestant and moisturizer, followed by moisturizer alone thereafter, or

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US 20020170928A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2002/0170928 A1**

Grychowski et al. (43) **Pub. Date: Nov. 21, 2002**

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(21) Appl. No.: 10/121,931

(22) Filed: **Apr. 12, 2002**

Related U.S. Application Data

(60) Provisional application No. 60/345,181, filed on Dec. 21, 2001. Provisional application No. 60/305,408, filed on Jul. 13, 2001. Provisional application No. 60/291,196, filed on May 15, 2001.

Publication Classification

(51) **Int. Cl.**[7] **G01F 13/00**

(52) **U.S. Cl.** **222/251**

(57) **ABSTRACT**

An actuator is used to dispense a medicament from a container having at least a first and second portion. The actuator includes a holder, a trigger member and a push member. The holder is adapted to engage at least the first portion of the container. The trigger member is pivotally connected to the holder at a pivot axis, wherein the trigger member is pivotable about the pivot axis in a first direction toward the grippable portion and a second direction opposite the first direction. The push member is connected to the trigger member, wherein the push member is pivotable about the pivot axis in the first direction as the trigger member is pivoted in the first direction and wherein the push member is pivotable about the pivot axis in the second direction as the trigger member is pivoted in the second direction. The push member is adapted to move at least the second portion of the container relative to the holder as the push member is pivoted in the first direction. In one preferred embodiment, the trigger member follows a path, and a stop member engages one of the container and push member and immobilizes the push member as the trigger member is moved along a predetermined portion of the path. In one preferred embodiment, a trip member engages the stop member and disengages it from one of the container and the push member, thereby allowing the push member to move the second portion of the container. In one preferred embodiment, the actuator includes an indicator mechanism for indicating the number of doses remaining in or dispensed from the container. A method of dispensing medicament from the container, and a method of assembling the actuator also are provided. A nasal applicator is also provided, and includes a diffuser having a passageway comprising a tapered portion.

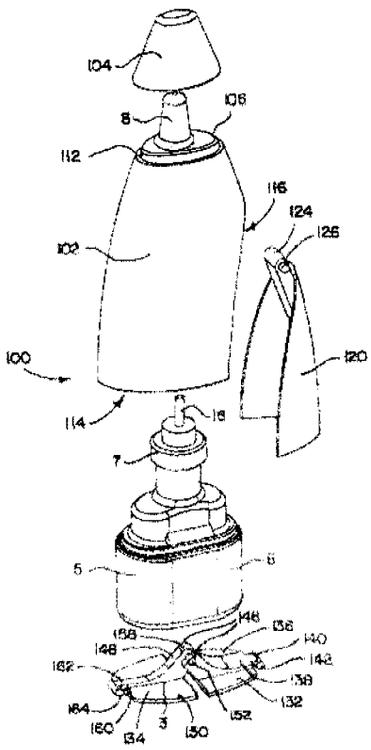
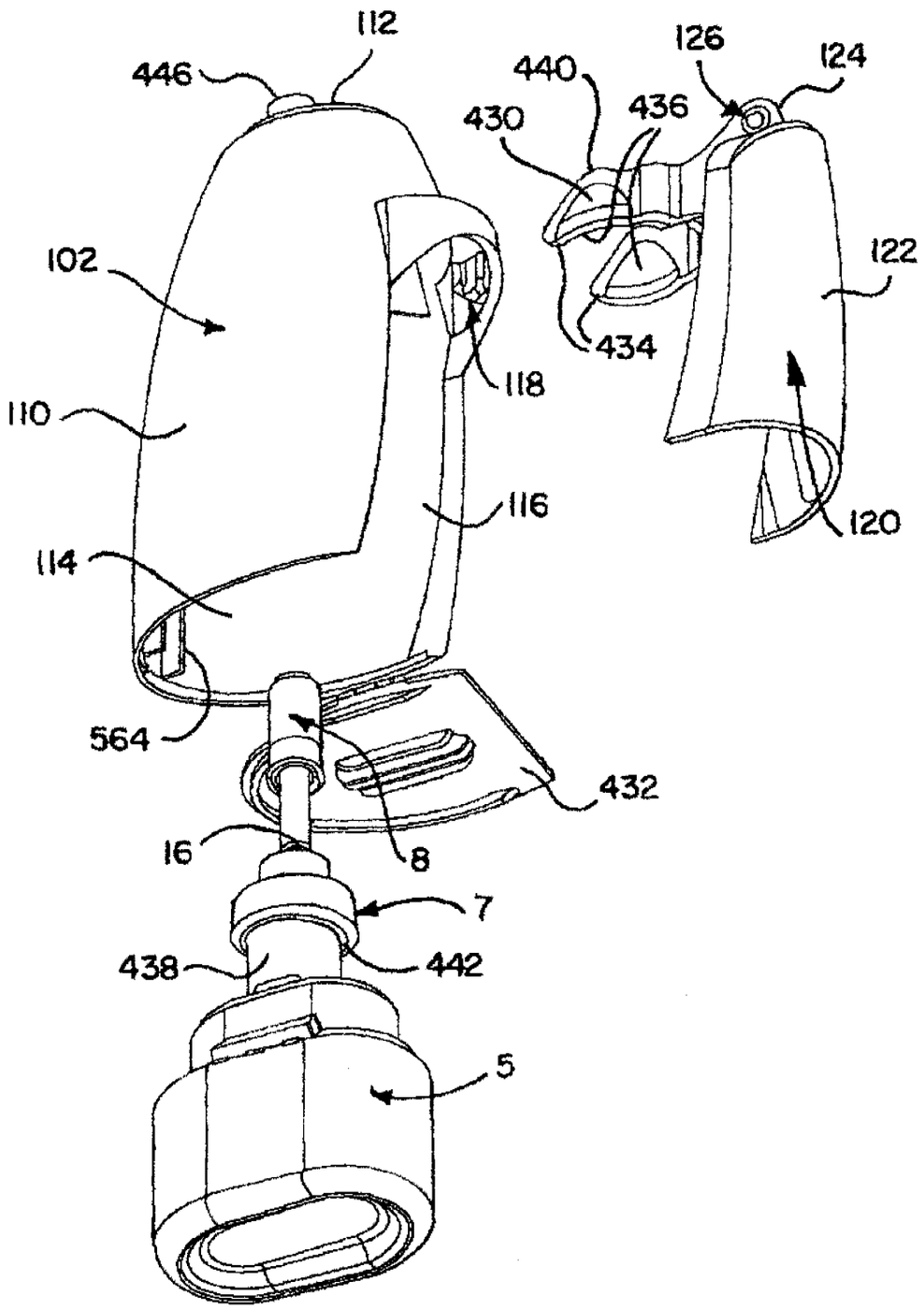


FIG. 39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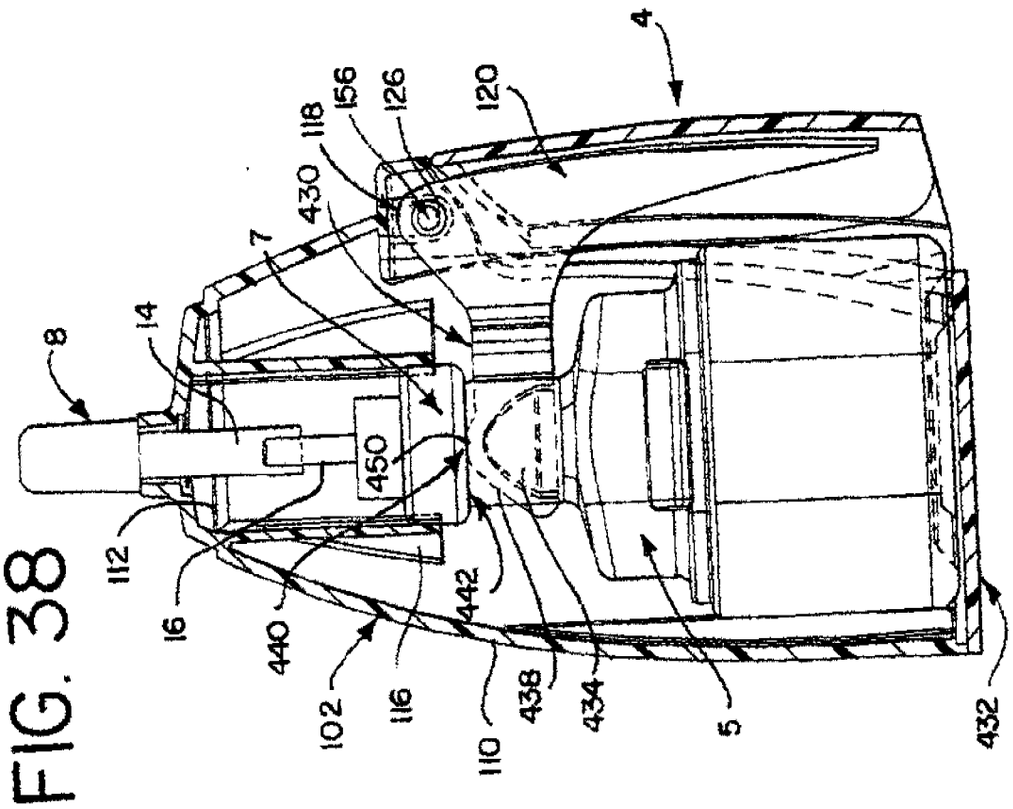
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FIG. 38

