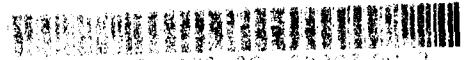


Clarke, Modet & C^o
COLOMBIA

175678
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



Ms. 04123506- 00007 00 2

Dep. 2-70 NUECREACIONE
Lve 379 FASENACIONALI
Folios: 11

SEÑORES

DIVISIÓN DE NUEVAS CREACIONES

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

E. S. D.

COD:008

RE.: SOLICITUD DE PATENTE EN COLOMBIA

EXPEDIENTE N° 04123506

TITULO: MONOXIDO DE CARBONO COMO BIOMARCADOR
Y AGENTE TERAPÉUTICO

SOLICITANTE: YALE UNIVERSITY AND JOHNS HOPKINS
UNIVERSITY

FECHA SOLICITUD: 09 DE DICIEMBRES DE 2004

ASUNTO: RESPUESTA A ACCIÓN OFICIAL

DILIA RODRIGUEZ D'ALEMAN, en mi condición de apoderada de la sociedad solicitante, por el presente escrito doy respuesta a su auto notificado por estado de 19 de julio de 2007, para el cual se presentó solicitud de prórroga y vence el 29 de noviembre de 2007 y me permito presentar las siguientes aclaraciones:

En búsqueda de superar las objeciones relacionadas con las excepciones a la patentabilidad de la invención y las reivindicaciones de uso, el solicitante presenta **nuevo capítulo reivindicatorio**, que reemplaza el que obra originalmente en la solicitud, y fue redactado para remediar las observaciones efectuadas por su Despacho. Igualmente, se modifica el título "**FORMULACIÓN FARMACÉUTICA A BASE DE MONÓXIDO DE CARBONO**", con el fin que corresponda con la invención que ahora se reivindica.

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En esencia el nuevo capítulo reivindicatorio ha sido modificado para eliminar del capítulo reivindicatorio las reivindicaciones de método de tratamiento y las reivindicaciones de uso por reivindicaciones cuyo objeto es una formulación farmacéutica.

El nuevo capítulo reivindicatorio se ajusta a las disposiciones del artículo 34, toda vez que la modificación en cuestión está basada en los siguientes apartes de la descripción:

- Inicio del primer párrafo del resumen de la invención (ver página 35 donde se indica que *"la presente invención describe formulaciones farmacéuticas novedosas"*,
- Final del mismo donde se establece que la formulación de la invención se caracteriza porque contiene una cantidad de monóxido de carbono que exceda el 0.3% del total de la composición,
- Inicio de la página 36 donde se indica que otro aspecto de la invención es *"la preparación de un medicamento"* que contiene monóxido de carbono y
- En el primer párrafo de la página 40 donde claramente se establece que *"El término 'monóxido de carbono' (o 'CO') según lo utilizado aquí describe monóxido de carbono molecular en su estado gaseoso, comprimido a forma líquida o disuelto en soluciones acuosas. El término 'formulación de monóxido de carbono' o 'formulación farmacéutica que contiene monóxido de carbono' es usado a través de la descripción para describir una formulación gaseosa o líquida que contiene monóxido de carbono que puede ser administrado a un paciente y/o a un órgano. Un médico con la experiencia adecuada reconocerá cual de las formas de la formulación farmacéutica, e.g., gaseosa, líquida o ambas formas gaseosa y líquida, es adecuada para una aplicación dada."*

Dado que las nuevas reivindicaciones son reivindicaciones en cuyo preámbulo de manera expresa se indica que el objeto de la solicitud es una formulación farmacéutica, es claro que el objeto reivindicado es un producto y no un método ni un uso.

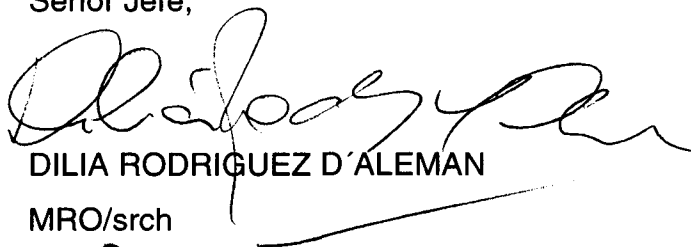
Clarke, Modet & C^o
COLOMBIA

En este orden de ideas, la solicitud es una solicitud de producto que según el artículo 14 de la Decisión 486 es objeto de protección vía patentes, a menos que ese Despacho compruebe que dicho objeto no cumpla con los requisitos de novedad, nivel inventivo y aplicación industrial. Dado que dicha composición es novedosa y tienen nivel inventivo pues causa unos efectos farmacéuticos inesperados en el paciente, es notorio que la presente solicitud cumple con los requisitos establecidos en los artículos 14, 16, 18 y 19 de la decisión 486.

Por lo tanto, se solicita respetuosamente a la Oficina de Patentes Colombiana retirar todas las objeciones.

Agradezco continuar con el presente trámite.

Señor Jefe,


DILIA RODRIGUEZ D'ALEMAN
MRO/srch

MRO

FORMULARIO ÚNICO DE CORRECCIONES Y MODIFICACIONES
2000-10

1) SOLICITUD DE:

☐ Corrección de error material

☒ Modificación a una solicitud

2) SOLICITANTE

Nombre: 1. YALE UNIVERSITY
2. JOHNS HOPKINS UNIVERSITY
Dirección: 1. Two Whitney Avenue, New Haven, CT 06511 Estados Unidos de América
2. 111 Marketplace, Suite 906, Baltimore, MD 21202 Estados Unidos de América
Nacionalidad o Domicilio: 1. New Haven, CT, Estados Unidos
2. Baltimore, MD, Estados Unidos
Lugar de Constitución: 1. CT Estados Unidos; 2. MD Estados Unidos

Teléfono: Fax:
E. Mail:

IDENTIFICACIÓN

C.C. ☐ NIT: ☐

C.E. ☐ OTRO ☐

NÚMERO _____

3) REPRESENTANTE O APODERADO

Nombre: DILIA MARÍA RODRÍGUEZ D'ALEMAN
Dirección: Carrera 11 N°. 86-53 Piso 6 Bogotá D.C.

