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Señc

SUPERINTENDENTE DE INDUSTRIA Y COMERCIO

DIVISION DE NUEVAS CREACIONES

E. S. D.

Re: P1.-**GLAXOSMITHKLINE BIOLOGICALS S.A.**-Solicitud de Patente de Invención en Fase Nacional PCT para **"NUEVO DISPOSITIVO"**.-Clase **B65D 51/00**.-Expediente número **06-009.437.-**

1. Me refiero a mi memorial de 20 de Abril de 2006.

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 **578** de 31 de Julio 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 08-3.593 , 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

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

No. 06-009437- -00002-0000

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Act 536 PETICION Folios 2

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 08 - 3,593
FECHA : ENERO 15 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	4007655	15/01/2008	9,163,000.00

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

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01 SOLICITUDES	95 EXAMEN DE PATENTABILIDAD DE INVEN	420,000.00
		TOTAL : $	420,000.00

SON: CUATROCIENTOS VEINTE MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No._____

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 April 2003 (10.04.2003)

PCT

(10) International Publication Number
WO 03/028785 A2

(51) International Patent Classification[7]: A61M

(21) International Application Number: PCT/US02/31834

(22) International Filing Date: 3 October 2002 (03.10.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/327,128 3 October 2001 (03.10.2001) US

(71) Applicant *(for all designated States except US)*: **MEDICAL INSTILL TECHNOLOGIES, INC.** [US/US]; 419 West Avenue, Stamford, CT 06902 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **PY, Daniel** [FR/US]; 419 West Avenue, Stamford, CT 06902 (US).

(74) Agents: **GIARRATANA, Mark** et al.; Cummings & Lockwood, Granite Square, 700 State Street, P.O. Box 1960, New Haven, CT 06509-1960 (US).

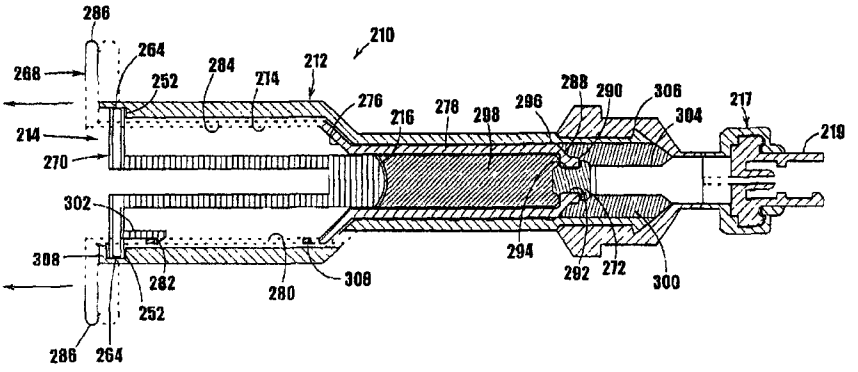
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, 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, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SYRINGE AND RECONSTITUTION SYRINGE



(57) Abstract: A syringe and a reconstitution syringe are provided for the delivery of controlled doses of any of numerous different sterile substances, such as vaccines, medicaments, pharmaceutical preparations, cosmetics, and food products. A plunger of the syringe defines a resealable stopper frictionally and slidably received within a hollow syringe body for dispensing the medicament or other substance through a dispensing tip of the syringe upon movement of the plunger. The resealable stopper defines a heat-sealable portion to allow the stopper to be penetrated by a needle or other filling device to fill the syringe with a medicament or other substance, and in turn allow the hole remaining upon withdrawal of the needle to be heat sealed by transmission of laser energy thereon. The plunger assembly further defines a plurality of cam-like members that each engage and cooperate with a respective helical path of steps formed on the inner wall of the syringe body to provide stepwise movement of the plunger and, in turn, precise metering of the substance dispensed therefrom. A reconstitution syringe defines within a syringe body plural compartments, wherein each compartment stores a respective component of a multi-component medicament or other preparation. An elastomeric plug is coupled to the plunger and connected between the two compartments to prevent intermixing of the components. Upon moving the plunger, the plug is released to thereby place the compartments in fluid communication with each other, and to facilitate intermixing of the components upon shaking the syringe.