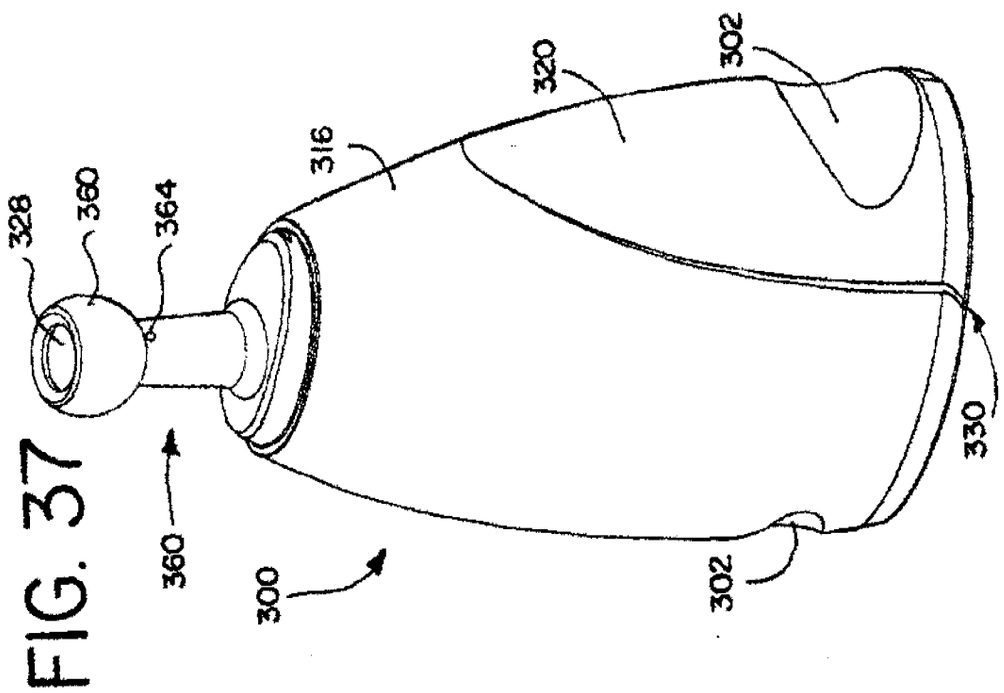
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FIG. 37

may include a series of holes around the center thereof This will give the finer particles **100** microns and less an escape route from the baffle area. In one preferred embodiment, the diffuser is separable from the actuator so as to allow the draining and cleaning of the inside of the diffuser between treatments.

[**0185**] It should be understood that the nozzle **8**, and/or the entire actuator, and the diffuser **20** can be made as a single integrally molded actuator or diffuser, referred to when combined as such as either a diffuser or a nozzle, and as having a diffuser portion and a nozzle portion, which in one embodiment can be disposed on the stem, or can further be integrally molded with the holding chamber. In this context, it should be understood that the "nozzle portion" refers to that portion of the diffuser or actuator that engages the stem portion of the container, whether made as a separate member or integrated with the diffuser portion. In one such embodiment, the diffuser, preferably integrated into an actuator, would have a nozzle portion with a first, lower passageway **14** having a generally cylindrical cross-section that communicates with the stem **16** extending from the holding chamber, and a diffuser portion with a second, upper passageway **30**, preferably having one or more of the tapered configurations described above. In either embodiment, whether integral or made separately, the nozzle and/or diffuser can be made of a hard plastic, or can be made of a more pliant material, such as silicone.

[**0186**] In yet another embodiment, shown in FIGS. **27-36**, a second, upper diffuser portion **260** of a diffuser **256** has a bulb-like or substantially spherical exterior shape or contour. More specifically, the exterior shape of the upper diffuser portion **260** is formed as a zone of a sphere, with a lower end thereof being connected to the lower nozzle portion **262** of the diffuser and the upper surface thereof being substantially flat, or tapered slightly downward and inward. In one preferred embodiment, the radius of the spherical portion is about **0.28** inches. A smaller radius may be provided to accommodate users with smaller nostril openings, such as children. Preferably, the upper portion has a height of between about 0.40 inches and about 0.45 inches, with the lower portion having a height of about 0.50 inches. Alternatively, the combined height of the upper and lower portions is about 0.83 inches.

[**0187**] In operation, the user simply inserts the bulbous upper portion into the nostril until it can go no further. At this location, the outlet **28** of the diffuser is located at the entry point of the nasal cavity, which leads to the nasal turbinates. In addition, the spherical shape facilitates the sealing of the entrance to the nasal cavities, which in turn helps to direct the ambient air to flow throughout the diffuser passageway and fully evacuate the remaining medicament during inhalation. The sizable shape of the spherical diffuser helps spread the soft tissues of the inside of the lining of the nostril's cavity at a distance from the high velocity particles exiting the stem The spherical diffuser is more forgiving in situations when the device is not properly directed during application of the medicament, and it has a "friendlier" appearance, especially when viewed by children.

[**0188**] The diffuser further includes a pair of inlets **264** communicating with the passageway **30** directly adjacent the nozzle portion output end. Preferably, the inlets **264** are not positioned directly opposite each other, and are not directed at and do not extend radially from the longitudinal axis **300** of the nozzle and passageways, but rather are offset from each other on opposite sides of the axis so as to create a cyclonic or swirling flow in the passageway. Additional vanes can be added within the passageway to further direct the flow. Preferably, the inlets are directed tangentially along the interior wall of the diffuser substantially perpendicular to the axis **300**. Preferably, the inlets **264** each have a diameter of 0.10 inches. The inlets facilitate the cleaning of the device, as they will allow water, or other cleaning fluids, to drain therethrough. Preferably, the outlet opening **28** has a diameter of between about 0.30 inches and about 0.56 inches. Accordingly, in one preferred embodiment, the ration of the inlet openings to the outlet is about 56:20. In one embodiment, the diameter of the outer rim portion of the diffuser at the top thereof is about 0.46 inches, with the rim tapering down to the outlet opening.

[**0189**] Preferably, the passageway **30** is tapered at about 6 degrees from bottom to top. In one preferred embodiment, the diameter of the passageway at the bottom of the diffuser portion is about 0.22 inches, with the diffuser tapering to an exit diameter of about 0.30 inches.

[**0190**] Referring to FIGS. **27-31**, the diffuser **256** is integrally formed as part of an actuator. The overall height of the device, including the container, is about 3.68 inches, with the height between the bottom of the container and the shoulder, which is the distance required for the fingers to activate the device, being about 1.95 inches, compared with about 3.00 inches for a conventional device. The nozzle portion **262** of the diffuser further includes a nozzle insert **282**, which is disposed on and engages the stem and is inserted into a cavity formed in the lower nozzle portion of the diffuser. Alternatively, the lower nozzle portion of the diffuser can be configured with a passageway shaped to engage the stem of the container. An upper portion **284** of the actuator holder, which is connected to the lower, nozzle portion **262** of the diffuser, has a pair of scalloped openings **286** formed opposite each other to provide room for the user's fingers as they engage the shoulder of the holder. A pair of protuberances **290**, or ribs, extend upwardly at the outer portion of the shoulder to help locate the user's fingers. In this embodiment, the user grips the shoulders **288** of the actuator with the index and middle fingers, or other available fingers, and pushes the bottom **178** of the container upwardly with their thumb or other available fingers so as to move the holding chamber of the container relative to the stem and thereby dispense a dose of medicament.