Teléfono: 6181088 Fax: 6350824
E. Mail: info@clarkemodet.com.co

IDENTIFICACIÓN

C.C. ☒ NIT: ☐

C.E. ☐ OTRO ☐

NÚMERO: 41.654.882
TP: 20824 CSJ

4) NUMERO DE EXPEDIENTE: 04123506

5) DESCRIPCIÓN DE LA CORRECCIÓN O MODIFICACIÓN SOLICITADA:

Se presenta nuevo capítulo reivindicatorio
Nuevo título como: "FORMULACIÓN FARMACÉUTICA A BASE DE MONÓXIDO DE CARBONO"

6) Comprobante de pago No.

7) Anexos:

☒ Comprobante de la tasa

☐ Poderes, si fuere el caso

☐ Certificado de Existencia y Representación legal, cuando el solicitante sea persona Jurídica

8)

Nombre: DILIA RODRÍGUEZ D'ALEMAN

Firma

C.C.: 41.654.882 TP: 20824 CSJ

9212

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 07 - 96,348
FECHA : NOVIEMBRE 26 DE 2007

***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
CLARKE MODET Y CD. COLOMB	CONSIGNACION	BANCO POPULAR	050-00110-6	53267311	26/11/2007	28,480,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-03	CAMBIO DE MODALIDAD Y MODIFICA	
12		MARCAS Y LEMAS COMERCIALES	99,000.00
		TOTAL :	\$ 99,000.00

PON: NOVENTA Y NUEVE MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

57

SE REIVINDICA:

1. Una formulación farmacéutica caracterizada porque contiene entre 0.0000001% y alrededor del 0.3% en peso de monóxido de carbono.
2. La formulación farmacéutica de la reivindicación 1, caracterizada porque el monóxido de carbono molecular es comprimido a forma líquida.
3. La formulación farmacéutica de la reivindicación 1, caracterizada porque el monóxido de carbono molecular está disuelto en soluciones acuosas.
4. La formulación farmacéutica de la reivindicación 1, caracterizada porque es una formulación gaseosa.
5. La formulación farmacéutica de la reivindicación 4, caracterizada porque contiene entre 0.0001% y del 0.25% de monóxido de carbono molecular en peso, preferiblemente 0.005%, 0.010%, 0.02%, 0.025%, 0.03%, 0.04%, 0.05%, 0.06%, 0.08%, 0.10%, 0.15%, 0.20%, 0.22%, o 0.24% de monóxido de carbono en peso.

6. La formulación farmacéutica de la reivindicación 5, caracterizada porque contiene preferiblemente entre 0.001% y alrededor del 0.24%, aún más preferiblemente de 0.005% a 0.22%, aún mejor de 0.005% a 0.05% de monóxido de carbono en peso.
7. La formulación farmacéutica de la reivindicación 6, caracterizada porque la mejor modalidad de la invención contiene de 0.010 a 0.20%, de 0.02% a 0.15%, de 0.025% a 0.10%, o de 0.03% a 0.08%, o de 0.04% a 0.06% de monóxido de carbono en peso.
8. La formulación farmacéutica de la reivindicación 1, caracterizada porque es una soluciones líquidas del CO.
9. La formulación farmacéutica de la reivindicación 8, caracterizada porque contiene entre 0.0001 a 0.0044 g CO/100 g de líquido.
10. La formulación farmacéutica de la reivindicación 9, caracterizada porque preferiblemente contiene por lo menos de 0.0001, 0.0002, 0.0004, 0.0006, 0.0008, 0.0010, 0.0013, 0.0014, 0.0015, 0.0016, 0.0018, 0.0020, 0.0021, 0.0022, 0.0024, 0.0026, 0.0028, 0.0030, 0.0032, 0.0035, 0.0037, 0.0040 o 0.0042 g CO/100 g de solución acuosa.

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11. La formulación farmacéutica de la reivindicación 9, caracterizada porque preferiblemente el monóxido de carbono es incorporado en el intervalo preferido que incluye de 0.0010 a 0.0030 g CO/100 g de líquido, de 0.0015 a 0.0026 g CO/100 g de líquido o de 0.0018 a 0.0024 g CO/100 g de líquido.

12. La formulación farmacéutica de acuerdo con una de las reivindicaciones anteriores caracterizada porque es administrada a pacientes que padecen o están en riesgo de padecer al menos un trastorno seleccionado del grupo conformado por: enfisema, bronquitis, fibrosis quística, neumonía, enfermedad pulmonar intersticial, cicatrización de heridas, artritis, la enfermedad de Parkinson y la enfermedad de Alzheimer; o promover la cicatrización de heridas en el paciente.

13. La formulación farmacéutica de la reivindicación 12, caracterizada porque caracterizada porque el trastorno es enfisema.

14. La formulación farmacéutica de la reivindicación 12, caracterizada porque caracterizada porque el trastorno es bronquitis.

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15. La formulación farmacéutica de la reivindicación 12, caracterizada porque
caracterizada porque el trastorno es fibrosis quística.

16. La formulación farmacéutica de la reivindicación 12, caracterizada porque
caracterizada porque el trastorno es neumonía.

17. La formulación farmacéutica de la reivindicación 12, caracterizada porque es una
enfermedad pulmonar intersticial.

18. La formulación farmacéutica de la reivindicación 12, caracterizada porque es artritis.

19. La formulación farmacéutica de la reivindicación 12, caracterizada porque es la
enfermedad de Parkinson.

20. La formulación farmacéutica de la reivindicación 12, caracterizada porque es la
enfermedad de Alzheimer.

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21. La formulación farmacéutica de la reivindicación 12, caracterizada porque promueve la cicatrización de heridas en el paciente.

22. La formulación farmacéutica de acuerdo con una de las reivindicaciones anteriores caracterizada porque es administrada a pacientes que padecen o esta en riesgo de padecer inflamación localizada en por lo menos uno de los órganos seleccionado del grupo conformado por: riñón, bazo y piel.

