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Act. 329 CTOINFORMACION Folios: 21

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

REF: Expediente 07 067.094

TITULO SOLICITADO: AYUDA PARA DISPENSADO DE PREPARACIONES
FARMACEUTICAS 0 COSMETICAS SEMISOLIDAS
ENVASADAS EN UN ENVASE DE TWO SACHE.

PUBLICACION: Gaceta 604 de 2910512009, NO de publicación 282.

PRIORIDAD: US 60/700.519 de 19/07/2005.

SOLICITANTE: BAYER SCHERING PHARMA
AKTIENGESELLSCHAFT.

APODERADO: J. IAN RAISBECK.

TRAMITE: SUSTENTACION DE OPOSICION

JOSÉ LUIS REYES VILLAMIZAR, mayor de edad, identificado como aparece at pie de ml firma, abogado en ejercicio, titular de la tarjeta profesional nümero 44655 del Consejo Superior de la Judicatura, obrando en calidad de apoderado de la sociedad LABORATORIO FRANCO-COLOMBIANO, LAFRANCOL S.A., dentro del trÆmitede la referenda, en ejercicio de to dispuesto por el articulo 42 inciso 20 de la DecisiOn 486 de 2000, por medio del presente escrito, procedo a sustentar la oposiciOn presentada oportunamente ante ese Despacho, en los siguientes tØrminos:

I. COMPLEMENTO DE INFORMACION

Comedidamente me permito presentar los argumentos que demuestran que la solicitud de la referenda incumple los requisitos de patentabilidad establecidos por

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los artculos 14, 16 y 18 de la Decision 486 de 2000, y que por ello no merece recibir el beneficio patentario, veamos:

En primer lugar, es importante resaltar, que tratÆndose la invención de un dispositivo de "ayuda para la dispensaciOn de formulaciones farmacŁuticas o cosmØticas" o "mØtodo para expulsar preparaciones farmacØuticas", reivindicar el
USO de dicho dispositivo para la "ayuda en la expulsiOn de la formulación farmacØutica" en (a administraciOn de compuestos activos de carÆcter hormonal,
tales como los gestÆgenos, losestrOgenos yio los andrógenos mencionados en (a solicitud en cuestión, especificamente en las reivindicaciones 2, 3 y 6, equivaidrIa
a restringir Per se el acto de la administraciOri de dichos principios activos cuyas

formulaciones farmacØuticas se encuentren envasadas en envases tipo sachØ. En It
efecto, a la luz de la normativa subregional resulta inaceptable pretender atribuirse exciusividad sobre un "USO", categoria no incluida en el concepto de "Productos o Procedimientos" que establece el articulo 14 de la DecisiOn 486 de 2000. Sin perjuicio de lo anterior me permito hacer notar que aün si los USOS o mØtodos terapØuticos fueran permitidos en nuestro medlo, Østos deberIan cumplir necesariamente con los requisitos materiales de patentabilidad, novedad, nivel Inventivo y Aplicación Industrial, en donde es evidente que el ültimo requisito resulta de imposible cumplimiento, en tanto la reproducción industrial del USO de este dispositivo para administrar formulaciones farmacØuticas envasadas en envases tipo sachØ, para tratar ciertas patologlas, corresponden al Æmbito de la terapØutica y no al de las actividades industriales.

Por si no fuesen suficientes los argumentos anteriores, cabe anotar tambiØn que en el estado de la tØcnica ya se describlan con anterioridad formulaciones farmacŁuticas con los mismos compuestos hormonales, envasadas en envases tipo sach61’2, Utiles en el control de la fertilidad o en terapias de reemplazo hormonal, 10 que afectarla la novedad de las reivindicaciones I y 4 en donde se hace menciOn explicita de este tipo de envase, puesto que dicho dispositivo para "una ayuda para el dispensado" involucra directamente su aplicabilidad sobre preparaciones farmacØuticas semisOlidas envasadas en un envase tipo sachØ.

Patente americana US 2001100336870 publicada el 25 de Octubre de 2001.

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En otro aspecto, y esta vez refiriØndonos directamente a la falta de nivel inventivo
del dispositivo y a sus caracterIsticas de diseæoque permiten "Un mØtodo para expulsar preparaciones farmacØuticas o cosmØticas semisolidas de un envase tipo sachØ", existen documentos que evidencian con anterioridad el mismo tipo de dispositivos que reivindican la misma utilidad y cuyos principios de diseæoestân estrechamente relacionados a los del dispositivo descrito en la solicitud colombiana en trâmite, veamos:

La publicación internacional WO 01/17892 publicada el 15 de Marzo de 2001 y titulada "DISPENSING DEVICE FOR FOOD PRODUCT" revela:

The present invention relates to the field of dispensing
viscous and semi -viscous food products that do not flow
sufficiently well by simple gravity force. The invention belongs to dispensers adapted for receiving a removable supple baqurtuol-. containing food such as sauce, condiment, cream and the like.

La patente americana US 5490613 publicada el 13 de febrero de 1996 y titulada "VISCOUS FLUID DISPENSER" revela:

2 Patente americana US 2005/0020554 publicada & 27 de enero dc 2005.

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The present invention relates to dispensers of a type adapted for dispensing viscous fluids and more particularly to such dispensers where the fluid is contained within and dispensed from a flexible or collapsible bag forming a portion of the dispenser.

Como se puede apreciar, el principlo de los dispositivos de estas dos anterioridades coincide con las caracteristicas del diseno del dispositivo de la solicitud colombiana en cuestiOn, principalmente en que todos estos rebasan en la presiOn ejercida por unos rodillos móviles al interior del artefacto, la cual permite verter al exterior el contenido del envase tipo sachØ. Si bien es cierto que en estas anterioridades no se hace mención explicita de formulaciones farmacØuticas, cualquier persona medianamente versada en la materia, podrIa inferir la utilidad de Østos dispositivos y su mecanismo de rodillos, inicialmente utilizados en composiciones alimenticias viscosas, para la administración de formulaciones farmacØuticas o cosmØticas con las mismas propiedades reolOgicas.

En conclusiOn la solicitud colombiana en trØmite carece de los requisitos fundamentales para otorgarsele el privilegio de patente de invenciOn, en primer lugar, porque reivindica el uso de un dispositivo para la administraciOn de formulaciones farmacØuticas, lo cual no es pertinente a las actividades industriales sine a las actividades mØdicas y en segundo lugar porque carece tanto de

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novedad como de nivel inventivo, al reivindicar formulaciones farmacOuUcas cuyos componentes y envases (tipo sachØ) se encuentran descritos con anterioridad en
el estado de la tØcnica, asi como las caracteristicas y principios de diseæo del dispositivo que permite la administración de las mismas.

Por todo lo anterior, ruego se analicen los argumentos expuestos con el rigor y detenimiento habituales, y que en consecuencia el Despacho decrete, ademÆsde la negaciOn de la solicitud en comento, el archivo del expediente que lo contiene.

Ill. ANEXOS

 Portadas y capItulos reivindicatorios de patente americana US 2001/00336870 publicada el 25 de Octubre de 2001, la patente americana US 2005/0020554 publicada el 27 de enero de 2005, La publicación internaciorial WO 01/17892 publicada el 15 de Marzo de 2001 y titulada "DISPENSING DEVICE FOR FOOD PRODUCT" y La patente americana US 5490613 publicada el 13 de febrero de 1996 y titulada "VISCOUS FLUID DISPENSER".

Seæor Supntennte,

JOSE LUIS REYES VILLAMIZAR

C.C. 79.152.473 de Usaquen
T.P. 44655 del C. S de la J.