[**0191**] In operation, the diffuser **20** separates the end of the nozzle, and the outlet **10** thereon, from the impaction surface of the nasal cavities, which reduces the irritation that can be caused by the direct impact of high velocity particles on the soft nasal tissues. In this way, the tapered passageway **30** slows the particles down, as well as increases the distance between the end of the nozzle, or cylindrical passageway, and the nasal cavities. In addition, when configured with inlets **40**, ambient air can be pulled into the passageway to help evacuate the passageway as the user inhales and to further enhance the particle distribution by breaking down larger particles into smaller particles that will be absorbed in the nasal cavity, in particular the nasal turbinates

[**0192**] Referring to **FIG. 37**, yet another alternative embodiment of an actuator **300** is shown. This embodiment

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 November 2003 (20.11.2003)

PCT

(10) International Publication Number
WO 03/095007 A2

(51) International Patent Classification[7]: A61M 11/02, B05B 11/00

(21) International Application Number: PCT/EP03/04858

(22) International Filing Date: 7 May 2003 (07.05.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

0210605.2	9 May 2002 (09.05.2002)	GB
0217798.8	1 August 2002 (01.08.2002)	GB
0219462.9	21 August 2002 (21.08.2002)	GB

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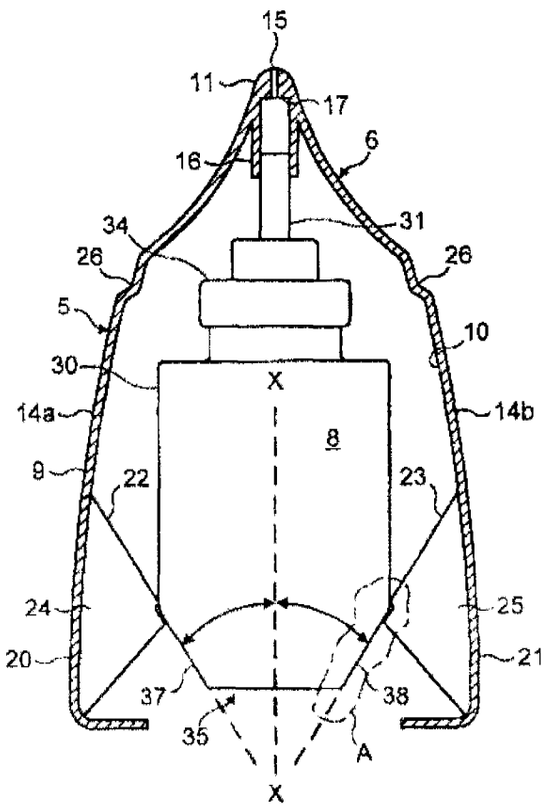
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,

[Continued on next page]

(54) Title: A FLUID DISPENSING DEVICE



(57) Abstract: A fluid dispensing device (5, 105, 205, 305, 405, 505) is disclosed having a housing (9, 109, 209, 309, 409, 509) and a fluid discharge device (8, 108, 208, 308, 408, 508). The fluid discharge device (8, 108, 208, 308, 408, 508) is arranged to be actuated by one or more levers (20, 21; 120, 121; 170; 220, 221; 320, 321; 420, 421; 520) so as to apply a force transversely to the fluid discharge device (8, 108, 208, 308, 408, 508) which is used to move a container (30, 130, 230, 330, 430, 530) forming part of the fluid discharge device (8, 108, 208, 308, 408, 508) along a longitudinal axis of the fluid discharge device (8, 108, 208, 308, 408, 508) to cause actuation of a pump forming part of the fluid discharge device (8, 108, 208, 308, 408, 508). A pre-load means (28; 27, 28; 39,40; 41, 42, 44; 144, 47a, 47b; 150, 152, 153); 224, 227; 342; 424a, 446; 425a; 427, 428; 560, 561) is used to prevent actuation of the pump until a pre-determined force is applied to each lever (20, 21; 120, 121; 170; 220, 221; 320, 321; 420, 421; 520) of sufficient magnitude to guarantee the production of a well developed efficient spray from the fluid dispensing device (5, 105, 205, 305, 405, 505).

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Fig.15 is a front view of the fluid dispensing device shown in Fig.14 with an end cap in place;

Fig.16 is an enlarged cross-section of the area indicated by the arrow 'E' on Fig. 17;

Fig.17 is a cross-section of a fluid dispensing device shown in Fig.14;

Fig.18 is a cross-section of a fluid dispensing device having an alternative mechanism to actuate the fluid discharge device to that shown in Fig.1 and having a pre-load means according to a sixth embodiment of the invention;

Fig.19 is a cross-section that is similar to that shown in Fig.18 but showing an alternative pre-load means according to the sixth embodiment of the invention;

Fig. 19A is an enlarged side view of the collar occupying area indicated by the arrow 'J' on Fig.19;

Fig. 19B is an enlarged perspective view of the collar of Fig. 19B;

Fig.20 is a front view of the fluid dispensing device shown in Figs. 18 and 19 but showing the use of a pre-load means according to the fourth embodiment of the invention;

Fig.21 is a side view in the direction of the arrow 'P' on Fig.20;

Fig.22 is a cross-section of a fluid dispensing device having an alternative mechanism to actuate the fluid discharge device to that shown in Fig.1 and having a pre-load means according to the second embodiment of the invention;

Fig.23 is a side view in the direction of arrow 'T' on Fig.22; and Fig. 24 is cross-section of the area indicated by the arrow 'F' on Fig. 22.

With reference to figures 1, 2a and 3 there is shown a fluid dispensing device 5 for spraying a fluid into a body cavity comprising a housing 9, a nozzle 11 for insertion into a body cavity, a fluid discharge device 8 moveably housed within the housing 9, the fluid discharge device 9 having a longitudinal axis and comprising a container 30

for storing the fluid to be dispensed and a compression pump having a suction inlet located within the container 30 and a discharge tube 31 extending along the longitudinal axis for transferring fluid from the compression pump to the nozzle 11 and finger operable means 20, 21 moveable transversely with respect to the longitudinal axis of the fluid discharge device to apply a force to the container 30 to move the container 30 along the longitudinal axis towards the nozzle 11 so as to actuate the compression pump and a pre-load means 28 to prevent actuation of the compression pump until a pre-determined force is applied to the finger operable means 20, 21.

The finger operable means is in the form of two opposing levers 20, 21 each of which is pivotally connected to part of the housing 9 and is arranged to act upon a base portion 35 of the container 30 so as to urge the container 30 towards the nozzle 11 when the two levers 20, 21 are squeezed together by a user.

The fluid dispensing device 5 comprises of a plastic moulded body 6 and the fluid discharge device 8 and further comprises of a protective end cap (not shown) having an inner surface for engagement with the body 6 to protect the dispensing nozzle 11.

The body 6 is made from a plastic material such as polypropylene and defines the housing 9 and the dispensing nozzle 11 so that the housing 9 and the nozzle 11 are made as a single plastic component.

The housing 9 defines a cavity 10 formed by a front wall, a rear wall and first and second end walls 14a, 14b. The dispensing nozzle 11 is connected to one end of the housing 9, extends away from the housing 9 and has an external tapering form.

The discharge outlet from the compression pump is in the form of the tubular delivery tube 31 and a tubular guide in the form of an outlet tube 16 is formed within the nozzle 11 to align and locate the delivery tube 31 correctly with respect to the nozzle 11.

An annular abutment 17 is formed at the end of the outlet tube 16. The annular abutment 17 defines the entry to an orifice 15 through which fluid can flow in use and is arranged for abutment with an end of the delivery tube 31.

The fluid discharge device 8 has a longitudinal axis X-X and each of the levers 20, 21 has an abutment surface 22, 23 arranged at an angle θ to the longitudinal axis X-X of the fluid discharge device 8 for abutment against the base portion 35 of the container so as to convert a force applied to the levers 20, 21 substantially transversely to the longitudinal axis X-X of the fluid discharge device 8 into a force along the longitudinal axis X-X of the fluid discharge device 8.

The nozzle 11 has a longitudinal axis that is aligned with the longitudinal axis X-X of the fluid discharge device 8. This has the advantage that when the compression pump is actuated the force applied to the tubular delivery tube 31 is along the axis of the tubular delivery tube 31 and no bending or deflection of the delivery tube 31 will occur due to the applied force.

At least part of the surface of the base portion 35 of the container 30 is inclined at an angle with respect to the longitudinal axis X-X of the fluid discharge device 8 so as to form an inclined surface, the or each inclined surface being arranged to be acted upon by the levers 20, 21 so as to convert a force applied to the levers 20, 21 substantially transversely to the longitudinal axis X-X of the fluid discharge device 8 into a force along the longitudinal axis X-X of the fluid discharge device 8.