23. La formulación farmacéutica de acuerdo con la reivindicación 22 caracterizada porque el órgano es un riñón.

24. La formulación farmacéutica de acuerdo con la reivindicación 22 caracterizada porque el órgano es el bazo.

25. La formulación farmacéutica de acuerdo con la reivindicación 22 caracterizada porque el órgano es la piel.

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

CONSULTA DE NUEVAS CREACIONES

Miercoles 25 de Junio de 2008

Ver Afectaciones	Ver Actuaciones	Datos Publicación	Consulta Actos Administrativos
		Cerrar Ventana	

Datos de PCT-PATENTE DE INVENCION CAPITULOS I Y II

Expediente 4 84713 Fecha de 2004-08-30 00:00:00
solicitud

Sector QUIMICA Clasificación Ipc A61K 1/0 ;
FARMACEUTICA

Certificado 0 Tipo concesión TOTAL

Datos Pct
-Inicio Fase nacional 13/09/2004
-Fecha presentación 13/02/2003
Internacional
-Solicitud Internacional N° PCT/US03/04665
-Publicación Internacional N° WO03/072024
-Fecha publicación 04/09/2003
Internacional

Iupac
-Nombre Iupac ~~MONOXIDO DE CARBONO~~
-Nombre Comun COMPOSICION DE MONOXIDO DE CARBONO
-Indicación TRATAMIENTO DE HIPERPLASIA, METODO PARA DESARROLLAR ANGIOPLASTI

Título ~~MÉTODOS DE TRATAMIENTO DE ENFERMEDAD VASCULAR~~

Solicitante(s) BETH ISRAEL DEACONESS MEDICAL CENTER, INC.
UNIVERSITY OF PITTSBURG OF THE COMMONWEALTH SYSTEMS OF HIGHER EDUCATION

Inventor(es) LEO E OTTERBEIN
AUGUSTINE M,K, CHOI
FRITZ H BACH
BRIAN ZUCKERBRAUN

Prioridad US 60/356.718 13/02/2002 AC

Gaceta
Numero Fecha NP
561 28/02/2006 1156 ver gaceta

Estado REQUERIMIENTO 45 2007-11-15 15:19:22

Resumen

- 1.- Un método para desarrollar angioplastia en un paciente, el método comprende:
 - (a) Desarrollar la angioplastia en el paciente; y
 - (b) Antes, durante, o después (a), administrar al paciente un composición farmacéutica que comprende una canti monóxido de carbono para tratar la hiperplasia íntima en el paciente.
- 2.- El método de la reivindicación 1, en donde la angioplastia comprende angioplastia de globo.
- 3.- El método de la reivindicación 1, en donde la angioplastia comprende angioplastia láser.
- 4.- El método de la reivindicación 1, en donde la angioplastia comprende aterectomía direccional.

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5.- El método de la reivindicación 1, en donde la angioplastia comprende aterectomía rotacional.

REGISTRO INICIAL

Expediente 4 84713 Secu even.0 Fecha de 2004-08-30 00:00:00
solicitud

Solicitante(s) BETH ISRAEL DEACONESS MEDICAL CENTER, INC.
UNIVERSITY OF PITTSBURG OF THE COMMONWEALTH SYSTEMS OF HIGHER EDUCATION

Apoderado DILIA MARIA RODRIGUEZ D'ALEMAN

Inventor(es) LEO E OTTERBEIN
AUGUSTINE M,K, CHOI
FRITZ H BACH
BRIAN ZUCKERBRAUN

Actos OFICIO 8481 de 09/09/2004

Administrativos OFICIO 14745 de 15/11/2007

Estado REQUERIMIENTO 45 2007-11-15 15:19:22

[Ver Anualidades](#)[Ver Afectaciones](#)[Ver Actuaciones](#)[Consulta Actos Administrativos](#)[Cerrar Ver](#)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
4 September 2003 (04.09.2003)

PCT

(10) International Publication Number
WO 03/072024 A2

- (51) International Patent Classification⁷: **A61K**
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- (22) International Filing Date: 13 February 2003 (13.02.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/356,718 13 February 2002 (13.02.2002) US
- (71) Applicants (*for all designated States except US*): **BETH ISRAEL DEACONESS MEDICAL CENTER, INC.** [US/US]; One Deaconess Road, Boston, MA 02115 (US). **UNIVERSITY OF PITTSBURGH OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION** [US/US]; 200 Gardener Steel Conference Center, Pittsburgh, PA 15260 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (*for US only*): **OTTERBEIN, Leo, E.** [US/US]; 910 Normandy Drive, New Kensington, PA 15068 (US). **CHOI, Augustine, M., K.** [US/US]; 43 Long Meadow Dr, Pittsburgh, PA 15238 (US). **BACH, Fritz, H.** [US/US]; 8 Blossom Lane, Manchester-by-the-Sea, MA 01944 (US). **ZUCKERBRAUN, Brian** [US/US]; 108 Maple Heights Road, Pittsburgh, PA 15232 (US).
- (74) Agent: **FRASER, Janis, K.**; Fish & Richardson P.C., 225 Franklin Street, Boston, MA 02110 (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, 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, HU, IE, IT, LU, MC, NL, PT, SE, SI, 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: METHODS OF TREATING VASCULAR DISEASE

(57) Abstract: The present invention relates to a method of treating patients suffering from, or at risk for, intimal hyperplasia and/or arteriosclerosis. The treatment includes administering a pharmaceutical composition that includes carbon monoxide to the patient.

WO 03/072024 A2

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192Summary

The present invention is based, in part, on the discoveries that CO prevents arteriosclerotic lesions and intimal hyperplasia following aortic transplant and carotid artery balloon injury in animals.

5 Accordingly, in one aspect, the invention provides a method of treating intimal hyperplasia in a patient. The method includes identifying a patient suffering from or at risk for intimal hyperplasia (e.g., intimal hyperplasia resulting from an angioplasty procedure or a transplant procedure, or resulting from a procedure or condition other than a transplant procedure), and administering to the patient a pharmaceutical
10 composition comprising an amount of carbon monoxide effective to treat intimal hyperplasia in the patient.