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US 20010033870A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2001/0033870 Al
Luo et al. (43) Pub. Date: Oct. 25, 2001

(54) TRANSDERMAL ADMINISTRATION OF
STEROID DRUGS USING
HYDROXIDE-RELEASING AGENTS AS
PERMEATION ENHANCERS

(76) Inventors: Eric C. Luo, Piano, TX (US);
Tsung-Min Hsu, San Diego, CA (US)

Correspondence Address:
REED & ASSOCIATES
800 MENLO AVENUE
SUITE 210

MENLO PARK, CA 94025 (US)

(21) Appi. No.: 09/737,833

(22) Filed: Dec. 14, 2000

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/569,889,
filed on May 11, 2000, which is a continuation-in-part
of application No. 09/465,098, filed on Dec. 16, 1999.

Publication Classification

(S I) Int. C1.7..........................A6IK 33/08; A6IK 31/56

(52) U.S. Cl............................424/688; 514/171; 424/600

(57) ABSTRACT

A method is provided for increasing the permeability of skin or mucosal tissue to transdermnally administered steroid drugs. The method involves use of a specified amount of a hydroxide-releasing agent, the amount optimized to increase the flux ofthe drug through a body surface while minimizing the likelihood of skin damage, irritation or sensitization. Formulations and drug delivery systems for co-administer-ing a hydroxide-releasing agent with a steroid drug are provided as well. Optimally, the steroid drugs are a combi-nation of an estrogen and progestin that maybe administered in female hormone replacement therapy, to provide female contraception, and the like.

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US 2001/0033870 Al

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TABLE 12

Weight and Weight Verccnt of Each Component (Eased on Total Solution Weight)
for Foer t%tradiol Trarrorterrrrnl Systems

Est-PM1 Est-PM2 Est-PM3 Est-PM4

F.stradiol 003 g (0.5%) 0.03 g (0.4%) 0.03 g (0.4%) 0.03 g (0.4%)
MgO 0 0.1.1 g (1.61/c) 0.3 g (4.1%) 0.45 g (6.1%)
DI water 0.5 g (8.0%) 1.2 g (16.9%) 1.2 g (16.51/,) 1.2 g (:16.2%)
Methyl alcohol 0.5 g (8.11%) 0.5 g (7.1%) 0.5 g (6.9%) 11.5 g (6.7%)
FIB adhesive 4 g (63.7%) 4 g (56.4%) 4 g (55.0%) 4 g (53.8%)
(30% solid)
Propylene glycol 0.25 g (4.0%) 0.25 g (3.5%) 0.25 g (3.4%) 0.25 g (3.4%)
tleptane 1 g (15.911b) 1 g (14.117c) 1 g (13.7%) 1 g (13.5%)

[0118]

TABLE 13

Weight and Theoretical Weight Percent of Each Component it the Dried Itilm for
Your Estradiol Tranaderirral Systems

Eat-PM1 Eat-PM2 Est-PM3 Eat-PM4

Estradiol 0.03 g (0.2%) 0.03 g (1.9th 0.03 g (1.7%) 0.03 g (1.6%)

SIgO 0 0.11 g (6.95-) 0.3 g (16.9%) 0.45 8(23.3%) S (’10 adhesive 1.2 g (61.1%) 1.2 g (75.5h 1.2 g (67.4%) 1.2 g (62.2%)

Propylene glycol 0.25 g (16.9%) 0.25 g (157 0.25 g (14.0%) 0.25 g (13.0%)

[(1119]

TABLE 14

Currrnlative Amount of Estradiol Across Human Cadaver Skin for
Estradiol T,aosdermal Syaterrre (erejcm2l

Eal-PMI Est-I’M2 %L-PM3 EotPM4

4.75 hours 0.08 0.09 1105 0.02
1.5.75 hours 0.21 0.31 0.19 0.13
19.75 hours 0.26 0.41 0.26 0.19
23.75 hotrta 0.32 11.53 0.36 0.27

[0120]

TABLE 15

Excess MgO Concentration and pI-I of Four Estradiol
Transdermal System

Est-PM1 Est-PM2 50-PM3 Est-l’M4

Is Excess MgO 0% 6.9% 16.9% 23.3%

Concentration
PH 7.48 8.95 9.66 10.28

[0121] The cumulative amount of estradiol that permeated
across the human cadaver skin at 24 hours for Est-PM2 (0.53
mg/cm2, Table 14) with a calculated excess MgO concen-
tration of 6.9% was slightly higher than that from the formulation without K0PO4 (Est-PM1, 0.32 mg/cm’) This result indicated that MgO enhances the permeation of estra-
diol.

[0122] The cumulative amount of estradiol across human cadaver skin at 24 hours decreased from 0.53 to 0.27 mg/crn when the excess MgO concentration in the dried

Oct. 25, 2001

patch was increased from 6.9% to 23.3% (Tables 14 and 15). This behavior may be because the high concentration of MgO made the adhesive matrix more hydrophobic and the amount of MgO that could be dissolved by the small amount of water 00 the top of the skin was reduced.

[0123] The pit of the estradiol patch measured using the procedures listed above increased from 7.48 to 10.28 when the MgO concentration in the dried patch was increased from 0% to 23.3%.

We claim:

1. A method for enhancing the flux of a steroid drug through a body surface, comprising administering the Ste-roid drug to a localized region of a human patient’s body surface in combination with a hydroxide-releasing agent applied to the body surface in a predetermined amount effective to enhance the flux of the drug through the local-ized region of the body surface without causing damage
thereto.

2. The method of claim 1, wherein the body surface is skin.

3. The method of claim 1, wherein the body surface is mitcosat tissue.

4. A method for transdcrmally administering a combina-tion of steroid drugs to a female individual, comprising administering a progestin and an estrogen to a localized region of a the individual’s body surface in combination with a hydroxide -releasing agent applied In the body surface in a predetermined amount effective to enhance the flux of the drug through the localized region of the body surface without causing damage thereto.
5. The method of claim 4, wherein the progestin is selected from the group consisting of acetoxypregnenoinne, allylestreoni, anagesione acetate, chiormadinone acetate, cyproterone, cyproterone acetate, desogesi.rcl, diiiydrogcsi-

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US 2001/0033870 Al

crone, dime thisterotie, ethisterone, ethynodiol diacetate, flurogestone acetate, gestadene, hydroxyprogesterone, hydroxyprogesterone acetate, hydroxyprogesterone caproate, hydroxyniethylprogcsterone, hydroxymethyl-progesterone acetate, 3-ketodesogestrel, levonorgestrcl, lynestrenol, medrogestonc, rnedroxyprogesterotie acetate, megestrol, megestrol acetate, melengestrol acetate, fore-thindrone, norethindrone acetate, norethisterone, norethis-terone acetate, norethynodrel, norgestimate, d,1-oorgestrel, 1 -norgestrcl, norgestrienone, normethisterone, progesterone, and combinations thereof.
6. The method of claim 5, wherein the progestin is selected from the group consisting of progesterone, medrox-yprogesteronc acetate, norethindrone, norethynodrel, d,i-riorgestrel and 1-norgcstrel.
7. The method of claim 6, wherein the progestin is progesterone.
8. The method of claim 4, wherein the estrogen is selected from the group consisting of 17a-estradiol, 1713-estradiol, ethioyl estradiol, pharmaceutically acceptable esters and ethers of 17-estradiol, 173-estradiol and ethinyl estradiol, estriol, estriol succinate, polyestrol phosphate, estrone, estrone acetate, estrone sulfate, piperazine estrone sulfate, quinestrol, mestranol and conjugated equine estrogens.
9. The method of claim 8, wherein the estrogen is 17 estradiol, ethinyl estradiol, or mestranol.
10. The method of claim 4, further including co-admin-istering an androgenic agent along with the progestin and estrogen.
11. The method of claim 10, wherein the androgenic agent is testosterone or an ester thereof.