Although in the disclosed embodiment both the levers and the container have surfaces inclined to the longitudinal axis of the fluid discharge device this need not be the case. Only the container or the levers need have an inclined surface or some other arrangement to apply the force from the levers to the container could be used.

The base portion 35 of the container 30 has two inclined surfaces 37, 38 each arranged for co-operation with a respective one of the levers 20, 21.

However it will be appreciated that the inclined surface of the base portion of the container could be a conical, frusto-conical or part spherical surface.

The inclined surface 37 is arranged to co-operate with the abutment surface 22 and the inclined surface 38 is arranged to co-operate with the abutment surface 23.

The abutment surface 22 is formed by an edge of a web 24 formed as part of the lever 20 and the abutment surface 23 is formed by an edge of a web 25 formed as part of the lever 21.

In the arrangement shown in Fig 2A, the pre-loading means is interposed between the levers 20, 21 and the container and as shown is in the form of small step 28 formed near to the end of each abutment surface 22, 23. In the ready for use position this lies against a side of the container 30 at the juncture of the side of the container with the base portion 35. The purpose of this step 28 is to prevent the levers 20, 21 from moving the container 30 until more than a pre-determined force has been applied to the levers 20, 21.

The step 28 formed on each lever 20,21 must be ridden over by the container 30 before the compression pump can be actuated. The step 28 is over-ridden when the pre-determined force is applied to each lever 20,21 and once this pre-determined force is exceeded the pressure being applied to the levers 20, 21 is such that the container 30 is very rapidly moved towards the nozzle 11. This prevents the levers 20, 21 being slowly squeezed together which will not produce a uniform spray and if done very slowly will merely cause the fluid to dribble out of the nozzle 11.

Fig. 2B shows an alternative arrangement in which the pre-load means comprises of a detent or protuberance 29 formed on the container 30 and complementary recess 27 formed on each lever 20,21. The size of the detent 29 is such that they are able to ride out of the recess 27 when the pre-determined force is applied to each lever 20, 21. It will be appreciated that in other alternatives, the recess could be formed in the container and the detent could be formed on the levers.

Each of the levers 20, 21 is pivotally connected to part of the housing 9 by a respective living hinge. In the embodiment shown each of the levers 20, 21 is pivotally connected to a respective one of the two side walls 14a, 14b by a respective living hinge 26 although other means of pivotal connection could be used.

With reference to Fig. 19 there is shown a fluid dispensing device 405 that is in many respects similar to that previously described with reference to Fig 18 but in which an alternative form of pre-load means is interposed between each lever 420, 421 and the respective actuating means 422. The same reference numerals are used for like parts and the construction of the fluid dispensing device 405 will not be described further except so far as it relates to the pre-load means.

The features of the actuating device 422 may be better understood having regard to Figures 19A and 19B, which show side and perspective views thereof.

The pre-load means comprises of an actuating device 441having a collar 440 for receipt by neck 429 of the container 430. The actuating device 441 is provided on opposing sides with ramps 422, each having a variable mechanical ratio such that until a pre-determined force is applied to each lever 420, 421 no significant force is transferred to the container 430.

This is achieved by having a first portion 425a of each ramp 422 inclined at a lesser angle (e.g. approx 20°) to a longitudinal (i.e. vertical, as shown) axis of the fluid discharge device 408 than is the remaining length 425b (e.g. angle approx. 45°) of each ramp 422. Therefore when a force is initially applied to each lever 420, 421 it is applied substantially normal to the longitudinal axis of the fluid discharge device 408 and virtually no force is converted into a force along the longitudinal axis of the fluid discharge device 408 and so the static friction between the first portion 425a of each ramp 422 and the cooperating lever 420, 421 is sufficient to maintain the levers 420, 421 stationary. However, when a pre-determined load is applied to each lever 420, 421 the static friction is overcome and each lever 420, 421 is able to start moving along the first portion 425a of the cooperating ramp 422. When each lever 420, 421 reaches the end of the first portion 425a, the change in inclination of the surface with which the lever 420, 421 is cooperating in combination with the magnitude of the force being applied ensures that each lever 420, 421 suddenly slides rapidly along the second portion 425b of the cooperating ramp 422 causing the container 430 to be moved rapidly towards the nozzle 411 to actuate the compression pump.

This ensures that the pump is only actuated when sufficient force is being applied to guarantee the production of an effective spray.

As visible in Figs. 19A and 19B, the actuating device 441 is also provided on opposing sides of the collar 440 with guide rails 426a, each perpendicularly arranged with respective to both ramps 422. The guide rails 426a interact with mating guides (not visible) on the housing 409 to ensure uniform longitudinal movement of the container 430 during actuation.

With reference to Figs. 20 and 21 there is shown a fluid dispensing means that is in most respects identical to that previously described with respect to Figs. 18 and 19 and for which the same reference numerals are used for identical parts. The only difference between the fluid dispensing device 405 shown in Figs. 20 and 21 and those shown in Figs. 18 and 19 is the arrangement of the pre-load means, which in this case is interposed between each of the levers 420, 421 and the housing 409. In addition, an end cap 407 is shown fitted in Figs. 20 and 21.

The pre-load means comprises of two detents or protrusions 428 formed on each of the levers 420, 421 for engagement with a bevelled surface 427 formed around the periphery of an aperture in the housing 409 through the respective lever 420, 421 projects.

When a light force is applied to the two levers 420, 421 they are prevented from moving into the housing by the abutment of the detents 428 with the bevelled surfaces 427. When the force applied to each lever 420, 421 reaches a pre-determined magnitude it is sufficient to deflect the side walls of the levers 420, 421 inwardly so allowing the detents 428 to ride across the bevelled surfaces 427 into the housing 409. A soon as the detents have passed over the bevelled surfaces 427 the levers 420, 421 are free to move towards the container 430 housed within the housing 409 so as to actuate the pump. Once again, this ensures that a reliable spray is produced.

When the force is released from the levers 420, 421 they are moved back towards their start positions but require the application of a small outward force in order to re-engage the detents 428 with the bevelled surfaces 427.

With particular reference to Figs. 22 to 24 there is shown a fluid dispensing device 505 having a housing 509 for housing a fluid discharge device 508. The housing has a nozzle 511 extending out from one end for engagement with a body orifice such as a nasal cavity.

The fluid discharge device is conventional in nature and as is previously described having a container 530 for the fluid to be dispensed, a compression pump fixed within the container 530 and a discharge tube 531 extending out from the pump to deliver fluid to an orifice 515 formed in the nozzle 511. As previously described the pump is actuated by pushing the discharge tube 531 into the pump, which is achieved by moving the container 530 towards the nozzle 511.

A finger operable means is provided to move the container 530, the finger operable means is in the form of a lever 520 slidably supported within the housing 509 to apply a force to the container 530 so as to move the container 530 towards the nozzle 511 and actuate the compression pump.

The lever 520 has two flanges each of which is slidably supported by means of rails 555, 556 that are engaged with U-shaped guides 557 formed in the housing 509.

A pre-load means is provided to prevent the pump being actuated before a pre-determined force is applied to the lever 520.

The pre-load means comprises of a spring 558 interposed between the lever 520 and the container 530 and a latching means 560, 561. The spring 558 is used to urge the container 530 towards the nozzle 511 so as to actuate the compression pump.

The spring is interposed between a collar 540 connected to the container 530 and a base plate 541. A transfer rod 542 extends out from each side of the base plate for

engagement with an inclined surface 543 formed on each flange of the lever 520. When the lever 520 is pushed or urged by a user towards the container 530 the transfer rods 542 move up the inclined surfaces 543 thereby compressing the spring 558. However, the container 530 is not moved because the collar 540 is connected to the housing 509 by the latching means 560, 561.

The latching means comprises of a rib 560 formed on an internal wall of the housing 509 and two outwardly extending arm 561 connected to the collar 540.

Each of the arms 561 is connected to the collar via a living hinge 563 so that when the collar 540 moves towards the nozzle 511 the arms 561 are able to abut against the collar 540 and so transfer load to the rib 560 but when the collar 540 is moving away from the nozzle 511 the arms 561 are able to flip up so as to allow them to pass freely over the rib 560. A return spring 565 is provided to return the lever 520 to its normal rest position when no force is being applied to it.

Operation of the fluid dispensing device is as follows.

The application of an initial force to the lever 520 causes the spring 558 to be compressed by the movement of the lever 520 without any movement of the container 530 occurring due to the engagement of the arms 561 with the rib 560. This will continue until a pre-determined force is applied, at which point the means used to prevent actuation of the compression pump, that is to say the arms 561 and the rib 560, are overcome by the force being applied to the container 530 by the spring 558 and the container 530 moves rapidly towards the nozzle 511 so as to actuate the compression pump.

