

Bogotá D.C. Noviembre 9 de 2007

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 06-127403- -00004-0000

Fecha: 2007-11-09 18:38:23 Dep: 2020 NUEORLACION
Tra: 2 PATENTES Lvs: 1 REGDEPOSITO
Act: 5 EXP. PLETO ON Folios: 2

Doctora
ALIX CARMENZA CESPEDES DE VERGEL
JEFE DIVISIÓN DE NUEVAS CREACIONES
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Ciudad

Referencia: Radicación: No. 2006-127403

Patente de Invención: NUEVA ASOCIACIÓN DE UN INHIBIDOR DE LA CORRIENTE SINUSAL IF Y DE UN INHIBIDOR DE LA ENZIMA DE CONVERSIÓN Y LAS COMPOSICIONES FARMACÉUTICAS QUE LA CONTIENEN

Asunto: Solicitud Examen de Patentabilidad

Publicación: Gaceta 579, Agosto 31 de 2007

JUAN MANUEL SERRANO CASTILLO, identificado con la cédula de ciudadanía No. 79'875.670 de Bogotá, portador de la tarjeta profesional de abogado No. 124.953 del C.S. de la J., en calidad de apoderado de la sociedad LES LABORATOIRES SERVIER, por medio del presente escrito me dirijo a su Despacho a fin de solicitar dentro del término legal se lleve a cabo el examen de patentabilidad de la solicitud de la referencia, de conformidad con lo establecido en el Artículo 44 de la Decisión 486 de la Comunidad Andina de Naciones.

Acompaño recibo que acredita el pago de las tasas correspondientes por valor de \$404.000.

De Usted, atentamente,


JUAN MANUEL SERRANO CASTILLO
C.C. No. 79'875.670 de Bogotá D.C.
T.P. No. 124.953 del C.S. de la J.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 06-127403- -00004-0000

Fecha: 2007-11-09 16:39:23 Dep. 2020 NULCREACION
Lvs 2 PATENTES Lvs 1 REGDEPOSITO
Act 558 RELACION Faltas 2

RECIBO OFICIAL DE CAJA : 07 - 91,854
FECHA : NOVIEMBRE 9 DE 2007

***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PAGO	Vr. PAGO
ALEXANDER BARRETO	CONSIGNACION	BANCO POPULAR	050-00110-6	47350838	09/11/2007	4,394,000.00
ALEXANDER BARRETO	CONSIGNACION	BANCO POPULAR	050-00110-6	47350840	09/11/2007	256,000.00
ALEXANDER BARRETO	CONSIGNACION	BANCO POPULAR	050-00110-6	47350841	09/11/2007	1,290,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01 SOLICITUDES	85 EXAMEN DE PATENTABILIDAD DE INVEN	404,000.00
TOTAL :			\$ 404,000.00

SON: CUATROCIENTOS CUATRO MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

DIVISIÓN DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 06-127403

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

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No **579** DE

FECHA **31 DE AGOSTO DE 2007** EL TÉRMINO HÁBIL SEÑALADO POR LA

LEY EXPIRA EL **28 DE NOVIEMBRE DE 2007**

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

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI _____

NO X

132

D1



US 20040242565A1

(19) **United States**

(12) **Patent Application Publication**

Toshima et al.

(10) **Pub. No.: US 2004/0242565 A1**

(43) **Pub. Date: Dec. 2, 2004**

(54) **MEDICINAL COMPOSITION FOR PREVENTION OF OR TREATMENT FOR CEREBROVASCULAR DISORDER AND CARDIOPATHY**

(76) **Inventors:** Yoshinori Toshima, Shizuoka (JP);
Asako Hitomi, Shizuoka (JP);
Shin-ichi Satoh, Shizuoka (JP); Ichiro
Ikegaki, Shizuoka (JP)

Correspondence Address:
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747 (US)