The invention also provides a method of performing angioplasty in a patient. The method includes performing angioplasty in the patient, and before, during, and/or after performing angioplasty, administering to the patient a pharmaceutical composition
15 comprising an amount of CO effective to treat intimal hyperplasia in the patient. The angioplasty can be any angioplasty procedure, e.g., balloon angioplasty; laser angioplasty; artherectomy, e.g., directional atherectomy, rotational atherectomy, or extraction atherectomy; and/or any angioplasty procedure using a stent, or any combination of such procedures.

20 The invention also provides a method of treating (e.g., preventing or decreasing) restenosis in a patient. The method includes providing a vessel containing a pressurized gas comprising carbon monoxide gas, identifying a patient suffering from or at risk for restenosis, releasing the pressurized gas from the vessel to form an atmosphere comprising carbon monoxide gas, and exposing the patient to the
25 atmosphere, wherein the amount of carbon monoxide in the atmosphere is sufficient to treat restenosis in the patient.

In another aspect, the invention provides a method of treating restenosis in a patient. The method includes identifying a patient suffering from or at risk for restenosis and administering to the patient a pharmaceutical composition comprising an
30 amount of carbon monoxide effective to treat restenosis in the patient. Restenosis can result from any angioplasty procedure, e.g., balloon angioplasty; laser angioplasty; artherectomy, e.g., directional atherectomy, rotational atherectomy, or extraction

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atherectomy; and/or any angioplasty procedure using a stent, or any combination of such procedures.

The invention also provides a method for performing vascular surgery, e.g., a transplant procedure, on a patient. The method includes: (a) performing vascular surgery (e.g., a transplant procedure) on a patient, and (b) before during and/or after (a), administering to the patient a pharmaceutical composition comprising an amount of CO effective to treat arteriosclerosis (e.g., intimal hyperplasia) in the patient.

In another aspect, the invention provides a method of inhibiting smooth muscle cell proliferation. The method includes providing a smooth muscle cell(s), and administering to the smooth muscle cell(s) an amount of CO effective to inhibit proliferation of the smooth muscle muscle cell(s). This can be carried out *in vivo* or *in vitro*.

A method of performing angioplasty in a patient is also provided, which includes providing an angioplasty device (e.g., a device described herein) capable of administering carbon monoxide to a patient, positioning the device in a blood vessel in need of angioplasty, performing angioplasty using the device, and before, during and/or after performing angioplasty, administering CO to the blood vessel using the device in an amount sufficient to treat intimal hyperplasia, to thereby perform angioplasty in the patient. The device can be any device capable of use in an angioplasty procedure, e.g., a device described herein. Alternatively or in addition, the device can be coated with a CO-releasing agent, e.g., a hydrogel, oil, or ointment, that releases CO or a CO-releasing compound.

In another aspect, the invention provides a vessel comprising medical grade compressed CO gas. The vessel can bear a label indicating that the gas can be used to reduce restenosis, arteriosclerosis, and/or intimal hyperplasia in a patient (e.g., a human patient), and/or that it can be used in an angioplasty procedure. The CO gas can be in an admixture with nitrogen gas, with nitric oxide and nitrogen gas, or with an oxygen-containing gas. ~~The CO gas can be present in the admixture at a concentration of at least about 0.025% e.g., at least about 0.05%, 0.10%, 0.50%, 1.0%, 2.0%, 10%, 50%, or 90%.~~

The invention also provides a kit that includes an angioplasty device (e.g., a balloon angioplasty device; a laser angioplasty device; an atherectomy device; and/or a stent) and a vessel containing CO (e.g., ~~a liquid and/or gaseous CO composition~~). The

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angioplasty device is capable of administering carbon monoxide to a patient. The kit can further include instructions for use of the carbon monoxide composition in a method for performing angioplasty in a patient.

In another aspect, the invention provides angioplasty devices (e.g., balloon
5 angioplasty devices, laser angioplasty devices, atherectomy devices, and stents, e.g., a device described herein) capable of administering CO to a patient and/or a blood vessel immediately before, during, and/or after an angioplasty procedure. In one embodiment, the angioplasty device comprises a CO composition. In another embodiment, the device is a balloon angioplasty device that includes an inflatable member (e.g., a
10 balloon) having a plurality of apertures, and a reservoir ~~containing CO (e.g., a liquid or gaseous CO composition)~~ connected to the inflatable member, such that CO can be delivered from the reservoir through the inflatable member and to the blood vessel.

Also within the invention is the use of CO in the manufacture of a medicament for treatment or prevention of a condition described herein, e.g., intimal hyperplasia,
15 restenosis, and/or arteriosclerosis. The medicament can also be used in a method for performing an angioplasty procedure and/or a transplantation procedure. The medicament can be in any form as described herein, e.g., a liquid or gaseous CO composition.

Unless otherwise defined, all technical and scientific terms used herein have the
20 same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Suitable methods and materials are described below, although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention. All publications, patent applications, patents, and other references mentioned herein are incorporated by reference in their
25 entirety. In case of conflict, the present specification, including definitions, will control. The materials, methods, and examples are illustrative only and not intended to be limiting.

Other features and advantages of the invention will be apparent from the following detailed description, and from the claims.

30 Brief Description of the Drawings

Fig. 1A is a photomicrograph (50X magnification) of a syngeneically transplanted aortic graft illustrating the effect of syngeneic transplantation on the graft.

145 145

Fig. 1B is a photomicrograph (50X magnification) of an allogeneically transplanted aortic graft illustrating the effect of allogeneic transplantation on the graft.

Fig. 1C is a photomicrograph (50X magnification) of an allogeneically transplanted aortic graft illustrating the effect of allogeneic transplantation on the graft
5 when the recipient is exposed to CO.

Fig. 1D is a photomicrograph (200X magnification) of a syngeneically transplanted aortic graft illustrating the effect of syngeneic transplantation on the graft.

Fig. 1E is a photomicrograph (200X magnification) of an allogeneically transplanted aortic graft illustrating the effect of allogeneic transplantation on the graft.

10 Fig. 1F is a photomicrograph (200X magnification) of an allogeneically transplanted aortic graft illustrating the effect of allogeneic transplantation on the graft when the recipient is exposed to CO.

Fig. 1G is a bar graph illustrating the mean relative areas (in arbitrary units) of the intima of aortic grafts transplanted syngeneically into air-exposed recipients
15 (Syng.), allogeneically into air-exposed recipients (Allo.), and allogeneically into CO-exposed recipients (Allo. + CO).