Upon releasing the force from the lever 520 it is returned to its rest position by the return spring 565 and a spring within the pump returns the container back to its rest position so that the arms 561 re-engage with the rib 560.

The use of a spring to move the container has the advantage that a known force is used to move the container and so a consistent spray can be produced.

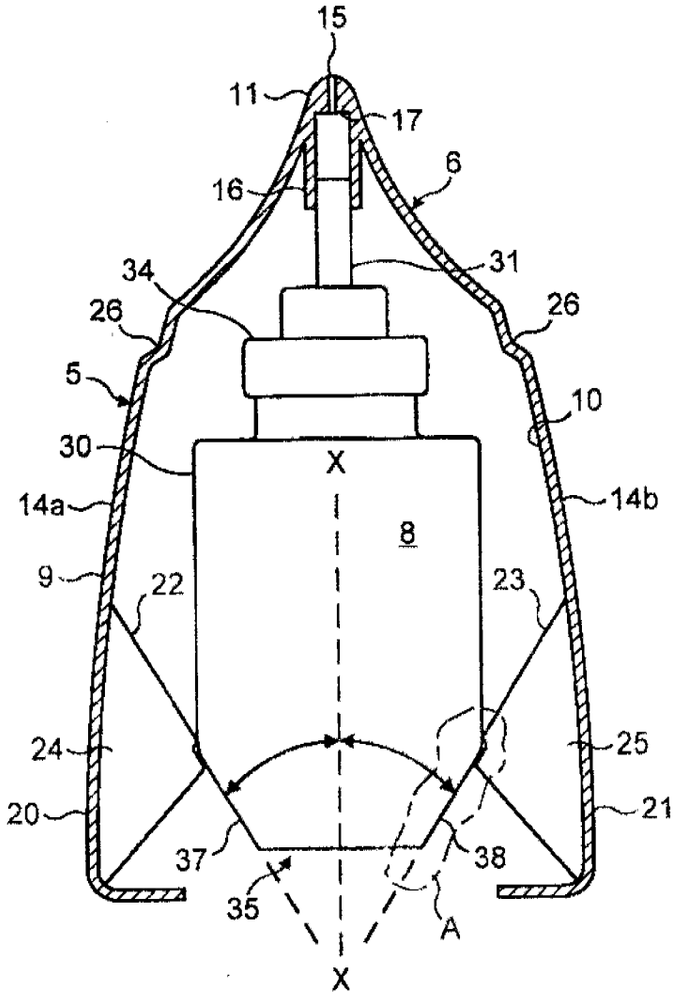


FIG. 1

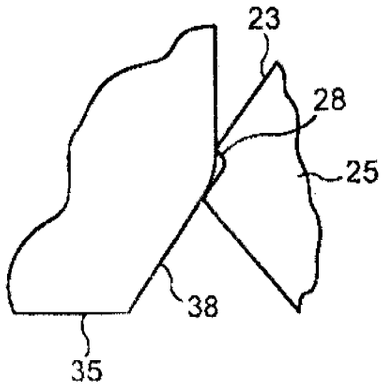


FIG. 2a

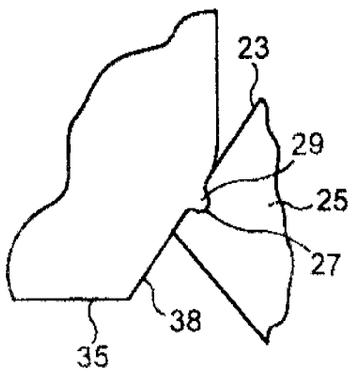


FIG. 2b

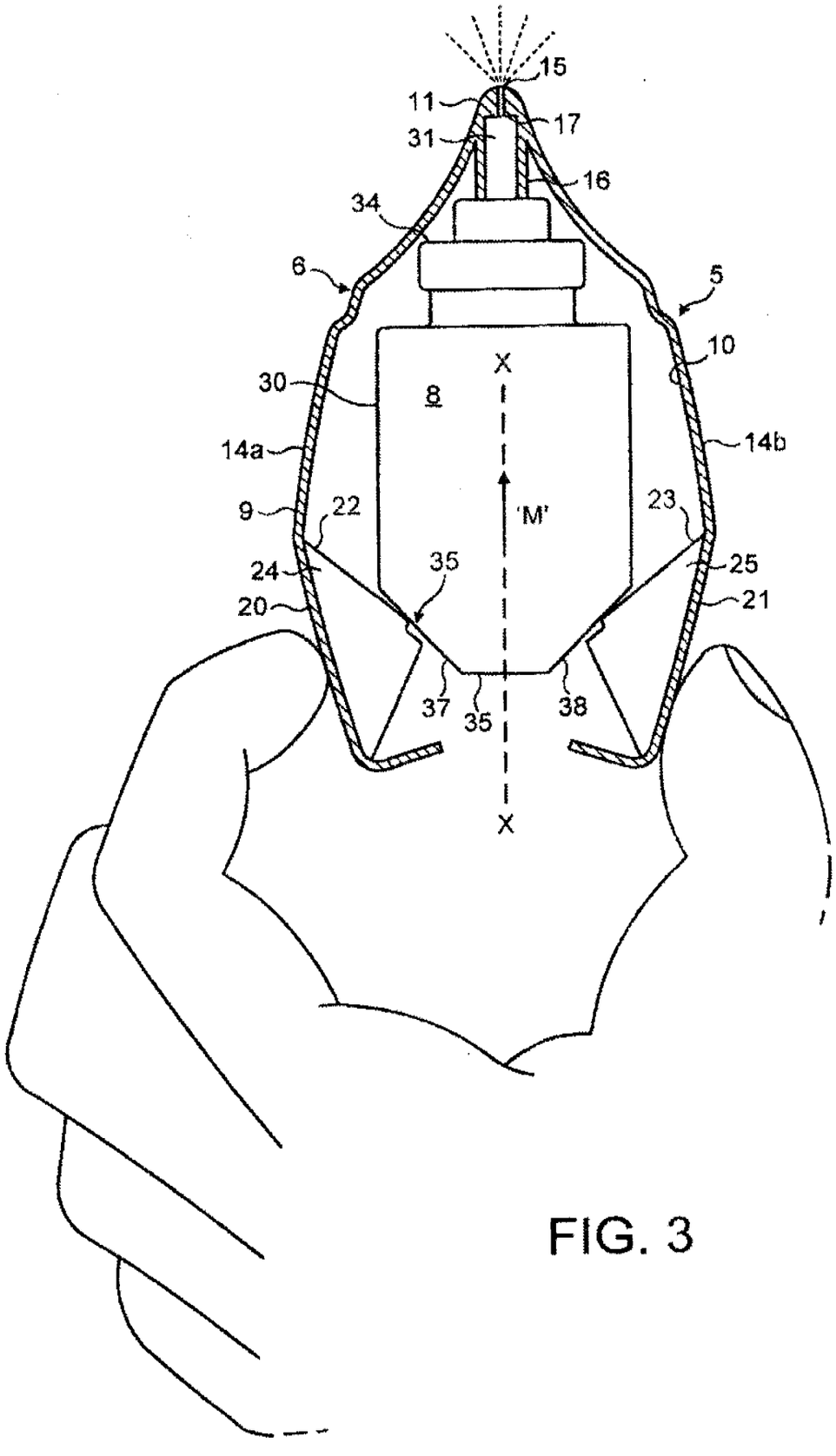
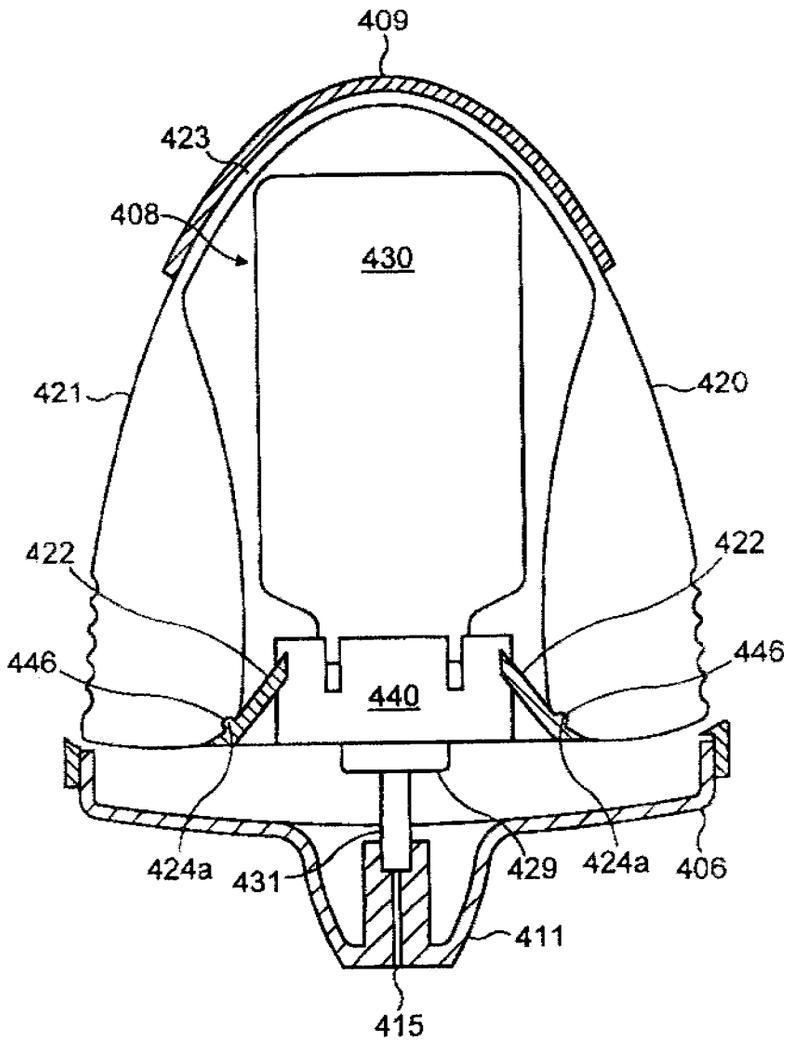