12. The method of claim 1, wherein the predetermined amount of the hydroxide-releasing agent is effective to provide a p11 in the range of approximately 8.0 to 13 at the localized region of the body surface, during drug adminis-
tration.

13. The method of claim 12, wherein the p11 is in the range of approximately 8.0 to 11.5.
14. The method of claim 13, wherein the p11 is in the range of approximately 8.5 to 11.5,
15. The method of claim 4, wherein the steroid drugs and the hydroxide-releasing agent applied to the body surface simultaneously.
16. The method of claim 4, wherein the steroid drugs and hydroxide -releasing agent are present in a single pharma-ceutical formulation.
17. The method of claitr.i 16, wherein the formulation is aqueous.

18. The method of claim 17, wherein the formulation has a pH in the range of approximately 8.0 to 13.
19. The method of claim 18, wherein the p1-I is in the range of approximately 8.0 to 11.5.
20- The method of claim 19, wherein the pH is in the range of approximately 85 to 11.5.
21. The method of claim 17, wherein the aqueous formu-lation is selected from the group consisting of a cream, a gel,
a lotion, and a paste.

22. The method of claim 21, wherein the formulation is a cream.

23. The method of claim 21, wherein the formulation is a gel.
24. The method of claim 16, wherein the formulation is nonaqucous.

14

Oct. 25, 2001

25 ’lhe method of claim 24, wherein the formulation is an ointment.

26. The method of claim 1, wherein the hydroxide-releasing agent is administered to the localized region of the body surface prior to drug administration, wherein the hydroide-relc&sing agent is in a solution comprised of a protic solvent having a pH in the range of approximately 8.0 to 13-

27. The method of claim 1, wherein the hydroxide-releasing agent releases free hydroxide ions in the presence of an aqueous fluid.
28. The method of claim 1, wherein the hydroxide-releasing agent is selected from the group consisting of inorganic hydroxides, inorganic oxides, metal salts of weak acids, and mixtures thereof.
29. The method of claim 28, wherein the hydroxide-releasing agent is an inorganic hydroxide.
30. The method of claim 29, wherein the inorganic hydroxide is selected from the group consisting of ammo-nium hydroxide, alkali metal hydroxides, alkaline earth metal hydroxides, and mixtures thereof.
31. The method of claim 30, wherein the inorganic hydroxide is sodium hydroxide.
32. The method of claim 30, wherein the inorganic hydroxide is potassium hydroxide.
33 The method of claim 28, wherein the hydroxide-releasing agent is an inorganic oxide.
34. The method of claim 33, wherein the inorganic oxide is selected from the group consisting of magnesium oxide, calcium oxide and mixtures thereof-
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’ihe method of claim 28, wherein the hydroxide-releasing agent is a metal salt of a weak acid.
36. The method of claim 35, wherein the hydroxide-releasing agent is selected from the group consisting of sodium acetate, sodium borate, sodium metahorate, sodium carbonate, sodium bicarbonate, tribasic sodium phosphate, dibasic sodium phosphate, potassium carbonate, potassium bicarbonate, potassium citrate, potassium acetate, dibasic potassium phosphate, iribasic potassium phosphate, dibasic ammoniuni phosphate, and mixtures thereof.
37. The method of claim 36, wherein the amount of inorganic hydroxide in the formulation is the total of (a) the amount required to neutralize any acidic species in the formulation plus (b) an amount equal to approximately 0.5 WI. % to 4.0 wt. 51 of the formulation.
38. The method of claim 37, wherein the amount of inorganic hydroxide in the formulation is the total of (a) the amount required to neutralize any acidic species in the formulation plus (b) an amount equal to approximately 0.75 wt. % to 2.0 wt. 51 of the formulation.
39. The method of claim 38, wherein the amount of inorganic hydroxide in the formulation is the total of (a) the amount required to neutralize any acidic species in the formulation plus (h) an amount equal to approximately 1.0 wt. % of the formulation.
40. The method of claim 29, wherein the formulation contains up to approximately 25 wt. % of the hydroxide-releasing agent.
41. The method of claim 40, wherein the formulation contains up to approximately 20 wt. % of the hydroxide-releasing agent.
42. The method of claim 33, wherein the formulation contains up to approximately 25 wt, % of the hydroxide-releasing agent.

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US 2001/0033870 Al

43 The method of claim 42, wherein the formulation contains up to approximately 20 wt. % of the hydroxide-releasing agent.
44. The method of claim 4, wherein the steroid drugs and the hydroxide-releasing agent are administered by applying a drug delivery device to the localized region of the patient’s body surface thereby forming a body surface-delivery device interface, the device comprising the drugs and the hydroxide-releasing agent, and having an outer backing layer that serves as the outer surface of the device during
USC.

45. The method of claim 44, wherein the steroid drugs and hydroxide -releasing agent are present in an adhesive, gel or liquid formulation contained within the device.
46, The method of claim 44, wherein the outer backing layer is occlusive.
47. A composition of flatter useful for the delivery of a steroid drug through a body surface, comprising an aqueous formulation of:

(a) a therapeutically effective amount of a steroid drug;

(h) a hydroxide -releasing agent in an amount effective to enhance the flux of the drug through the body surface without causing damage thereto; and

(c) a pharmaceutically acceptable carrier suitable for topical or transdermal drug administration.
48 A composition of matter useful for the delivery of a combination of steroid drugs through a body surface, com-prising an aqueous formulation of:

(a) a therapeutically effective amount of a progestin and an estrogen;

(b) a hydroxide -releasing agent in an amount effective to enhance the flux of the drugs through the body surface without causing damage thereto; and

c) a pharmaceutically acceptable carrier suitable for topical or transdermal drug administration.
49. The composition of claim 47, having a pH in the range of approximately 8.0 to 13.
50. The composition of claim 49, having a p11 in the range of approximately 8.0 to 11.5.
5.1 -The composition of claim 50, having a p11 in the range of approximately 8.5 to 11.5.
52. The composition of claim 47, wherein the composi-tion is substantially free of additional permeation enhancers.
53. The composition of claim 47, wherein the composi-tion is substantially free of organic solvents.
54. The composition of claim 47, wherein the hydroxide. releasing agent is selected from the group consisting of inorganic hydroxides, inorganic oxides, metal salts of weak acids, and mixtures thereof.
55. The composition of claim 54, wherein the hydroxide-releasing agent is an inorganic hydroxide.