Fig. 1H is a bar graph illustrating the mean relative areas (in arbitrary units) of the media of aortic grafts transplanted syngeneically into air-exposed recipients (Syng.), allogeneically into air-exposed recipients (Allo.), and allogeneically into CO-
20 exposed recipients (Allo. + CO).

Fig. 1I is a bar graph illustrating the intima/media area ratio of aortic grafts transplanted syngeneically into air-exposed recipients (Syng.), allogeneically into air-exposed recipients (Allo.), and allogeneically into CO-exposed recipients (Allo. + CO).

Fig. 2A is a bar graph illustrating accumulation of activated leukocytes
25 (measured by counting total nuclei) in the adventitia of aortic grafts transplanted syngeneically into air-exposed recipients (Syngeneic), allogeneically into air-exposed recipients (Allogeneic) and allogeneically into recipients exposed to various concentrations of CO (CO 250 ppm; CO 500 ppm; and CO 750-1000 ppm).

Fig. 2B is a set of bar graphs illustrating accumulation of CD45, ED1, MHCII, and CD54 positive cells in the adventitia of aortic grafts transplanted syngeneically into
30 air-exposed recipients (Syng.), allogeneically into air-exposed recipients (Allog.), and allogeneically into CO-exposed recipients (Allo. + CO).

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Fig. 11B is a bar graph illustrating the mean intimal and media areas, and the intima/media area ratios, of carotid arteries from Sprague-Dawley rats exposed to room air (white bars) or NO (Black bars; 1 hour; 250 ppm) prior to balloon injury of the carotid artery.

5 Fig. 12A is a composite picture of a Western blot illustrating PAI-1 expression in SMC treated with and without serum (Serum and No Serum, respectively) and with and without CO (Air and CO, respectively) for 24 or 48 hours. Liver = whole cell lysates from rat liver homogenates treated without endotoxin (LPS). Liver + LPS = whole cell lysates from rat liver homogenates treated with endotoxin (LPS). TNF- α = control wherein TNF- α was added to the cell culture to stimulate expression of PAI-1.

Fig. 12B is a picture of a Western blot illustrating PAI-1 expression in untransplanted (control), transplanted (Allo. + Air), and CO-treated transplanted (Allo. + CO) aortas 56 days after transplantation.

Fig. 12C is a picture of a Commassie blue stained polyacrylamide gel used for the Western blot of Fig. 12B, which illustrates PAI-expression in untransplanted (control), transplanted (Allo. + Air), and CO-treated transplanted (Allo. + CO) aortas 56 days after transplantation.

Figs. 13A-13B illustrate an example of balloon angioplasty device capable of administering CO to a patient during an angioplasty procedure, at various stages of operation.

Figs. 13C-13D illustrate alternative embodiments of the balloon angioplasty device.

Figs. 14A-14B illustrate an example of a stent capable of administering CO to a patient during an angioplasty procedure, at various stages of operation.

25 Fig. 15 illustrates an example of balloon angioplasty device with multiple balloons designed to administer CO to a patient during an angioplasty procedure.

Fig 16 illustrates an example of an atherectomy device capable of administering CO to a patient during an angioplasty procedure.

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Detailed Description

The term "~~carbon monoxide~~" (or "CO") as used herein describes molecular carbon monoxide in its gaseous state, compressed into liquid form, or dissolved in

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aqueous solution. ~~The term "carbon monoxide composition" or "pharmaceutical composition comprising carbon monoxide"~~ is used throughout the specification to describe a gaseous or liquid composition containing carbon monoxide ~~that can be administered to a patient and/or a blood vessel, e.g., a patient (or blood vessel) subjected~~ to angioplasty, bypass surgery, transplant, or any other procedure that may/will result in intimal hyperplasia and/or arteriosclerosis. ~~A skilled practitioner will recognize which form of the pharmaceutical composition, e.g., gaseous, liquid, or both gaseous and liquid forms, is preferred for a given application.~~

The term "intimal hyperplasia" is an art-recognized term and is used herein to refer to proliferation of cells, e.g., smooth muscle cells, within the intima of a blood vessel. The skilled practitioner will appreciate that intimal hyperplasia can be caused by any number of factors, e.g., mechanical, chemical and/or immunological damage to the intima. Intimal hyperplasia can often be observed in patients, for example, following balloon angioplasty or vascular surgery, e.g., vascular surgery involving vein grafts (e.g., transplant surgery). "Arteriosclerosis," "arteriosclerotic lesion," "arteriosclerotic plaque," and "arteriosclerotic condition" are also art recognized term terms, and are used herein to describe a thickening and hardening of the arterial wall. The term "vasculature" as used herein refers to the vascular system (or any part thereof) of a body, human or non-human, and includes blood vessels, e.g., arteries, arterioles, veins, venules, and capillaries. The term "restenosis" refers to re-narrowing of an artery following angioplasty.

The term "angioplasty" is an art-recognized term and refers to any procedure, singly or in combination, involving remodeling of a blood vessel, e.g., dilating a stenotic region in a patient's vasculature to restore adequate blood flow beyond the stenosis. Such procedures include percutaneous transluminal angioplasty (PTA), which employs a catheter having an expansible distal end, i.e., an inflatable balloon (known as "balloon angioplasty"); laser angioplasty; extraction atherectomy; directional atherectomy; rotational atherectomy; stenting; and any other procedure for remodeling a blood vessel, e.g., an artery.

The terms "effective amount" and "effective to treat," as used herein, refer to an amount or a concentration of carbon monoxide utilized for a period of time (including acute or chronic administration and periodic or continuous administration) that is effective within the context of its administration for causing an intended effect or

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physiological outcome. Effective amounts of carbon monoxide for use in the present invention include, for example, amounts that prevent or reduce intimal hyperplasia following a procedure, e.g., angioplasty. Effective amounts of carbon monoxide also include amounts that prevent or reduce arteriosclerosis in a patient, e.g., a transplant patient. The term "treat(ment)" is used herein to describe delaying the onset of, inhibiting, or alleviating the detrimental effects of a condition, e.g., intimal hyperplasia and/or arteriosclerosis.