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substances, such as vaccines, and other medicaments and pharmaceutical preparations, whereby the components can be mixed immediately prior to use and metered doses of such substances can be dispensed from the syringe.

Summary of the Invention

One aspect of the present invention is directed to a syringe that may be used for the delivery of any of numerous different sterile substances, such as vaccines, medicaments, pharmaceutical preparations, cosmetics, and food products. In accordance with one aspect of the present invention, the syringe comprises a syringe body defining therein a chamber for receiving a predetermined substance to be dispensed from the syringe. A plunger of the syringe is slidably received within the syringe body for dispensing the substance upon movement therein. The plunger includes a resealable stopper penetrable by a needle or like filling member for introducing the predetermined substance through the stopper and into the chamber of the syringe body. The penetrable region of the resealable stopper is fusible in response to the application of thermal energy thereto for hermetically sealing the penetrable region upon removing the needle or like filling member therefrom.

In one embodiment of the present invention, the resealable stopper includes a base portion formed of a first material compatible with the predetermined substance contained within the syringe. The base portion defines a peripheral surface for slidably contacting an inner wall of the syringe body and a substance-exposed surface defining the portion of the stopper exposed to the predetermined substance contained within the syringe. A resealable portion overlies the base portion, and both the resealable portion and base portion are penetrable by the needle or like filling member for introducing the predetermined substance through the stopper and into the syringe body. The penetrable region of the base portion is substantially infusible in response to the application of thermal energy thereto, and the penetrable region of the resealable portion is fusible in response to the application of thermal energy thereto for hermetically sealing the penetrable region upon removing the needle or like filling member therefrom.

In another embodiment of the present invention, the penetrable region of the resealable stopper is heat resealable to hermetically seal the needle aperture by applying laser radiation at a predetermined wavelength and power thereto. The resealable stopper comprises a thermoplastic body defining (i) a predetermined wall thickness in an axial direction thereof, (ii)

a predetermined color and opacity that substantially absorbs the laser radiation at the predetermined wavelength and substantially prevents the passage of the radiation through the predetermined wall thickness thereof, and (iii) a predetermined color and opacity that causes the laser radiation at the predetermined wavelength and power to hermetically seal a needle aperture formed in the needle penetration region thereof in a predetermined time period of less than approximately 2 seconds and substantially without burning the needle penetration region. In a currently preferred embodiment of the present invention, the needle penetration region is formed of a thermoplastic blend of a first material consisting essentially of a styrene block copolymer and a second material consisting essentially of an olefin. Preferably, the first and second materials are blended within a range of about 50 : 50 to about 95 : 5 by weight.

In one embodiment of the present invention, the syringe includes means for controlling the travel of the plunger assembly to deliver a pre-determined dose of the substance contained within the syringe. The means for controlling the travel of the plunger assembly may include, for example, cam-like members formed on the upper guide portion of the plunger assembly which engage and cooperate with steps formed on the inner wall of the upper chamber of the syringe body. As the plunger assembly is rotated, the cam-like members travel along the steps to create step-wise movement of the plunger assembly into the syringe. The step-wise movement results in delivery of a precise, pre-determined quantity of the substance contained in the syringe with each step-wise or incremental movement of the plunger.

Another aspect of the present invention is directed to a syringe provided in the form of a reconstitution syringe that includes multiple compartments for storage of any of numerous different multi-component substances for forming vaccines, medicaments, or other pharmaceutical preparations. In a currently preferred embodiment of the present invention, the syringe body includes an upper chamber, a transition portion, and a lower chamber that contains the compartments for storage of the multi-component substances. The plunger assembly preferably includes an outer frame which extends to a point within the lower chamber of the syringe body. At the end of the outer frame within the lower chamber of the syringe body, an elastomeric plug is held in an opening in the outer frame. A closure member is contained within the outer frame of the plunger assembly and extends from the top of the syringe body to approximately the top of the lower chamber of the syringe body. The closure member includes a base that seals the lower portion of the outer frame. In a currently preferred embodiment of the reconstitution syringe of the present invention, the top of the closure

Because the syringe is hermetically sealed after it is filled with the medicament or other preparation, the syringe may be stored for extended periods of time without spoilage due to ingress of air and without the addition of preservatives to prevent such spoilage.