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Oct. 25, 2001

56. The composition of claim 55, wherein the inorganic hydroxide is selected from the group consisting of ammo-nium hydroxide, alkali metal hydroxides, alkaline earth metal hydroxides, and mixtures thereof.
57. The composition of claim 56, wherein the inorganic hydroxide is sodium hydroxide.
58. The composition of claim 56, wherein the inorganic hydroxide is potassium hydroxide.
59. The composition of claim 54, wherein the hydroxide-releasing agent is an inorganic oxide.
60 The composition of claim 59, wherein the inorganic oxide is selected from the group consisting of magnesium oxide, calcium oxide and mixtures thereof.
61. The composition of claim 54, wherein the hydroxide-releasing agent is a metal salt of a weak acid.
62. The composition of claim 61, wherein the hydroxide-releasing agent is selected from the group consisting of sodium acetate, sodium borate, sodium metahorate, sodium carbonate, sodium bicarbonate, tribasic sodium phosphate, dibasic sodium phosphate, potassium carbonate, potassium bicarbonate, potassium citrate, potassium acetate, dibasic potassium phosphate, trihasic potassium phosphate, dibasic ammonium phosphate, and mixtures thereof.
63. A system for the topical or transdermal administration of a steroidal drug, comprising:

(a) at least one drug reservoir containing the drug and a hydroxide-releasing agent in an amount effective to enhance the flux of the drug through the body surface without causing damage thereto;

(b) a means for maintaining the system in drug and enhancer transmitting relationship to the body surface; and

(c) a hacking layer that serves as the outer surface of the device during use.
64. The system of claim 63, wherein the backing layer is occlusive.

65 The system of claim 63, wherein the drug reservoir comprised of a polymeric adhesive.
66. The system of claim 65, wherein the polymeric adhesive serves as the means for maintaining the system in drug and enhancer transmitting relationship to the body
service.

67. The system of claim 63, wherein the drug reservoir comprised of a hydrogel.

69. The system of claim 63, wherein the drug reservoir is comprised of a sealed pouch containing the drug and hydroxide-releasing agent in a liquid or semi-solid formnu-lation.

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(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2005/0020554 Al
Alimed et at. (43) Pub. Date: Jan. 27, 2005

(54) STABILITY OF HORMONE FORMULATIONS

(76) Inventors: Salah U. Ahmed, New City, NY (US);
Sanjeev K. Gupta, Washington Twp.,
NJ (US); Quanirul H. Mjumder,
Pomona, NY (US); Iltifat Hasan,
Boonton, NJ (US)

Correspondence Address:
STERNE, KESSLER, GOLDSTEIN & FOX
PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005 (US)

(21) AppI. No.: 10/860,595

(22) Filed: Jun. 4, 2004

Related U.S. Application Data

(60) Provisional application No. 60/476,223, filed on Jun.
6, 2003.

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Publication Classification

(51) mt. CL7...A6IK 31/56
(52) U.S. Cl... 514/182

(57) ABSTRACT

The present invention is directed to a method of preparing a pharmaceutical dosage form, the method comprising (a) encasing a pharmaceutical dosage form comprising an estro-gen in a container essentially impervious to oxygen, and (h) purging the container with an inert gas, and pharmaceutical dosages formed by the method thereof The present inven-tion is also directed to a pharmaceutical kit comprising (a) a container impervious to oxygen, wherein the container Contains an atmosphere of essentially inert gas, and h) a pharmaceutical dosage form, wherein the pharmaceutical dosage form comprises an estrogen and wherein the phar-maceutical dosage form is encased in the container.

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packs. The nitrogen purged blister packs, as well as the control blister packs, were placed in a Pharma Center Shelbyville 92036 pouch (Alcan, Inc., Montreal, Canada).

[0031] The blister packs were then stored for either 3 or 6
months. After storage, estrogenic activity was assayed using typical standard analytical methods (U.S. Pharmacopeia, p. 639, United States Pharmacopeial Convention, Inc., Rock-ville, Md. (1995)). Tablets stored in blister packs purged with nitrogen demonstrated 1.3% degradation of estrogen at 3 months ofstorage and:1.2% degradation after 6 months of storage. Tablets without nitrogen purging demonstrated 7.4% degradation of estrogen after 3 months of storage, and 8.9% degradation of estrogen after 6 months of storage.

[0032] This example illustrates one possible formulation
of the present invention, While the invention has been particularly shown and described with reference to some embodiments thereof, it will be understood by those skilled in the art that they have been presented by way of example only, and not limitation, and various changes in form and details can be made therein without departing from the spirit and scope of the invention. Thus, the breadth and scope of the present invention should not be limited by any of the above-described exemplary embodiments, but should he defined only in accordance with the following claims and their equivalents.

[0033] All documents cited herein, including journal
articles or abstracts, published or corresponding U.S. or foreign patent applications, issued or foreign patents, or any other documents, arc each entirely incorporated by reference herein, including all data, tables, figures, and text presented in the cited documents.

What is claimed is:

1. A method of preparing a pharmaceutical dosage form, said method comprising:

(a) encasing a pharmaceutical dosage form comprising an estrogen in a container essentially impervious to oxy-gen; and

(h) purging said container with an inert gas.
2. The method of claim 1, wherein said pharmaceutical dosage form is stored in said inert gas.
3. The method of claim 1, wherein said pharmaceutical dosage form is a contraceptive.

4. The method of claim 1, wherein said pharmaceutical dosage form is useful for hormone replacement therapy. S. The method of claim 1, wherein said container encases a single dosage form. The method of claim 1, wherein said container is a blister pack.
7. The method of claim 1, wherein said estrogen is selected from the group consisting of estradiol, estradiol-1711, estradiol valerate, conjugated equine estrogens, pipera-zinc esirone sulphate, estrone, estriol, estriol succinate, polyestriol phosphate, ethinyl estradiol, quinestranol, rnestrarjol and combinations thereof.

8. The method of claim:1, wherein said estrogen is ethinyl estradiol.

9. The method of claim 1, wherein said pharmaceutical dosage form further comprises a progestin.
10. The method of claim 9, wherein said progestin is

selected from the group consisting of dl-norgestrel, levonorgestrel, norethindrone (norethisterone), norethin-

Jan. 27, 2005

drone acetate, ethynodiol diacetate, inedroxyprogesterone acetate, cyproterone acetate, trimegestone, norethynodrel and combinations thereof.
11. The method of claim 9, wherein said progestin is levonorgestrel.
12. The method of claim 1, wherein said inert gas is nitrogen.
13. The method of claim 1, wherein said inert gas in said container is between about 80% to about 100% by volume of the total gaseous content.
14. The method of claim 1, wherein said inert gas in said container is between about 90% to about 100% by volume of the total gaseous content.
15. The method of claim 1, wherein said inert gas in said container is between about 95% to about 100% by volume of the total gaseous content.
16. The method of claim 1, wherein said inert gas in said container is between about 98% to about 100% by volume of the total gaseous content.
17. The method of claim 1, further comprising enclosing said container in a pouch comprising a desiccant.
18 The method of claim 17, wherein said desiccant is silica gel.
19. The method of claim 1, wherein said pharmaceutical dosage form comprises etbinyl estradiol and levonorgesirel; and

said inert gas is nitrogen gas.
20. Apharrnaceutical dosage form made by the method of claim 1.
21. A pharmaceutical kit comprising:

(a) a container impervious to oxygen, wherein said con-tainer contains an atmosphere of essentially inert gas; and

(b) a pharmaceutical dosage form comprising an estrogen, wherein said pharmaceutical dosage form is encased in said container.
22. The pharmaceutical kit of claim 21, wherein said pharmaceutical dosage form is a contraceptive.
23. l’he pharmaceutical kit of claim 2.1, wherein said pharmaceutical dosage form is useful for hormone replace-ment therapy.
24. The pharmaceutical kit of claim 21, wherein said container encases a single dosage form.
25. The pharmaceutical kit of claim 21, wherein said container is a blister pack.
26. The pharmaceutical kit of claim 21, wherein said estrogen is selected from the group consisting of estradiol, estradiol-1713, estradiol valerate, conjugated equine estro-gens, piperazine cstrone sulphate, estrone, estriol, estriol succinate, polyestriol phosphate, ethinyl estradiol, quinestranol, mestranol and combinations thereof.
27. The pharmaceutical kit of claim 21, wherein said estrogen is ethinyl estradiol.
28. The pharmaceutical kit of claim 21, wherein said pharmaceutical dosage form further comprises a progestin.
29. The pharmaceutical kit of claim 28, wherein said progcstin is selected from the group consisting of dl-norg-

estrel, levonorgestrel, norethindrone (norcthisterone), nnre- thindrone acetate, ethynodiol diacetate, mcdroxyprogester- one acetate, cyproterone acetate, norethynodrel and

combinations thereof.
30. The pharmaceutical kit of claim 28, wherein said progestin is levonorgcstrel
31. The pharniaceutical kit of claim 21, wherein said inert gas is nitrogen.