For gases, effective amounts of CO generally fall within the range of about 0.0000001% to about 0.3% by weight, e.g., 0.0001% to about 0.25% by weight, preferably at least about 0.001%, e.g., at least about 0.005%, 0.010%, 0.02%, 0.025%, 0.03%, 0.04%, 0.05%, 0.06%, 0.08%, 0.10%, 0.15%, 0.20%, 0.22%, or 0.24% by weight of CO. Preferred ranges of CO include 0.002% to about 0.24%, about 0.005% to about 0.22%, about 0.01% to about 0.20%, and about 0.02% to about 0.1% by weight. For liquid solutions of CO, effective amounts generally fall within the range of about 0.0001 to about 0.0044 g CO/100 g liquid, e.g., at least about 0.0001, 0.0002, 0.0004, 0.0006, 0.0008, 0.0010, 0.0013, 0.0014, 0.0015, 0.0016, 0.0018, 0.0020, 0.0021, 0.0022, 0.0024, 0.0026, 0.0028, 0.0030, 0.0032, 0.0035, 0.0037, 0.0040, or 0.0042 g CO/100 g aqueous solution. Preferred ranges include, e.g., about 0.0010 to about 0.0030 g CO/100 g liquid, about 0.0015 to about 0.0026 g CO/100 g liquid, or about 0.0018 to about 0.0024 g CO/100 g liquid. A skilled practitioner will appreciate that amounts outside of these ranges may be used depending upon the application.

The term "patient" is used throughout the specification to describe an animal, human or non-human, to whom treatment according to the methods of the present invention is provided. Veterinary and non-veterinary applications are contemplated by the present invention. The term includes but is not limited to mammals, e.g., humans, other primates, pigs, rodents such as mice and rats, rabbits, guinea pigs, hamsters, cows, horses, cats, dogs, sheep and goats.

The term "transplantation" is used throughout the specification as a general term to describe the process of transferring an organ or tissue into a patient. The term "transplantation" is defined in the art as the transfer of living tissues or cells from a donor to a recipient, with the intention of maintaining the functional integrity of the transplanted tissue or cells in the recipient (see, e.g., *The Merck Manual*, Berkow, Fletcher, and Beers, Eds., Merck Research Laboratories, Rahway, N.J., 1992). The

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Preparation of Gaseous Compositions

A CO composition may be a gaseous composition. Compressed or pressurized gas useful in the methods of the invention can be obtained from any commercial source, and in any type of vessel appropriate for storing compressed gas. For example, 5 compressed or pressurized gases can be obtained from any source that supplies compressed gases, such as oxygen, for medical use. The term "medical grade" gas, as used herein, refers to gas suitable for administration to patients as defined herein. The pressurized gas including CO used in the methods of the present invention can be provided such that all gases of the desired final composition (e.g., CO, He, NO, CO₂, 10 O₂, N₂) are in the same vessel, except that NO and O₂ cannot be stored together. Optionally, the methods of the present invention can be performed using multiple vessels containing individual gases. For example, a single vessel can be provided that contains carbon monoxide, with or without other gases, the contents of which can be optionally mixed with the contents of other vessels, e.g., vessels containing oxygen, 15 nitrogen, carbon dioxide, compressed air, or any other suitable gas or mixtures thereof.

Gaseous compositions administered to a patient according to the present invention typically contain 0% to about 79% by weight nitrogen, about 21% to about 100% by weight oxygen and about 0.0000001% to about 0.3% by weight (corresponding to about 1 ppb or 0.001 ppm to about 3,000 ppm) CO. Preferably, the 20 amount of nitrogen in the gaseous composition is about 79% by weight, the amount of oxygen is about 21% by weight and the amount of CO is about 0.0001% to about 0.25% by weight. The amount of CO is preferably at least about 0.001%, e.g., at least about 0.005%, 0.01%, 0.02%, 0.025%, 0.03%, 0.04%, 0.05%, 0.06%, 0.08%, 0.10%, 0.15%, 0.20%, 0.22%, or 0.24% by weight. Preferred ranges of CO include 0.005% to 25 about 0.24%, about 0.01% to about 0.22%, about 0.015% to about 0.20%, and about 0.025% to about 0.1% by weight. It is noted that gaseous CO compositions having concentrations of CO greater than 0.3% (such as 1% or greater) may be used for short periods (e.g., one or a few breaths), depending upon the application.

A gaseous CO composition may be used to create an atmosphere that comprises 30 CO gas. An atmosphere that includes appropriate levels of CO gas can be created, for example, by providing a vessel containing a pressurized gas comprising CO gas, and releasing the pressurized gas from the vessel into a chamber or space to form an atmosphere that includes the CO gas inside the chamber or space. Alternatively, the

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WHAT IS CLAIMED IS:

1. A method of performing angioplasty in a patient, the method comprising:
 - (a) performing angioplasty on the patient; and
 - (b) before, during, or after (a), administering to the patient a pharmaceutical
- 5 composition comprising an amount of carbon monoxide effective to treat intimal hyperplasia in the patient.
2. The method of claim 1, wherein the angioplasty comprises balloon angioplasty.
- 10 3. The method of claim 1, wherein the angioplasty comprises laser angioplasty.
4. The method of claim 1, wherein the angioplasty comprises directional atherectomy.
5. The method of claim 1, wherein the angioplasty comprises rotational atherectomy.
- 15 6. The method of claim 1, wherein the angioplasty comprises extraction atherectomy.
7. The method of claim 1, wherein the angioplasty comprises a stenting procedure.
- 20 8. The method of claim 1, wherein the angioplasty comprises balloon angioplasty and a stenting procedure.
9. A method of treating restenosis in a patient, the method comprising:
 - (a) providing a vessel containing a pressurized gas comprising carbon monoxide
- 25 gas;
- (b) identifying a patient suffering from or at risk for restenosis;
- (c) releasing the pressurized gas from the vessel, to form an atmosphere comprising carbon monoxide gas; and
- (d) exposing the patient to the atmosphere, wherein the amount of carbon monoxide in the atmosphere is sufficient to treat restenosis in the patient.