FIG. 3


409
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446
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424a
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424a
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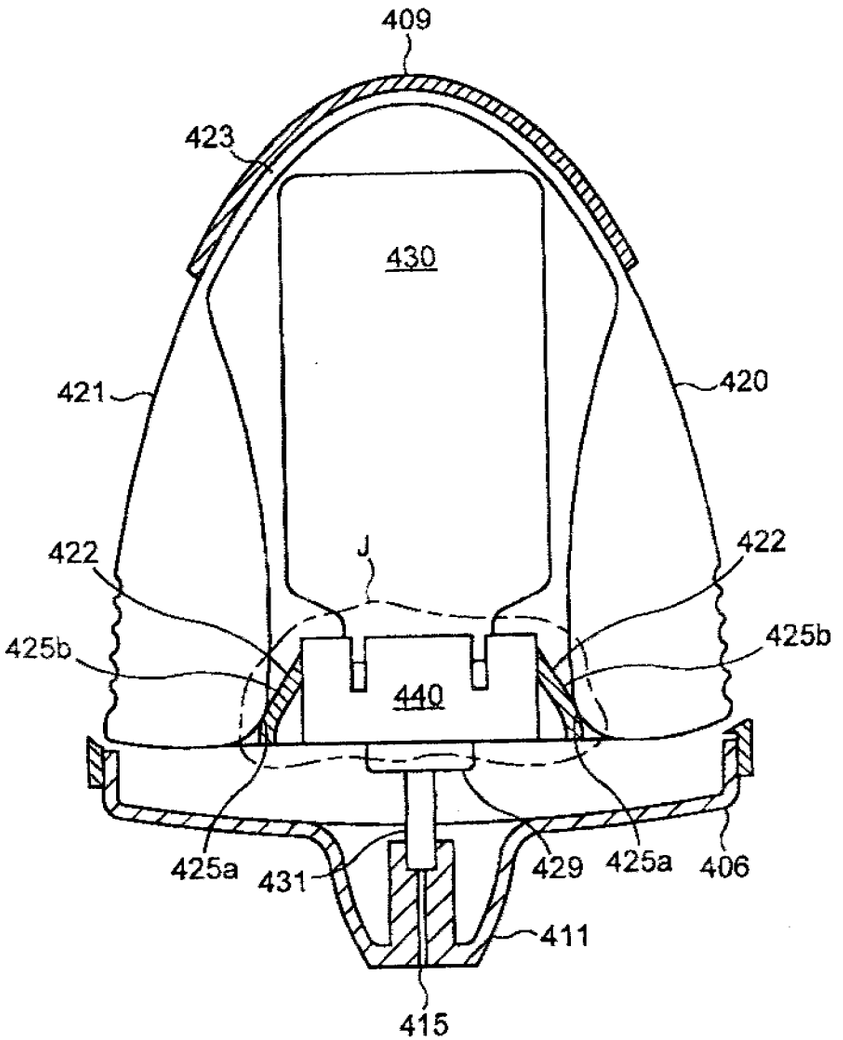
FIG. 18


409
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425b
425b
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425a
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425a
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FIG. 19