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4

32. The pharmaceutical kit of claim 21, wherein said inert gas in said container is between about 80% to about 100% by volume of total gaseous content.
33. The pharmaceutical kit of claim 21, wherein said inert gas in said container is between about 90% to about I 00% by volume of total gaseous content.
34. The pharmaceutical kit of claim 21, wherein said inert gas in said container is between about 95% to about 100% by volume of total gaseous content.
35. The pharmaceutical kit of claim 21, wherein said inert gas in said container is between about 98% to about 100% by volume of total gaseous content.

Jan. 27, 2005

36. The pharmaceutical kit of claim 21, further compris-ing enclosing said container in a pouch comprising a des-iccant.
37. The method of claim 36, wherein said desiccant is silica gel.
38. The pharmaceutical kit of claim 21, wherein

said pharmaceutical dosage form comprises ethinyl estra-diol and levonorgestrel; and

said inert gas is nitrogen gas.

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(71) Applicant (for all designated States except US): SOCI-ETE DES PRODUITS NESTLE S.A. [CH/CH]; P.O. Box
353, CH-l800 Vevey (CH).

(72) Inventors; and
(75) Inventors/Applicants (for US only); CIIRISMAN, Ran-dall, C. [US/US]; 25 Luna Trail, Southbury, CT 06488
(US). GUTIERREZ, Antonio [US/US]; 53 Studio Hill
-_ Circle, Kent, CT 06757 (US). OVERBAUGII, William, F. [US/US]; 6 Burgess Road, Lakeside, CT 06758 (US).

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(74) Agent: BORNE, Patrice; 55, avenue NestlØ, CH-1800 Vevey (CH).

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[Continued on next page]

(57) Abstract; The invention relates to a dispenser for viscous fluid food product, the dispenser comprising: a housing (12) config- ured and dimensioned for receiving a food pouch (4); the pouch is of the type of a pouch having first and second ends, a sidewall

that can be arranged to form first and second opposed surfaces (410,411), and an outlet (40), the pouch being capable of containing a viscous fluid food product therein; means for pressing the pouch so as to urge the viscous fluid food product content toward the outlet; wherein the means comprises a roller (30) having a pressing surface disposable in a position adjacent the first surface (410) Cofthe pouch and a planar surface (21) disposed adjacent the second surface of the pouch, closure means (9, 84) engaged with the outlet (40) for closing the outlet, the means being capable of opening the outlet so as to cause the roller (30) to move along the pouch surface toward the outlet by gravity for expelling the viscous fluid food product through the outlet.

WO 01/17892

What is claimed is:

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1. A dispenser for viscous fluid food product, the dispenser
comprising:
5 a housing configured and dimensioned for receiving a
food pouch; the pouch is of the type of a pouch having first and second ends, a sidewall that can be arranged to form first and
second opposed surfaces, and an outlet, the pouch being capable of containing a viscous fluid food product therein;
10 means for pressing the pouch so as to urge the viscous
fluid food product content toward the outlet; wherein the means comprises a roller having a pressing surface disposable in a
position adjacent the first surface of the pouch and a planar
surface disposed adjacent the second surface of the pouch,
15 closure means engaged with the outlet for closing the
outlet, the means being capable of opening the outlet so as to
cause the roller to move along the pouch surface toward the outlet
by gravity for expelling the viscous fluid food product through the

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outlet

2. A dispenser according to claim 1, wherein the planar
surface is substantially vertically arranged along at least a major portion of the sidewall surface of the pouch, the roller contacts
the pouch at the first end, and the pouch outlet is positioned at
25 the second end of the pouch.

3. A dispenser according to claim 2, wherein the planar
surface constitutes an interior surface of at least a portion of a wall of the housing.

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4. A dispenser according to any of the preceding claims,
wherein the roller means is arranged to be compressible.

S. A dispenser according to claim 4, wherein the roller means
35 is formed of an elongated main cylindrical portion comprising an

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WO 01/17892 PCT/EPOO/07465

inner weight and an outer sheath of a soft resilient compressible material.

6. A dispenser according to claim 5, wherein the sheath of
5 compressible material has a hardness in the range of 25 to 45 shore

A.

7. A dispenser according to claim 6, wherein the sheath of
compressible material has a hardness of 28 to 35 shore A,
10 preferable about 30 shore A.

B. A dispenser according to any of claims 5, 6 or 7 wherein
the soft resilient material is an insulated silicone rubber.

15 9. A dispenser according to any of claims S to 8 wherein the

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main portion of the roller means further includes an external
gliding surface made of a plastic resistant film.

10. A dispenser according to claim 9, wherein gliding surface
20 is a film of plastic heat-shrinked around the sheath of soft
compressible material.

11. A dispenser according to claim 10, wherein said film is a polyolefin film.
25

12. A dispenser for a viscous fluid food product, the
dispenser comprising:
a housing configured and dimensioned for receiving a pouch
having first and second ends, a sidewall that can be arranged to
30 form first and second opposed surfaces, and an outlet, the pouch
containing a viscous fluid food product therein; the housing comprising at least one panel comprising a support surface adapted
to receive the pouch in a position adjacent to the support surface; said panel being moveable between a loading position whereby the
35 pouch is capable to be laid at rest on the support surface and a

WO 01/17892 PCTIEPOO/07465

dispensing position whereby the outlet is downwardly oriented configuration; and,
connecting means for securing the pouch onto the support
surface of the moveable panel so that the pouch is maintained
5 substantially adjacent to the support surface when moving the panel
from its loading position to its dispensing position.

13. A dispenser according to claim 12, wherein the moveable
panel has a top edge and a bottom edge; wherein the bottom edge of
10 the panel is pivotally attached to the housing by hinge means
adapted to move the panel from its loading position to its
dispensing position.

14. A dispenser according to claim 12 or 13, wherein said
15 connecting means include at least one clamping assembly comprising
. a bar -shaped pressing member having a first end pivotally attached
to the panel and a second end adapted to engage a latch member
attached to the panel; wherein the bar-shaped pressing member is
capable of exerting a connection on at least one portion of the
20 pouch along at least two spaced apart positions along the pouch.

15. A dispenser according to claim 14, wherein said portion
of the pouch is a seal flange of the pouch.

25 16. A dispenser according to claim 14 or 15, wherein the
clamping assembly is positioned in the upper region of the panel to
be capable to secure the upper seal flange of the pouch.

17. A dispenser according to any of claims 14 to 16, wherein
. 30 the clamping assembly has a width adapted to support different
sizes of pouch.

18. A dispenser according to any of claims 14 to 17, wherein
a second clamping member is positioned in the lower region of the
35 panel to secure the lower seal flange of the pouch.

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W001/17892 PCT/EPOO/07465

19. A dispenser according to claim 18, wherein the second
clamping assembly has a width adapted to support different sizes of pouch.