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10. A vessel comprising medical grade compressed carbon monoxide gas, the vessel bearing a label indicating that the gas can be used to reduce restenosis in a patient.

11. The vessel of claim 10, wherein the carbon monoxide gas is in admixture with an
5 oxygen-containing gas.

12. The vessel of claim 11, wherein the carbon monoxide gas is present in the admixture at a concentration of at least about 0.025%.

10 13. The vessel of claim 11, wherein the carbon monoxide gas is present in the admixture at a concentration of at least about 0.05%.

14. The vessel of claim 11, wherein the carbon monoxide gas is present in the admixture at a concentration of at least about 0.10%.

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15. The vessel of claim 11, wherein the carbon monoxide gas is present in the admixture at a concentration of at least about 1.0%.

16. The vessel of claim 11, wherein the carbon monoxide gas is present in the
20 admixture at a concentration of at least about 2.0%.

17. A vessel comprising medical grade compressed carbon monoxide gas, the vessel bearing a label indicating that the gas can be used to reduce arteriosclerosis in a patient.

25 18. The vessel of claim 17, wherein the carbon monoxide gas is present in the admixture at a concentration of at least about 0.025%.

19. The vessel of claim 17, wherein the carbon monoxide gas is present in the admixture at a concentration of at least about 0.05%.

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20. The vessel of claim 17, wherein the carbon monoxide gas is present in the admixture at a concentration of at least about 0.10%.

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21. The vessel of claim 17, wherein the carbon monoxide gas is present in the admixture at a concentration of at least about 1.0%.

22. The vessel of claim 17, wherein the carbon monoxide gas is present in the
5 admixture at a concentration of at least about 2.0%.

23. A vessel comprising medical grade compressed carbon monoxide gas, the vessel bearing a label indicating that the gas can be used in conjunction with an angioplasty procedure in a patient.
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24. The vessel of claim 23, wherein the carbon monoxide gas is present in the admixture at a concentration of at least about 0.025%.

25. The vessel of claim 23, wherein the carbon monoxide gas is present in the
15 admixture at a concentration of at least about 0.05%.

26. The vessel of claim 23, wherein the carbon monoxide gas is present in the admixture at a concentration of at least about 0.10%.

20 27. The vessel of claim 23, wherein the carbon monoxide gas is present in the admixture at a concentration of at least about 1.0%.

28. The vessel of claim 23, wherein the carbon monoxide gas is present in the admixture at a concentration of at least about 2.0%.
25

29. A method of treating restenosis in a patient, comprising:
 (a) identifying a patient suffering from or at risk for restenosis; and
 (b) administering to the patient a pharmaceutical composition comprising an amount of carbon monoxide effective to treat restenosis in the patient.

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30. The method of claim 29, wherein the restenosis results from balloon angioplasty.

31. The method of claim 29, wherein the restenosis results from laser angioplasty.

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32. The method of claim 29, wherein the restenosis results from directional atherectomy.

5 33. The method of claim 29, wherein the restenosis results from rotational atherectomy.

34. The method of claim 29, wherein the restenosis results from extraction atherectomy.

10 35. The method of claim 29, wherein the restenosis results from a stenting procedure.

36. A method of treating intimal hyperplasia in a patient, comprising:

(a) identifying a patient suffering from or at risk for intimal hyperplasia not resulting from a transplant procedure; and

15 (b) administering to the patient a pharmaceutical composition comprising an amount of carbon monoxide effective to treat intimal hyperplasia in the patient.

37. The method of claim 36, wherein the intimal hyperplasia results from balloon angioplasty.

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38. The method of claim 36, wherein the intimal hyperplasia results from laser angioplasty.

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39. The method of claim 36, wherein the intimal hyperplasia results from directional atherectomy.

40. The method of claim 36, wherein the intimal hyperplasia results from rotational atherectomy.

30 41. The method of claim 36, wherein the intimal hyperplasia results from extraction atherectomy.

42. The method of claim 36, wherein the intimal hyperplasia results from a stenting procedure.

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43. A method of performing angioplasty in a patient, comprising:

(a) providing an angioplasty device capable of administering carbon monoxide to a patient;

(b) positioning the device in a blood vessel in need of angioplasty;

5 (c) performing angioplasty using the device; and

(d) before, during or after (c), using the device to administer carbon monoxide to the blood vessel in an amount sufficient to treat intimal hyperplasia.

44. A kit comprising:

10 (a) an angioplasty device; and

(b) a vessel containing a carbon monoxide composition.

45. The kit of claim 44, wherein the angioplasty device is capable of administering carbon monoxide to a patient.

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46. The kit of claim 44, further comprising:

(c) instructions for use of the carbon monoxide composition in a method for performing angioplasty in a patient.

20 47. The kit of claim 44, wherein the carbon monoxide composition is a liquid composition.

48. The kit of claim 44, wherein the carbon monoxide composition is a gaseous composition.

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49. An angioplasty device comprising:

an inflatable member comprising a plurality of apertures; and

a reservoir comprising carbon monoxide gas and connected to the inflatable member, whereby the gas is provided to the inflatable member during inflation of the
30 inflatable member.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES

2020
Bogotá,

Abogada
Dilia Rodríguez D'Aleman

ASUNTO

Radicación	04-123506
Trámite	011
Evento	379
Actuación	430
Oficio	Nº 9 2 2 5
Folios	21

Patente de Invención	☒	Patente de Modelo de Utilidad	☐
Vía Nacional	☐		
Vía PCT (fase nacional)	☒	Cap. I	☐
		Cap. II	☒
No. Sol. Internacional		PCT /US02/14836	
Fecha de Presentación Internal.		Mayo 09 de 2002	

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 le comunica:

1. Documentos estudiados

- 1.1. Descripción: Folios: 30 a 66 como se radicó inicialmente.
- 1.2. Reivindicaciones: 1 a 12. Folios 67 a 68 como se radicó inicialmente. Reivindicación 15 cancelada. Reivindicaciones 13-15 modificadas. Folio 79. Nuevo capítulo reivindicatorio Folios 183 – 188.

1.3. Prioridad: No reivindica prioridad. Por lo tanto se toma como fecha para el estudio de patentabilidad la de presentación internacional. Folios: 4 a 28.