In the currently preferred embodiments of the present invention, at least a portion of the resealable stopper is formed of a thermoplastic material defining a needle penetration region that is pierceable with a needle to form a needle aperture therethrough, and is heat resealable to hermetically seal the needle aperture by applying laser radiation at a predetermined wavelength and power thereto. In an alternative embodiment of the present invention, the entire body of the stopper is formed of the thermoplastic material. In another embodiment of the invention as described above, an overlying portion of the stopper if formed of the fusible thermoplastic material, and an underlying portion of the stopper is formed of an infusible material, such as vulcanized rubber. Preferably, each thermoplastic portion or body defines (i) a predetermined wall thickness in an axial direction thereof, (ii) a predetermined color and opacity that substantially absorbs the laser radiation at the predetermined wavelength and substantially prevents the passage of the radiation through the predetermined wall thickness thereof, and (iii) a predetermined color and opacity that causes the laser radiation at the predetermined wavelength and power to hermetically seal the needle aperture formed in the needle penetration region thereof in a predetermined time period and substantially without burning the needle penetration region (i.e., without creating an irreversible change in molecular structure or chemical properties of the material). In a currently preferred embodiment, the predetermined time period is approximately 2 seconds, is preferably less than or equal to about 1.5 seconds, and most preferably is less than or equal to about 1 second. Also in a currently preferred embodiment, the predetermined wavelength of the laser radiation is about 980 nm, and the predetermined power of each laser is preferably less than about 30 Watts, and most preferably less than or equal to about 10 Watts, or within the range of about 8 to about 10 Watts. Also in a currently preferred embodiment, the predetermined color of the material is gray, and the predetermined opacity is defined by a dark gray colorant added to the stopper material in an amount within the range of about 0.3% to about 0.6% by weight.

In addition, the thermoplastic material may be a blend of a first material that is preferably a styrene block copolymer, such as the materials sold under either the trademarks KRATON or DYNAFLEX, and a second material that is preferably an olefin, such as the materials sold under either the trademarks ENGAGE or EXACT. In a currently preferred

distal end 288 of the outer frame is shaped to fit into a complementary shaped annular groove 294 formed on the elastomeric plug 272 to hold the elastomeric plug in place and form a seal between the distal end of the outer frame and the plug. The elastomeric plug 272 may be made of any appropriate material known to those skilled in the art for use in storage of medicaments or other substances to be contained within the syringe, such as, for example, vulcanized rubber or any of numerous different types of polymeric materials.

An annular protuberance 296 is provided on the outer frame 268 at the base of the frustoconical portion 290. The annular protuberance 296 fits frictionally within the lower chamber 218 of the syringe body 212 to form a seal between the outer frame of the plunger and the syringe body. As can be seen in Fig. 9, the frustoconical portion 290 of the distal end 288, the elastomeric plug 272, and the annular protuberance 296 define a boundary within the lower chamber of the syringe body and divide the lower chamber of the syringe body into two compartments 298 and 300.

The closure member 270 is slidingly received within the outer frame 268 of the plunger. As can be seen, the closure member is generally cylindrical, and extends from the top of the upper chamber 254 of the syringe body to a pre-determined location within the lower portion of the outer frame 268. The predetermined point is at a point corresponding to the top of the lower chamber 218 of the syringe body. At the end of the closure member 270 within the lower chamber 218 of the syringe is a resealable stopper 216, which hermetically seals the top of the first compartment 298 of the syringe. In this embodiment of the invention, the resealable stopper 216 forms a hermetic seal with the inner surface of the outer frame 268 of the plunger assembly 214.