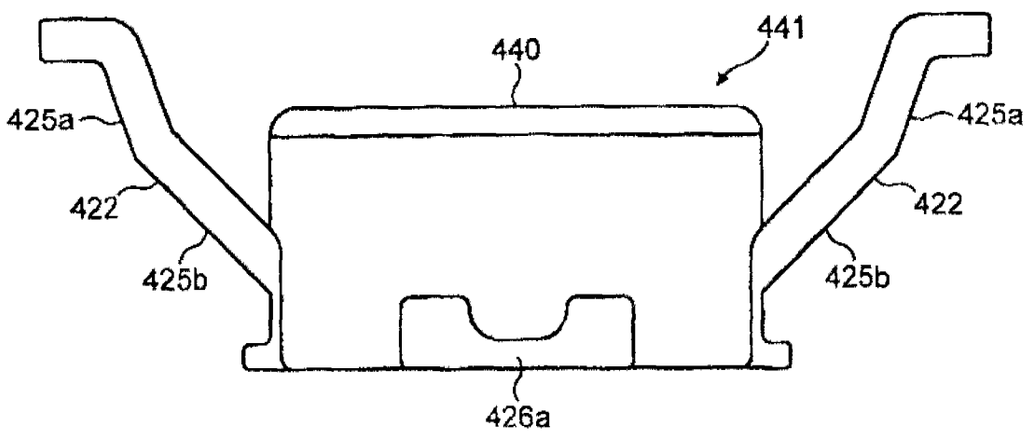

FIG. 19a

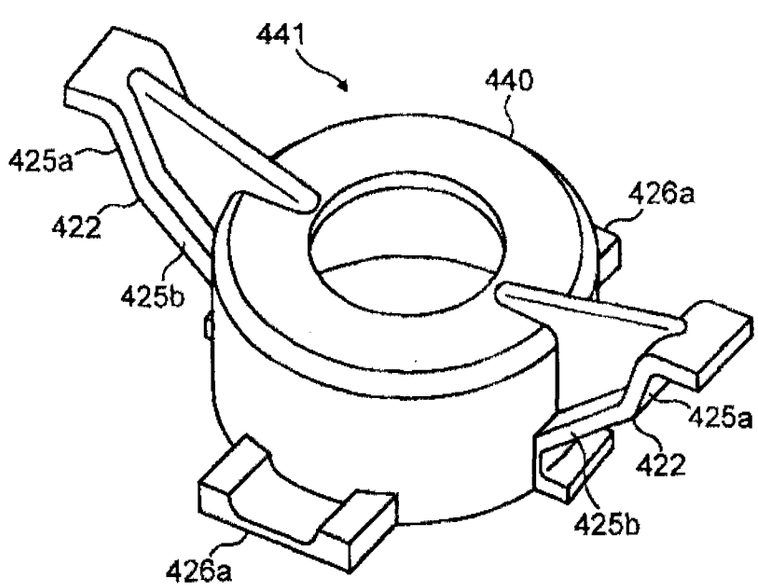

FIG. 19b

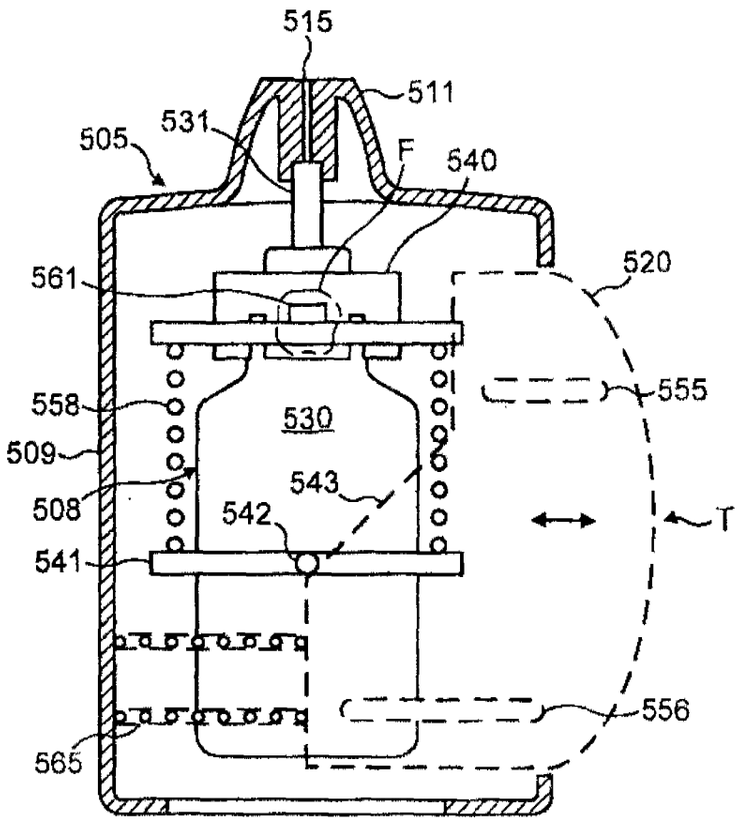

FIG. 22

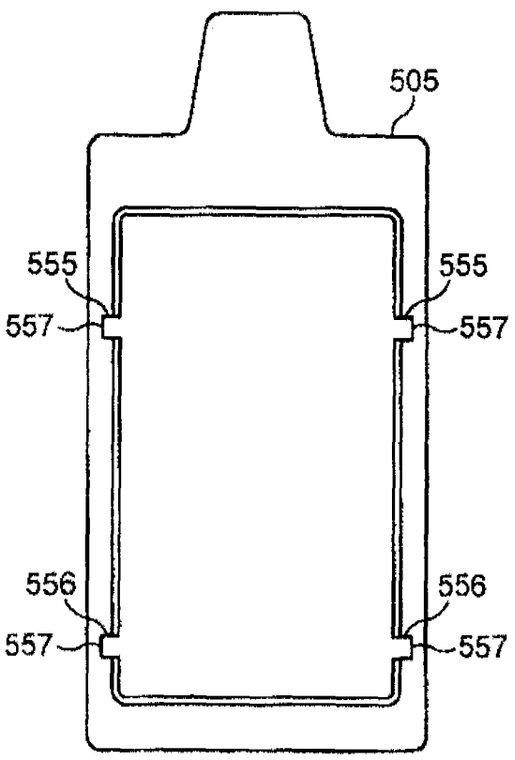

FIG. 23

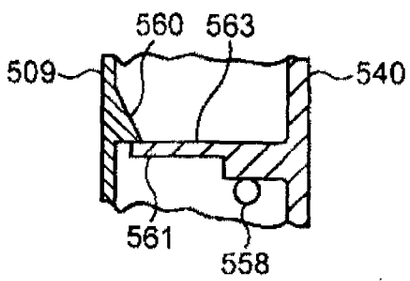

FIG. 24

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
23 September 2004 (23.09.2004)

PCT

(10) International Publication Number
WO 2004/080606 A1

(51) International Patent Classification[7]: B05B 11/00

(21) International Application Number: PCT/GB2004/001002

(22) International Filing Date: 11 March 2004 (11.03.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0305583.7 11 March 2003 (11.03.2003) GB

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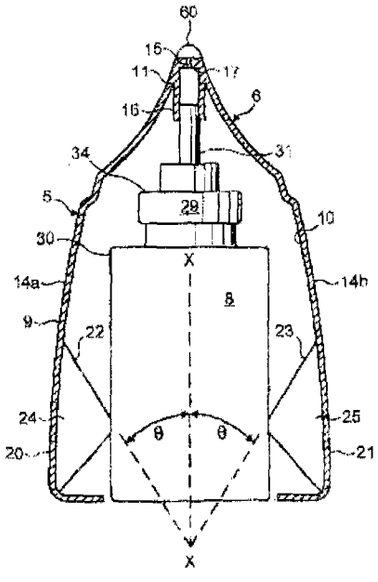
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: A FLUID DISPENSING DEVICE WITH STOPPER



(57) Abstract: A fluid dispensing device (5) is disclosed having a body housing (9) a pump action fluid discharge device (5) having a dispensing nozzle (11). The fluid dispensing device (5) comprises a body defining a cavity and a dispensing nozzle (11) having a dispensing orifice (15). a fluid discharging device (8) housed in the cavity, the fluid discharging device having a hollow casing defining a reservoir for containing a volume of fluid and a plunger slidingly engaged within the hollow casing, the plunger having a tubular portion which extends from a first end of the hollow casing for co-operation with the dispensing nozzle (11) to enable pumped delivery of fluid from the reservoir to the dispensing nozzle (11), wherein the dispensing orifice (15) of the dispensing nozzle (11) is provided with a reversible stopper(60).

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With reference to Figures 24a to 24e there is shown a further embodiment of a fluid dispensing device for spraying a fluid into a body cavity, which is in many respects similar to that previously described.

The fluid dispensing device 1405 comprising a housing 1409, a nozzle 1411 for insertion into a body cavity, a fluid discharge device 1408 moveably housed within the housing 1409, the fluid discharge device 1408 comprising a container 1430 for storing the fluid to be dispensed and a compression pump 1429 having a suction inlet located within the container 1430 and a discharge outlet for transferring fluid from the pump 1429 to the nozzle 1411 and finger operable means 1420 to apply a force to the container 1430 to move the container 1430 towards the nozzle 1411 so as to actuate the pump 1429. The finger operable means is in the form of a lever 1420 pivotally connected to part of the housing 1409 and arranged to act upon the container 1430 so as to urge the container 1430 towards the nozzle 1411 when lever 1420 is squeezed inwardly by a user. The body 1409 is also provided with a window 1450 through which the level of the fluid in the container 1430 can be checked.

The nozzle 1411 is formed as an integral part of the body member 1406 and the body member 1406 is provided with a protective end cap 1407 for protection of the nozzle 1411. The outer surface or a part of the outer surface of the nozzle could be made from a soft-touch plastics material. First and second lugs 1449a, 1449b project from the protective end cap 1407 for receipt within suitably arranged channels provided within the body 1406 such as to allow secure attachment of the end cap 1407 to the body 1406. When so-received, first lug 1449a further interferes with movement of lever 1420 such as to prevent actuation (i.e. to lock movement) of the lever 1420 when the end cap 1407 and lugs 1449a, 1449b are in place (i.e. in the nozzle covered position).

The end cap 1407 also has a protruding stopper 1460 which has a convex, resilient end 1461 form arranged for sealing engagement with the dispensing orifice 1415 of

the nozzle 1411 so as provide an essentially airtight seal to nozzle orifice 1415 to prevent fluid drain back when the stopper 1460 is in place.

The fluid discharge device 1408 has a longitudinal axis Z-Z and the lever 1420, has a guide surface in the form of a beak 1422 arranged for interaction with a drive dog 1492 provided to a collar 1490 fixed around the neck of the container 1430. It will be appreciated that sideways force (i.e. substantially transversely to the longitudinal axis Z-Z of the fluid discharge device 1408) applied to the lever 1420 results in movement of the dog 1492 along the guide surface defined by the beak 1422 thereby resulting in upward movement (i.e. along the longitudinal axis Z-Z) of the fluid discharge device 1408.

In a subtle aspect, the ramp form guide surface 1422 has a variable mechanical ratio arranged such that until a pre-determined force is applied to the lever 1420 no significant force is transferred to the container 1430.

In more detail, a first portion 1423a of the ramp 1422 is inclined at a lesser angle (e.g. approx 20°) to a longitudinal (i.e. vertical, as shown) axis of the fluid discharge device 1408 than is the remaining length 1423b (e.g. angle approx. 45°) of the beak 1422. Therefore when a force is initially applied to the lever 1420 it is applied substantially normal to the longitudinal axis of the fluid discharge device 1408 and virtually no force is converted into a force along the longitudinal axis of the fluid discharge device 1408 and so the static friction between the first portion 1423a of the beak 1422 and the drive dog 1492 is sufficient to maintain the lever 1420, stationary. However, when a pre-determined load is applied to the lever 1420 the static friction is overcome and the dog 1492 is able to start moving along the first portion 1423a of the cooperating beak 1422. When the dog 1492 reaches the end of the first portion 1423a, the change in inclination of the surface with which the dog 1492 is cooperating in combination with the magnitude of the force being applied ensures that the dog 1490 suddenly slides rapidly along the second portion 1423b of the cooperating beak 1422 causing the container 1430 to be moved rapidly towards the nozzle 1411 to actuate the compression pump.