1.4. Respuesta del solicitante: Folios 178 a 188.

2. Objeto de la invención

Título de la solicitud: **Monóxido de carbono como un biomarcador y agente terapéutico.**

Nuevo título de la invención: **Formulación farmacéutica a base de monóxido de carbono (Folio 178).**

El **objeto de la presente solicitud** de patente de invención es proporcionar formulaciones farmacéuticas que contienen monóxido de carbono.

El **problema planteado** por el solicitante es la necesidad de formulaciones para pacientes que sufren los efectos del estrés oxidativo, o presentan estados de enfermedad subsiguientes al mismo como asma, enfisema, bronquitis y neumonía entre otras.

Para **solucionar este problema técnico**, la solicitud en estudio proporciona formulaciones que contienen cantidades efectivas de monóxido de carbono.

Reivindicaciones 1 a 26: Formulación farmacéutica caracterizada porque contiene cantidades efectivas de monóxido de carbono y el CO molecular es comprimido a forma líquida, esta disuelto en soluciones acuosas, o hace parte de una formulación gaseosa.

- *Clasificación Internacional de Patentes (IPC):* A61K45/00, A61K47/06, A61K47/08.

3. De la solicitud de Patente

3.1. Reivindicaciones (artículo 30 D 486)

Esta Oficina se permite señalar que dentro de las reivindicaciones se encontró falta de claridad debido a que:

- *Reivindicaciones 12 - 25:* Las formulaciones de las presentes reivindicaciones se están caracterizando por su uso, mas no por las características técnicas esenciales de una formulación farmacéutica, como lo son sus componentes y cantidades.

4. Determinación del Estado de la Técnica

La fecha que se ha tenido en cuenta para determinar el Estado de la Técnica es la fecha de presentación de la presentación internacional: 09/05/2002.

Teniendo en cuenta la fecha indicada se realizó la búsqueda en el estado de la técnica de documentos relacionados con la solicitud encontrándose el siguiente documento más relevante:

Nº	Documento	Título	Fecha
D1	CO04 84713	Métodos de tratamiento de enfermedad vascular	F. Prioridad: 13/02/2002

Documento D1 folios 189 a 204.

5. Análisis de patentabilidad (artículo 14 D486)

5.1. Novedad (artículo 16 D486)

- **La reivindicación 1** se refiere a una formulación farmacéutica caracterizada porque contiene entre 0.000001% y alrededor del 0.3% en peso de monóxido de carbono. Dicho CO es comprimido a forma líquida y está disuelto en soluciones acuosas (**Reivindicaciones 2 y 3**) y está presente entre 0.0001% y 0.25%, preferiblemente 0.005%, 0.010%, 0.02%, 0.025%, 0.03%, 0.04%, 0.05%, 0.06%, 0.08%, 0.10%, 0.15%, 0.20%, 0.22% o 0.24% de CO en peso (**Reivindicación 5**); o por lo menos 0.0001, 0.0002, 0.0004, 0.0006, 0.0008, 0.0010, 0.0013, 0.0014, 0.0015, 0.0016, 0.0018, 0.0020, 0.0021, 0.0022, 0.0024, 0.0026, 0.0028, 0.0030, 0.0032, 0.0035, 0.0037, 0.0040 o 0.0042g CO/100g de solución acuosa (**Reivindicación 10**).

Dicha formulación ve afectada su novedad, por el documento D1 que enseña una **composición farmacéutica que contiene monóxido de carbono (CO)** molecular en su estado gaseoso, comprimido a forma líquida, o disuelto solución acuosa (Folios 196-197). Dicha formulación contiene un rango de cantidades efectivas para el CO, que oscilan en un rango comprendido entre 0.000001% y 0.3% en peso, por ejemplo entre está presente entre 0.0001% y 0.25% en peso, preferiblemente al menos 0.005%, 0.010%, 0.02%, 0.025%, 0.03%, 0.04%, 0.05%, 0.06%, 0.08%, 0.10%, 0.15%, 0.20%, 0.22% o 0.24%. Los rangos preferidos de CO incluyen 0.002% a 0.24%, de 0.005% a 0.22%, de 0.01% a 0.20% y 0.02% a 0.01% por peso.

- Para soluciones liquidas, las cantidades efectivas de CO están presentes en un rango de 0.0001 a 0.0044 g CO/100 g liquido, por ejemplo al menos 0.0001, 0.0002, 0.0004, 0.0006, 0.0008, 0.0010, 0.0013, 0.0014, 0.0015, 0.0016, 0.0018, 0.0020, 0.0021, 0.0022, 0.0024, 0.0026, 0.0028, 0.0030, 0.0032, 0.0035, 0.0037, 0.0040 o 0.0042g CO/100g de solución acuosa. Los rangos preferidos incluyen por ejemplo de 0.0010 a 0.0030 g CO/100 g liquido, de 0.0015 a 0.0026 g CO/100 g liquido, o de 0.0018 a 0.0024 g CO/100 g liquido (Folio 198).

Teniendo en cuenta que la formulación divulgada en el documento D1 se superpone a la de la reivindicación 1, no es novedosa, pues ya se conocía en el estado de la técnica. Por lo tanto sus dependientes 2 a 11, tampoco lo son.

6. Conclusión:

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados así:

N°	Documento N°	Reivindicaciones afectadas	Requisito que afecta
D1	CO04 84713	1 - 11	Novedad

7. Respuesta a los argumentos del solicitante:

Una vez revisada la respuesta al concepto técnico N° 985 del 19 de julio de 2007, se tuvo en cuenta el nuevo capítulo reivindicatorio allegado por el solicitante, y se procedió a realizar nuevamente el análisis de patentabilidad del numeral 5, en donde se concluye que:

La formulación farmacéutica de las reivindicaciones 1 a 11 no es NOVEDOSA, toda vez que en la anterioridad nacional **CO04 84713** ya se había dado a conocer una composición farmacéutica **igual** a la reivindicada en la presente solicitud.

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a 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
11 JUL. 2008

CONCEPTO TÉCNICO No. 1669	EXAMINADOR TÉCNICO Código No. 202071
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