5 20. A dispenser according to claims 18 or 19, wherein the
panel includes a closure means capable of engaging with the outlet
of the pouch for closing the outlet, the closure means being
capable of opening the outlet to dispense the food product upon a sufficient pressure is exerted to release the closure means from
10 the outlet of the pouch; wherein the closure means comprises a
first half valve sub -assembly attached to the moveable panel and a
second half valve forming the stationary part of the closure means; wherein the second halve valve is the bar shaped member which is arranged in a face-to-face relation with the first half -valve when
15 the clamping member is in closed position to secure the lower part
of the pouch.

21. A dispenser for a viscous fluid food product, the
dispenser comprising:
20 a housing configured and dimensioned for receiving a pouch
having first and second ends, a sidewall that can be arranged to
form first and second opposed surfaces, and an outlet, the pouch containing a viscous fluid food product therein;
means for pressing the pouch so as to urge the viscous fluid
25 food product content toward the outlet, the means comprising at
least one roller means having a pressing surface disposable in a position of contact with the first surface of the pouch,
guiding means arranged with the roller means so as to guide
the roller means in translation along a pressing path adjacent the

retaining

first surface of the pouch;
retaining means coupled to said roller means and arranged to prevent the roller means from disengaging the guiding means when
the roller is at rest in the dispenser; wherein both the guiding means and retaining means are housed within said housing.

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WO 01/17892 FCTJEPOO/07465

22. A fitmentless pouch comprises a main reservoir adapted
for receiving the viscous fluid product and an outlet portion integrally extending from the lower part of the main reservoir, a sealing assembly of at least one flat plastic films comprising at
5 least a lower seal flange adapted to demarcate the contour of the
lower limit of the reservoir including the outlet portion.

23. A pouch according to claim 22, wherein the outlet of the
pouch has a substantially downardly tapered shape with a smaller
10 seal end.

24, A pouch according to claim 22, wherein the outlet has a
width of from 3.18 to 5.1 cm.

15 25. A pouch according to claim 22, wherein the outlet is made
openable by means of a precut line provided along the all width of
the lower flange at a certain distance above the closure seal line.

26. A pouch according to claim 24, wherein the precut line is
20 made by laser or mechanical cutting.

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United States Patent [191 Taylor et a].

[54] VISCOUS FLUID DISPENSER

[751 Inventors: R. Gregory Taylor, Pleasanton; Larry F. Morice, San Ramon, bath of Calif.

[731 Assignee: The Clorox Company, Oakland, Calif.

[21] AppI. No,: 271,815

[22] Filed: Jul. 7, 1994

[51] mt. C1.6...B651D 35/28 [52] U.S. CI.. 2221102; 222/105 [581 Field of Search.....................................222/101, 102, 222/103,105

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US005490613A

[11] Patent Number: 594909613

[45] Date of Patent: Feb. 13, 1996

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Primary ExaminerKevin P. Shaver
Attorney, Agent, or Firm--Joel J. Hayashida, Michael J. Mazza; Harry A. Facial

[57] ABSTRACT

A dispenser for viscous fluids includes a housing having a hanger assembly for suspending a collapsible bag with a dispenser outlet extending from an opening at the bottom of the housing, and a pair of rollers riding in parallel pairs of slots vertically extending in opposite sides of the housing. The rollers form a nip for receiving the collapsible bag whereby the rollersjointly doctor or extrude fluid in the bag toward the dispenser outlet at a substantially constant deliv-ery rate in response to operation of the dispenser.

S Claims, 7 Drawing Sheets

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Also because of the constant force applied by the rollers
to the bag, fluid within the bag is uniformly purged through
the outlet 18 and toward the dispenser device 20. It is also
noted again that the bag 16 is entirely closed or sealed except
for the outlet 18 and dispenser device 20, as described

above. Accordingly, fluid within the bag 16 remains unex- posed to the atmosphere until it exits from the bag outlet by means of the dispenser device 20. This is important in

connection with fluids which may suffer for example from oxidation or the lile.

10 The method of operation for the dispenser assembly 10 is
believed apparent from the preceding description. However, the method of operation is described briefly below in order to assure complete disclosure of the invention.

Initially, the length of each of the rollers 26 and 28 is 15 preferably slightly less than the inside spacing between the sides ofthe housing portions 12A and 12B so that the rollers can be tilted to engage their axles 34 and 36 in the vertical
guide slots 24A and 248. With the rollers positioned within the housing and the housing 12 configured as described above, the rollers are preferably moved into the roller 20

retaining slot extensions 42A and 42B with the housing in a closed position as illustrated for example in FIG. 4. Since the
axles 34 and 36 are free to rotate within the retaining slot extensions, they tend to move to the lowermost portions in
the slot extensions. 25

The housing is then opened by rotating the movable housing portion 12B about the binge 30 into the position illustrated in FIG. 3. As the movable housing portion 12B is rotated in this manner, the axles 34 and 36 on the second roller 28 move downwardly and then inwardly along the 30 retaining slot extensions 4213 so that the roller 28 remains positioned and suspended with the movable housing portion 128 in its raised position.

With the housing being open, the pegs 62 of the hanger means 14 are exposed to permit and facilitate suspending of 35

the bag 16 as described above with the opening 60 in the reinforced upper end 58 ofthe bag receiving the pegs 62 and the outlet 18 ofthe bag extending through the opening 22 of the housing to expose the dispenser device 20 beneath the
housing. 40

The housing is then closed. The rollers 26 and 28 are moved along the slot extensions 42A and 42B toward the top of the vertical guide slots 24A and 24B where they are secured together by means of the yokes 48 to establish the

nip 54 with the bag 16 arranged therebetween. 45
With the rollers in this configuration, they are applying substantial force under the influence of gravity against the bag,

The dispenser assembly 10 is then in condition for use 50 with the rollers 26 and 28 operating under the influence of
gravity in response to actuation of the dispenser device 20.

When the dispenser device 20 is opened, the rollers apply uniform force to the bag so that fluid exits the bag outlet

through the dispenser device 20 at a substantially constant 5.5 delivery rate as long as the dispenser device 20 remains

open. Thus, the dispenser assembly 10 is particularly adapted for intermittent use with constant fluid flow being assured at any time when the dispenser device 20 is opened.

The interconnection of the rollers by the yokes 48 form 60 the nip 54 assures that the rollers extrude or doctor substan-tially all fluid from the bag toward the outlet 18 as the rollers travel downwardly through the housing under the influence of gravity. It is noted that the collapsed portion ofthe bag 16 is exaggerated, the clearance or nip 54 actually being defined 65 by the amount of space taken up by the collapsed portion of the bag itself.