At the end of the closure member 268 opposite the fusible stopper 216, the closure member defines two opposed cam-like members 264 that extend perpendicularly from the axial wall of the closure member. The cam-like members 264 cooperate with the steps 252 formed on the inner wall of the upper chamber 254 of the syringe body to provide step-wise movement of the plunger assembly during dispensing of the multi-component medicament or other preparation. In the illustrated storage mode of the reconstitution syringe, one cam-like member 264 is engaged with the uppermost step 252 formed on the inner wall of the syringe body. On at least one of the cam-like members, an arm 302 extends perpendicularly from the cam-like member within the inner wall of the outer frame 268 of the plunger. At the end of the arm 302,

What Is Claimed Is:

1. A syringe comprising:

a syringe body defining therein a chamber for receiving a predetermined substance to be dispensed from the syringe; and

a plunger slidably received within the syringe body for dispensing the substance upon movement therein, wherein the plunger includes a resealable stopper penetrable by a needle or like filling member for introducing the predetermined substance through the stopper and into the chamber of the syringe body, and wherein a penetrable region of the resealable stopper is fusible in response to the application of thermal energy thereto for hermetically sealing the penetrable region upon removing the needle or like filling member therefrom.

2. A syringe as defined in claim 1, wherein the resealable stopper includes:

a base portion formed of a first material compatible with the predetermined substance contained within the syringe, the base portion defining a peripheral surface for slidably contacting an inner wall of the syringe body and a substance-exposed surface defining the portion of the stopper exposed to the predetermined substance contained within the syringe; and

a resealable portion overlying the base portion, the resealable portion and base portion being penetrable by a needle or like filling member for introducing the predetermined substance through the stopper and into the syringe body, wherein the penetrable region of the base portion is substantially infusible in response to the application of thermal energy thereto, and the penetrable region of the resealable portion is fusible in response to the application of thermal energy thereto for hermetically sealing the penetrable region upon removing the needle or like filling member therefrom.

3. A syringe as defined in claim 1, wherein the resealable portion of the stopper is formed of at least one of a thermoplastic and elastomeric material.

4. A syringe as defined in claim 2, wherein the base portion of the stopper is formed of vulcanized rubber.

5. A syringe as defined in claim 2, wherein the base portion of the stopper defines an interior cavity, and the resealable portion is received within the interior cavity of the base portion.

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

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International Bureau

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PCT

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(21) International Application Number: PCT/US01/40134

(22) International Filing Date: 16 February 2001 (16.02.2001)

(25) Filing Language: English

(26) Publication Language: English

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09/781,846 12 February 2001 (12.02.2001) US

(71) Applicant and
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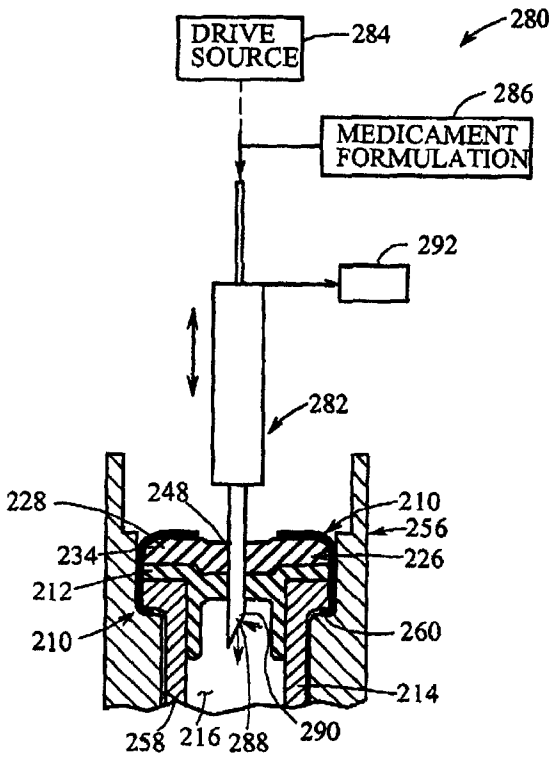
(74) Agents: GIARRATANA, Mark, D. et al.; Cummings & Lockwood, Granite Square, 700 State Sreet, P.O. Box 1960, New Haven, CT 06509-1960 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, 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, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, 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, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: MEDICAMENT VIAL HAVING A HEAT-SEALABLE CAP, AND APPARATUS AND METHOD FOR FILLING THE VIAL



(57) Abstract: A resealable cap (110, 210) for a medicament vial (114, 214) has a base portion (112, 212) formed of vulcanized rubber or like material known for providing a stable environment for the medicament contained within the vial, and a resealable portion (126, 226) overlying the base portion. The resealable portion (126, 226) is made of low-density polyethylene or like material, and can be punctured by a needle or like injection member (140, 282) for dispensing medicament into the vial (114, 214). Prior to filling, the cap (110, 210) is assembled to the vial (114, 214) and the cap/vial assembly is sterilized. Then, a needle (140, 282) is inserted through the cap (110, 210) and medicament is introduced through the needle and into the vial. Upon withdrawal of the needle (140, 282), the penetrated region of the cap (248) is fused by laser (276) or direct heat sealing (264) to hermetically seal the needle hole (294) in the cap.