This ensures that the pump is only actuated when sufficient force is being applied to guarantee the production of an effective spray.

To use the fluid dispensing device 1405 of Figures 24a to 24e a user first has to remove the protective cap 1407 thereby unsealing the nozzle orifice 1415 by removing the stopper end 1460 therefrom. The user then grasps the fluid dispensing device 1405 and places a thumb on lever 1420.

Provided that only a light pressure is applied to the lever 1420 no fluid will be discharged and the user is able to manoeuvre the dispensing nozzle 1411 of the fluid dispensing device 1405 into a body orifice such as a nasal cavity into which fluid is required to be dispensed.

If the user then squeezes the levers 1420 inwards with increasing force the threshold force defined by the interaction of dog 1492 with first part of guide surface 1423a of the beak 1422 is overcome resulting in the container 1430 being moved rapidly towards the nozzle 1411 to actuate the pump 1429 and dispense fluid to the dispensing orifice 1415. Upon release of the pressure applied to the lever 1420 the pump is reset by its internal return spring.

A fluid dispensing apparatus for housing a fluid discharging device forming a second aspect of the invention is also disclosed. The fluid dispensing apparatus is in all respects the same as the fluid dispensing device previously described with the exception that it does not contain a fluid discharging device.

The fluid discharging apparatus therefore comprises of a body defining a cavity; and a dispensing nozzle having a dispensing orifice, wherein the dispensing orifice of the dispensing nozzle is provided with a reversibly mounted stopper, wherein, in use, a fluid discharging device (e.g. pump action fluid dispenser) is positioned within the cavity for co-operation the dispensing nozzle.

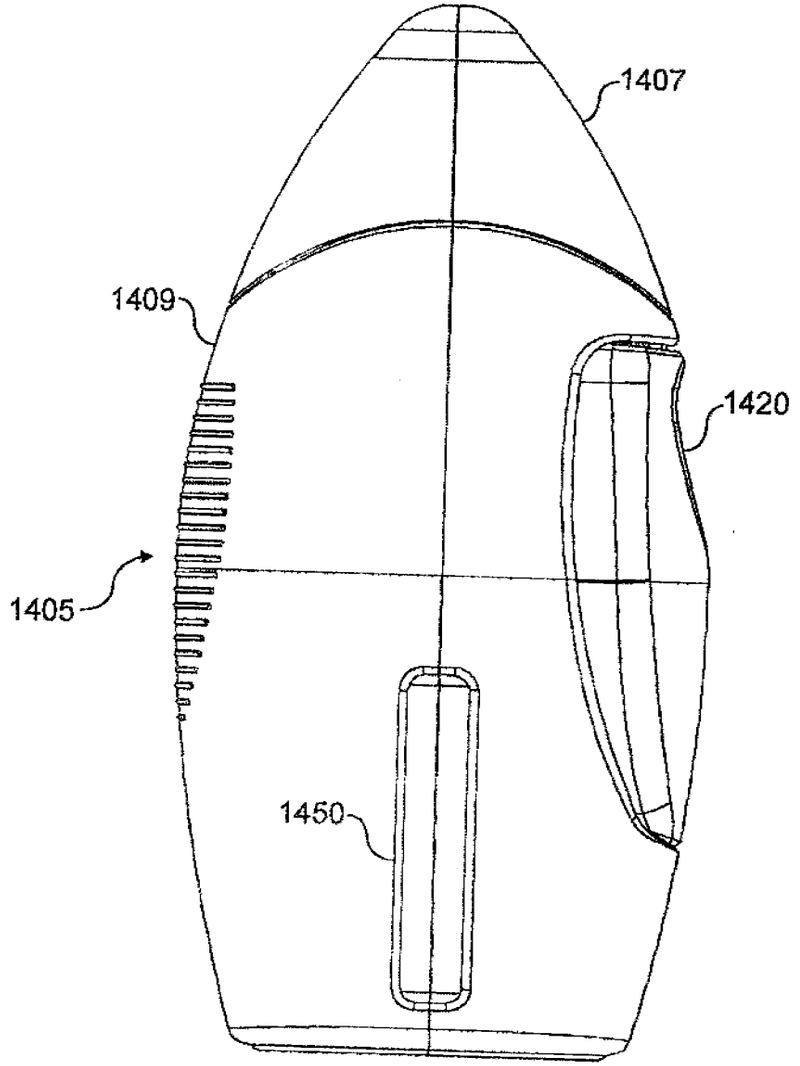

FIG. 24a

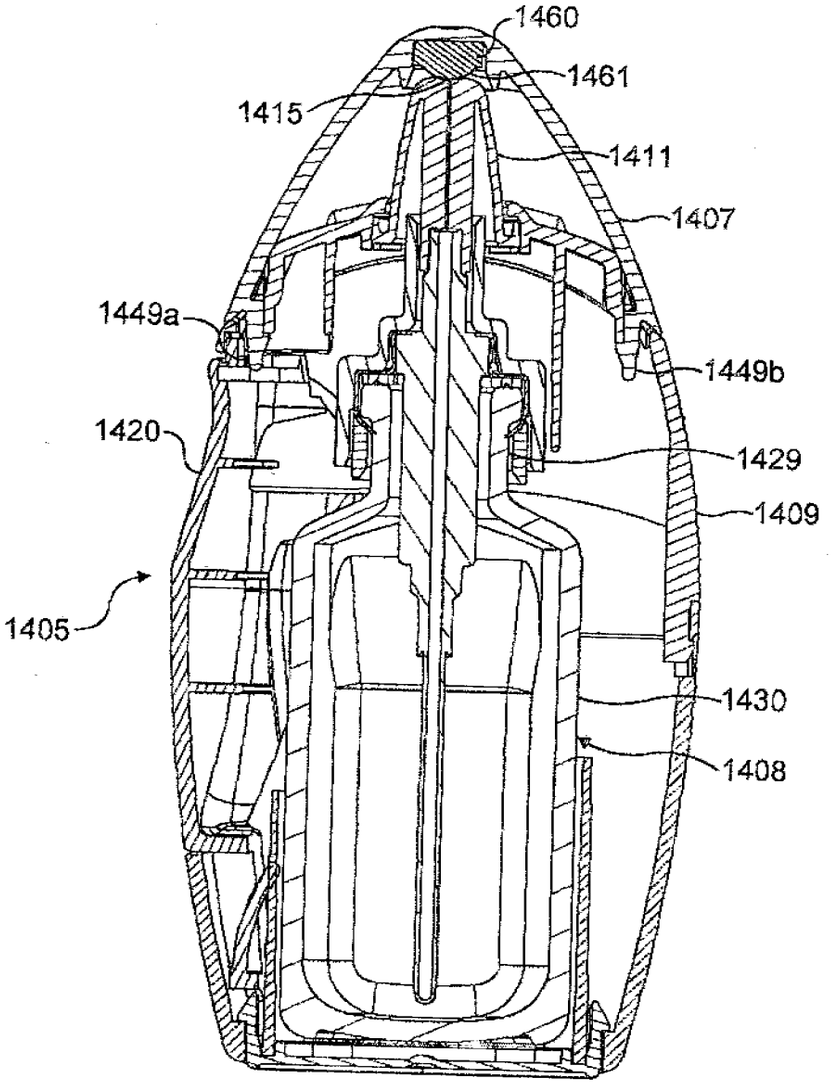

FIG. 24b

FIG. 24c

FIG. 24d

FIG. 24e

US 20050211241A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2005/0211241 A1

Anderson et al. (43) Pub. Date: Sep. 29, 2005

(54) FLUID DISPENSING DEVICE

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(21) Appl. No.: 10/513,200

(22) PCT Filed: May 7, 2003

(86) PCT No.: PCT/EP03/04857

(30) Foreign Application Priority Data

May 9, 2002 (GB) 0210605.2

Publication Classification

(51) Int. Cl.[7] A61M 11/00

(52) U.S. Cl. 128/200.22

(57) ABSTRACT

A fluid dispenser is disclosed having a housing and a pump action fluid discharge device. The pump action fluid discharge device is arranged to be actuated by a pair of opposing levers which are pivotally connected to part of the housing. When the levers are squeezed together the fluid discharge device is urged towards a nozzle causing a single dose of fluid to be dispensed from the nozzle.