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Operation in this manner continues until the rollers 26 and 28 approach the lower ends of the vertical guide slots 24A and 248, that is, the position illustrated in FIG. 4. At that point, the rollers are closely adjacent the outlet 18 with the tapered sides 64 ofthe bag further assuring that substantially all fluid is extracted or doctored from the bag.
At that point, the rollers can then be raised and retained in the slot extensions 42A and 428. The empty bag 16 can be removed from the housing and a fresh bag filled with fluid installed in the same manner to facilitate continued opera-tion of the dispenser assembly.
Accordingly, there has been described above a preferred embodiment of a dispenser assembly including a housing and collapsible bag adapted for a method of use as also described above. Variations and/or modifications of the apparatus and method are believed obvious in addition to those specifically described above. For example, it is noted that the housing 12 need not form an enclosure as described above. It could, for example, be a generally open structure while accomplishing its function. Other variations are of course possible both within the housing and elements mounted upon the housing as well as in the collapsible bag
16. Accordingly, the scope of the present invention is defined only by the following appended claims which are further exemplary of the invention.
What is claimed is:
1. A dispenser for viscous fluids, comprising
a housing having an opening in a lower portion thereof, a collapsible bag having an outlet,
dispenser means arranged in the bag outlet for dispensing fluid from the bag, hanger means in the form of multiple pegs arranged in an upper portion of the housing for suspending the bag generally vertically with the bag outlet extending through the housing opening,
roller means forming a nip and having a mass sufficient for collapsing the bag under the influence of gravity in order to positively extrude the fluid from the bag in response to operation of the dispenser means, and guide means allowing the roller means to descend under the influence of gravity from an initial position adjacent the hanger means only when the fluid is expelled from the bag,
the collapsible bag forming an elongated flexible closure and having reinforced openings at its upper end for

mating with the multiple pegs, the outlet being in a lower end of the bag, and dispenser means arranged in

the bag outlet for dispensing fluid extruded from the

bag by the roller means and otherwise forming an enclosed compartment for the fluid whereby fluid in the

collapsible bag remains unexposed to the atmosphere until it exits from the bag outlet, the collapsible bag being laterally tapered adjacent the outlet at its lower
end and having a thickness corresponding to the nip formed by the roller means to facilitate extrusion of
substantially all fluid from the bag by the roller means,
2. The dispenser of claim 1 wherein the housing further

comprises a movable portion for at least one ofinstalling or replacing the collapsible bag.
3. The dispenser of claim IL wherein the housing includes support means so that the housing is free-standing.

4, The dispenser of claim 1 wherein said housing com- prises a first portion which is fixed and a second portion

5,490,613
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which is movable for at least one of installing or replacing
the bag, the fixed housing portion having a roller retaining
slot extension turned approximately 180° relative to its
linear slot, the movable housing portion having a roller retaining slot extension turned at least 270° relative to its linear slot

5. The dispenser of claim 4 wherein the multiple pegs are located on the housing adjacent the upper ends of the slots, the bag having reinforced openings mating with the pegs.
6. The dispenser of claim 5 wherein the tapered bag adjacent the outlet facilitates doctoring of all fluids there-from by the rollers.
7. The dispenser of claim S wherein the housing includes support means on its fixed portion so that the housing is free-standing.
8. Adispenser for viscous fluids, the dispenser adapted for use with a collapsible bag having an outlet and dispenser means arranged in the bag outlet for dispensing fluid there-from, comprising
a housing having an opening in a lower portion thereof, hanger means arranged in an upper portion of the housing for suspending the bag generally vertically with the bag outlet extending through the housing opening,

Is

10 a pair of rollers each having a mass sufficient for collaps-
ing the bag under the influence of gravity in order to positively expel the fluid from the bag in response to operation of the dispenser means, and
guide means for maintaining the rollers in opposed rela-tion with the collapsible bag therebetween and the rollers initially adjacent the hanger means, the guide means allowing movement of the opposed rollers
10 toward the housing opening whereby the rollers extrude
substantially all fluid in the bag toward the bag outlet
at a substantially constant delivery rate in response to operation of the dispenser means, the guide means

15 comprising two parallel pairs of linear slots formed

vertically by opposite sides of the housing, the rollers
having axles extending through the slots,
the housing having a movable portion for at least one of installing or replacing the bag, the housing forming
20 roller retaining slot extensions turned relative to the
two parallel paris of linear slots respectively for sup-porting the rollers during at least one of installation or replacement of the bag.

2020

Bogota, D.C.,

Doctor:
Ian Raisbeck Llinas
Apoderado

ASUNTO: Radicación PCT No 07-67094
Trâmite 011
Evento 379
ActuaciOn 440
Folios 027

Industria y Comercio
SUPERI

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NTENDENCIA

Oficio N°:

Con fundamento en lo previsto por el articulo 43 de la Decision 486 de la Comisiôn de la Comunidad Andina, se le comunica que la oposición presentada por el doctor JosØ Luis Reyes Villamizar, en su calidad de apoderado del Laboratono Franco Colombiano S.A. Lafrancol S.A., reüne los requisitos formales exigidos por la ley al momento de su presentaciOn.

En cumplimiento de lo dispuesto en la citada norma, se le concede el tØrmino de sesenta (60) dIas hÆbilessiguientes a la fecha de notificación del presente oficlo, para que haga valer sus argumentaciones y presente pruebas.

Notifiquese el presente oficlo conforme a lo dispuesto en el numeral 5.2, literal e), del capitulo quinto del titulo primero de la Circular Unica NO 10 de 2001.

ALIX CARMENA CESPEDES DE VERGEL
Directora de Nvas Creaciones (C).

El anterior oficio fue notificado por fijación en lista de fecha,____

202021

Sede Centro: Carrera 13 No. 27-00 Pisos 2, 5, 7 y 10 Sede CAN: Tr. 40A No. 38-50 Conmutador: 5870000 Fax: 5870284 Llnea 018000-910165
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/103 A AVISO DE NOTIFICACION Industria y Cornercio
CORREO CERTIFICADO SUPER I N TEND EN CIA

Radicación 7.67094- -6-0 Fecha: 2010-07-29 08:52:03
TrÆmite: 11 PATENTEIYII
Evento: 379 FASENACIONALII
Actuación: 432 COMUNICACTOADM
Destinatario:.J IAN RAISBECK Folios I

Seæor(a) (es)
J IAN RAISBECK
DIAGONAL 34 NO. 5-28
BOGOTA D.C.

Referenda RESOLUCION: 38881
Fecha: 28/07/2010
Expediente: 7-67094
TrÆmite: 11 PCT-PATENTE DE INVENCION CAPITULOS I Y II
Evento: 379 FASE NACIONAL INCLUIDO CAPITULO II
Actuación 432 COMUNICACION ACTO ADMINISTRATIVO

Comedidamente le solicito presentarse a este Despacho ubicado en la Carrera 13 No. 27 - 00 Piso Tercero (3), de la ciudad de Bogota D.C., dentro del tØrmino de cinco (5) dIas hÆbiles contados a partir del envIo de la presente citación, en horario de 8:00 a.m. a 4:30 p.m. jornada continua, con elfin de notificarle personalmente el contenido de la resoluciOn de la referenda proferida dentro del expediente tramitado con el nümero de radicaciOn citado en el asunto.

De no hacerse presente en el tØrmino indicado anteriormente, Ia providoncia en mención se notificarØ por edicto, el cual se fijarÆ por el tØrmino de diez (10) dIas en el Centro de Documentaciôn e lnformaciOn.

Para su comodidad el texto completo de la resoluciôn se encontrarÆdisponible en la pØgina web de la Entidad desde el dta hØbil siguierite al de su notificación, la cual podrÆ ser consultada desde un computador con acceso a Internet, en la pÆginawww.sic.gov.co, con el nUmero de resolución a travØs de la opcion servicios en Ilnea bases de datos - otros servicios - consulta actos administrativos.

En caso de que se haya notificado, haga caso omiso de este aviso.

Secretaria General

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AVISO DE NOTIFICACION

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Actuación:

Industria y Comercio
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379 FASE NACIONAL INCLUIDO CAPITULO II
432 COMUNICACION ACTO ADMINISTRATIVO

Comedidamente le solicito presentarse a este Despacho ubicado en la Carrera 13 No. 27 - 00 Piso Tercero (3), de la ciudad do Bogot D.C., dentro del tØrmino do cinco (5) dias hÆbiles contados a partir del envIo do la presente citaciôn, en horarlo do 8:00 a.m. a 4:30 p.m. jornada continua, con elfin de notificarle personalmente el contenido do la resoluciOn de la referencia proferida dentro del expediente tramitado con 01 nümero do radicación citado en el asunto.