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laser or other suitable radiation source 276 optically coupled to a scanning mirror 278 mounted over the vial/cap assembly. Although not shown in FIG. 10, the vials are preferably mounted within the same type of support as shown in FIGS. 9A through 9C in order to allow the resealable caps to be rapidly cauterized in succession prior to filling each vial with medicament, as described further below.

In the currently preferred embodiment of the present invention, the laser 276 is a commercially available CO_2 or YAG laser. The CO_2 laser operates at a wavelength of approximately 10.6 μm. At this wavelength, absorption of the laser energy is governed by the electrical conductivity of the material. Therefore, an insulating material, such as the elastomeric material of the resealable member 226, absorbs and converts most of the incident energy into thermal energy to cauterize the receiving surface 248. The YAG laser operates at wavelength of approximately 1.06 μm. At this frequency, absorption is governed by the lattice atoms. Thus, a clear or transparent polymer with little ionization would be permeable to the laser beam. Accordingly, when employing a YAG laser, it is desirable to add a colorant to the elastomeric material of the resealable member in a manner known to those of ordinary skill in the pertinent art in order to enhance its absorption of the laser energy. A significant advantage of the YAG laser is that the superficial layer of the penetrable region of the resealable member, and any germs, bacteria or other contaminants thereon, are transformed into plasma to rapidly and thoroughly sterilize the effected surface. If necessary, a UV-filtration coating may be applied to the surfaces of the enclosure for the apparatus of the invention to prevent the operators from receiving any unnecessary UV exposure.

What Is Claimed Is:

1. A resealable cap for sealing a predetermined medicament within a vial, comprising:

a base portion formed of a first material compatible with the predetermined medicament within the vial, the base portion defining a peripheral surface for slidably contacting an open end of the vial and a medicament-exposed surface defining the portion of the cap exposed to the predetermined medicament contained within the vial; and

a resealable portion overlying the base portion, the resealable portion and base portion being penetrable by a needle or like filling member for introducing the predetermined medicament through the cap and into the vial, wherein the penetrable region of the base portion is substantially infusible in response to the application of thermal energy thereto, and the penetrable region of the resealable portion is fusible in response to the application of thermal energy thereto for hermetically sealing the penetrable region upon removing the needle or like filling member therefrom.

2. A resealable cap as defined in claim 1, wherein the resealable portion is formed of at least one of a thermoplastic and elastomeric material.

3. A resealable cap as defined in claim 1, wherein the base portion if formed of vulcanized rubber.

4. A resealable cap as defined in claim 1, in further combination with a locking member engageable with the cap and vial for securing the cap to the vial.

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES

2020
Bogotá, D.C.,

Abogado:

ALICIA LLOREDA RICAURTE

ASUNTO:	Radicación No.	06 00 9437
	Trámite	002
	Evento	001
	Actuación	430
	Oficio	6837
	Folios	013

Como resultado del Examen de Fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se comunica:

1. **Documentos estudiados:**

Descripción:	Folios 39 a 49 como se radicó inicialmente.
Reivindicaciones:	Folios 50 a 54 como se radicó inicialmente.
Dibujos:	Folios 55 a 56 como se radicó inicialmente.
Prioridad:	GB 0318242.5 (2003-08-04)

2. **Objeto de la Invención**

Titulo de la invención: "Nuevo Dispositivo"

Problema Técnico Planteado: "Los materiales elastoméricos conocidos que se utilian en le sellado de viales de productos farmacéuticos producen gases cuando son calentados por rayos láser y algunos permiten la difusión del rayo láser, factores que alteran la calidad del producto farmacéutico envasado"

Solución: "Proporcionar un material elastomérico que presente un coeficiente de absorción de luz adecuado para evitar la alteración del producto envasado"

IPC: B65D 51/00

3. Análisis de la Solicitud de Patente

Titulo:

El título de la invención tal y como se ha presentado no es conciso, claro ni es representativo de la invención. Se requiere al solicitante para que presente una modificación al título actual.