Do no hacerse presente en el tØrmino indicado anteriormente, la providencia en menciOn se notificarÆ por edicto, el cual so fijarÆ por el tØrmino do diez (10) dias en el Centro do
Documentaciôn e lnformación.

Para su comodidad el texto completo de la rosoluciôn Se encontrarÆdisponible en la pÆgina web do la Entidad dosde el dia hÆbil siguiente al de su notificación, (a cual podrÆ ser consultada desde un computador con acceso a Internet, on la pÆginawww.sic.gov.co, con el nümero de resolución a travØs do la opción servicios on Ilnea bases do datos - otros servicios - consulta actos administrativos.

En caso do quo se haya notificado, haga caso omiso do este aviso.

Secrotaria General

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

Sede Centro: Carrera 13 No. 27-00 pisos 3, 5, 7 y 10 PBX: 5870000
Al contester favor indique el nOmero de Bede CAN: Av. Carrera 50 No, 26- 55 mt. 2 Tel 5880070 radicaciOn consignado en el sticker Call Center 6513240 - Linea 01800-910165 Web: www.sic.gov.co e-mail: info@sic.gov.co
Bogota D.C. Colombia

I RF FS & REYFS

Seæora
Jefe de la DivisiOn de Nuevas Creaciones

Superintendencia de Industria y Comercio E. S. D.

Ref.: Resolución
Fecha
Expediente No.

38881
28/07/2010
07-67094

Yo JOSE LUIS REYES VILLAMIZAR, identificado como aparece al pie de mi firma, autorizo al seæor ALBERTODIAZ MORENO identificado con C.C. No.19.146.160 de Bogot, para que en mi nombre se notifique de la resoluciOn enunciada en la referencia.

Atentamente,

Cl
JOSE LUIS REYES VILLAMIZAR
C.C. No. 79.152.473 de Usaquen
T.P. No. 44655 del C.S. de la Jud.

Industria y Comercio
S U P E R I N T E N D E N C I A

REPUBLICA DE COLOMBIA SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

RESOLUCION No
Por la cual se declara abaridonada LInªsOIiäitUd

Rad. POT! 07-67094

EL SUPERINTENDENTE DE INDUSTRIA V COMERCIO

en ejerciclo de sus facultades legales, en especial de las conferidas en el numeral 38 del articulo 30 del Decreto 1687 de 2010, y

CONSIDERANDO:

PRIMERO: Que mediante escrito radicado en esta Superintendencta el dIa 03 de julio del 2007 con el No 07-067094-00000-0000, el doctor Ian Raisbeck Llinas, en su calidad de apoderado de Bayer Schering Pharma Aktiengesellschaft, presentO la solicitud de patente de invenciôn titulada "AYUDA PARA DISPENSADO DE PREPARACIONES FARMACEUTICAS 0 C0SMTICAS SEMOSOLIDAS ENVASADAS EN UN ENVASE DE TIPO SACHE", correspondiente a la solicitud internacional POT/EP 2006/007107 de fecha 19 de julio del 2006, para que se iniciara la fase nacional en virtud del Tratado de Cooperación en Materia de Patentes (PCT).

SEGUNDO: Que efectuado el examen de forma en cuanto a los requisitos que debe Ilenar la solicitud y cumplidas las exigencias legales, se ordenô publicar el extracto en la Gacta de la Propiedad Industrial No 604 del 29 de mayo del 2009.

TERCERO: Que med iante escrito radicado en esta Entidad el dIa 31 de agosto del 2009 con el N° 07-067094-00003-0000, encontrârdose dentro del tØrmino establecido para el efecto, el doctor JosØ Luis Reyes Villamizar, en su calidad de apoderado de Lafrancol S.A., presento oposiciOn fundanientada, la cual curnplio los requisitos formales previstos por Ia normativa andina. (Folios 100 a 139).

CUARTO: Que mediarite oficio No 3877 del dia 04 de diciembre del 2009 se corriO traslado del documento de oposición al solicitante, por el tØrmino de sesenta dias para que Se pronunciara al respecto, sin obtener respuesta alguna en tal sentido.

QUINTO: Que el articulo 44 de la Decision 486 de la ComisiOn de la Comunidad Andina, establece que: "Dentro del plazo de se/s meses contados desde ía publicac(On de la solicitud, independientemente que se hubicren presentado oposiciones, el solicitante deberÆ pedir que Se examine si/a invención es patentable. Los Palses Miembros podrÆncobrar una tasa para la realizacion de este examen. Si transcurriera dicho plazo sin que el solicitante hubiera pedido quo so realice el examen, Ia solicitud caerÆ enabandono."

SEXTO: Que contados seis meses desde la publicacion en la Gaceta de la Propiedad Industrial, no se presentó peticiOn de parte i1eI interesado para efectuar el examen de

Pgina 1 de 2 Sede Centro, Carrera 13 No. 27-00 Pisos 3, 4, 5 y 10 Sede CAN: Av, Carrera 50 No. 27-55, Int, 2.
Conmutadores 5870000 y 5880234
Fax; 5870284, Linea 0180000-910165
Web: w.sic.ciov,co e-mail: infoas1c.aov.co
Bogota D.C. - Colombia

Inclustria y Comercio
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REPUBLICA D COLOMBIA SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

RESOLUCION No ..
Por Ia cual se declara abandonada una solicitud

Rad. PCT/ 07-67094

fonda, por 10 que este Despacho considera abandonada la solicitud en los tØrminos del mencianado artIculo 44 de la Decision 486 de la Comisiôn de la Comunidad Andina y, en consecuencia,

RESUELVE:

ARTICULO PRIMERO: Declarar abandonada la solicitud de patente de invención titulada "AYUDA PARA DISPENSADO DE PREPARACIONES FARMACEUTICAS 0 COSMETICAS SEMOSOLIDAS ENVASADAS EN UN ENVASE DE TIPO SACHE", que entró en fase nacional en virtud del Tratado de CooperaciOn en Materia de Patentes (PCT).

ARTICULO SEGUNDO: Notificar personalmente el conteriido de la presente resoluciOri al doctor Ian Raisbeck Llinas, en su calidad de apoderado de Bayer Scheririg Pharma Aktiengesellschaft, y al doctor JosØ Luis Reyes Villamizar, en su calidad de apoderado de Lafrancol SA., o a quienes hagan sus veces, entregandolea copia de la misma y advirtiØndoles que contra ella procede el recurso de reposiciOn, ante el Superintendente de Industria y Comercio, el cual podia ser interpuestoen el momento de la notificaciOn 0 dentro de los cinco 5 dIas hÆbilessiguientesa ella.

NOTIFiQUESE Y CUMPLASE

Dada en Bogota, D.C., a los p UL 2010
EL SUPERINTENDENTE DE INDUSTRIA Y COMERCIO, /

Doctor
IAN RAISBECK LLINAS

Diagonal 34 NO 5 - 28.
Bogota D.C.

Doctor
JOSÉ LUIS REYES VILLAMIZAR

Carrera 17 No 88 - 23, Of, 205.
Bogota D.C.

202Q21

PÆgina 2de 2

GUSTAVO VALBUENA QUIFiONES

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Fax: 5870284, Linea 0180000-910165
Web: w.sic.av.co e-mail: info@sic.gov.qo
Bogota D.C. - Colombia