Reivindicaciones:

En la reivindicación 5 se caracteriza un material elastomérico cuya base se selecciona entre los materiales Evoprene™, Cawiton™ y C-flex™. Al respecto se recuerda al solicitante que estos compuestos deben nombrarse de acuerdo a la nomenclatura IUPAC y no mediante nombres comerciales.

4. Determinación del Estado de la Técnica

El Estado de la Técnica se determinó con base en la fecha de presentación 2003/08/03 y se encontraron los siguientes documentos que anticipan el objeto de esta solicitud:

Item	Documento	Título	Fecha de Publicación
D1	WO 03/028785	"Syringe and reconstitution siringe"	03-10-2001
D2	WO 02/064439	"Medical vial having a heat-sealable cap, and apparatus and method for filling the vial"	12-02-2001

5. Análisis de Patentabilidad (Art 14 D486)

Novedad (Art 16 D486)

Análisis de las diferencias con respecto al estado de la técnica:

Características esenciales de la Solicitud	D1	D2	D3
	WO 03/028785	WO 02/064439	WO 02/064439
Material elastomérico	SI	SI	SI
Coeficiente de absorción para luz de 0.5-2.5 mm^{-1}	SI	NO	NO

La reivindicación 1 de la presente solicitud hace referencia a un material elastomérico con un coeficiente de absorción para luz de 0.5-2.5 mm_{-1}. D1 hace referencia a un cuerpo termoplástico de color negro y opacidad tal que proteja el contenido del envase. (Folios 67 y 68)

La reivindicación 2 se refiere a una mezcla del material elastomérico con un colorante opaco de manera que permita obtener un coeficiente de

absorción que esté incluido dentro del rango de la reivindicación 1. La materia enseñada en D1 incluye esta característica. (Folio 68)

La reivindicación 4 habla acerca de la naturaleza del copolímero empleado, y de acuerdo a D1 y D2, ya se sugería para lograr este efecto técnico emplear bloques de estireno para dicha la obtención de dichos elementos. (Folio 68)

La reivindicación 6 se refiere a un material polímero mezclado con un pigmento o mezcla de pigmentos con un portador, características que fueron nombradas con anterioridad en D1, así como también en D2. (Folio 69, línea 10-20) (Folio 73, línea 15)

La reivindicación 7 y 8 también referente al color habla de color gris o verde grisáceo, materia que también fue descrita en D1. (Folio 69, líneas 25 a 30)

Las reivindicaciones 9 a 14 describen una composición de material termoplástico, portador y colorante, que para el experto en la materia era fácil de obtener teniendo en cuenta D1 y D2.

De las reivindicaciones 15 a la 18, la solicitud está relacionada con los coeficientes de difusión del material, materia que como ya se había descrito anteriormente estaba descrita en D1.

La reivindicaciones de la 19 a la 22 están relacionada con un cierre para envases farmacéuticos, cuyas características habían sido enseñadas por la D1 y D2.

Las reivindicaciones de la 23 a la 28 presentan un proceso mediante el cual el medicamento estéril puede ser introducido en los viales de la descripción y cómo se sella el hoyo que la aguja inyectora deja en el material elastomérico por medio de calor, con un rayo láser como fuente energética, dicho procedimiento había sido descrito ya por D1 y D2.

Por lo tanto, se concluye que esta solicitud carece de novedad.

6. Conclusión

Los requisitos de Patentabilidad de la presente Solicitud se encuentran afectados así:

N°	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	WO 03/028785	1-28	Novedad
D2	WO 02/064439	1-28	Novedad

78 79

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 60 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 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
Jefe de División de Nuevas Creaciones

El anterior requerimiento fue notificado por fijación en lista, de fecha 12 JUN. 2009

CONCEPTO TECNICO NUMERO: 1899	EXAMINADOR TÉCNICO Código:202092