(21) **Appl. No.: 10/488,699**

(22) **PCT Filed: Jul. 30, 2002**

(86) **PCT No.: PCT/JP02/07712**

(30) **Foreign Application Priority Data**

Sep. 11, 2001 (JP) 2001-274846

Publication Classification

(51) **Int. Cl.⁷ A61K 31/551**

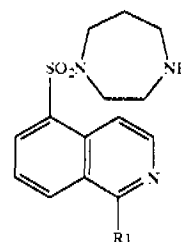
(52) **U.S. Cl. 514/218**

(57) **ABSTRACT**

A pharmaceutical composition comprising at least one of components (a) and at least one of components (b) shown in below:

(a) a compound represented by the general formula (I)

(I)



(wherein R1 represents a hydrogen atom or a hydroxyl group) or an acid addition salt or hydrate thereof; and

(b) an ameliorant of cerebral circulation, a vasodilator, a cerebral protecting drug, an brain metabolic stimulants, an anticoagulant, an antiplatelet drug, a thrombolytic drug, an ameliorant of psychiatric symptom, an antihypertensive drug, an antianginal drug, a diuretic, a cardiotonic, an antiarrhythmic drug, an antihyperlipidemic drug, an immunosuppressant, or a pharmaceutically acceptable salt (except the components shown in (a)). It is useful as a preventive or remedy for cerebrovascular disorders and cardiac diseases.

US 2004/0242565 A1

Dec. 2, 2004

2

[0014] Moreover, the drug of components (b), which is used together with the component (a) represented by the general formula (1) according to the present invention, includes pharmaceutically acceptable salts thereof.

[0015] (2) The pharmaceutical composition according to item (1), in which the vasodilator shown in (b) is a calcium channel blocking drug and the calcium channel blocking drug is nimodipine.

[0016] (3) The pharmaceutical composition according to item (1), in which the thrombolytic drug shown in (b) is a tissue plasminogen activator and the tissue plasminogen activator is alteplase.

[0017] (4) The pharmaceutical composition according to item (1), in which the antiplatelet drug shown in (b) is clopidogrel or aspirin.

[0018] (5) The pharmaceutical composition according to item (1), in which the antianginal drug shown in (b) is a calcium channel blocking drug and the calcium channel blocking drug is amlodipine or nifedipine.

[0019] (6) The pharmaceutical composition according to item (1), in which the antianginal drug shown in (b) is a nitrate drug and the nitrate drug is isosorbide.

[0020] (7) The pharmaceutical composition according to item (1), in which the antianginal drug shown in (b) is a β -adrenaline receptor antagonist and the β -adrenaline receptor antagonist is atenolol.

[0021] (8) The pharmaceutical composition according to item (1), which is provided for prevention or treatment of a cerebrovascular disorder.

[0022] (9) The pharmaceutical composition according to item (8), in which the cerebrovascular disorder is selected from the group consisting of: cerebral infarction, cerebral thrombosis, cerebral embolism, cerebral hemorrhage, cerebral vasospasm, subarachnoid hemorrhage, transient ischemic attack, cerebral arteriosclerosis, head trauma, and cerebral edema; and psychiatric symptom, neurologic symptom, disorder in activities of daily living disability, amnesia, and dementia, which are based on those diseases.

[0023] (10) The pharmaceutical composition according to item (8), in which the cerebrovascular disorder is selected from the group consisting of: cerebral infarction and cerebral vasospasm; and neurologic symptom and disorder in activities of daily living disability, which are based on those diseases.

[0024] (11) The pharmaceutical composition according to item (8), in which the cerebrovascular disorder is selected from the group consisting of: cerebral vasospasm developed after subarachnoid hemorrhage; and neurologic symptom and disorder in activities of daily living disability, which are associated with those diseases.

[0025] (12) The pharmaceutical composition according to item (2), which is provided for prevention or treatment of a cerebrovascular disorder.

[0026] (13) The pharmaceutical composition according to item (12), in which the cerebrovascular disorder is selected from the group consisting of: cerebral infarction, cerebral thrombosis, cerebral embolism, transient ischemic attack, cerebral arteriosclerosis, head trauma, and cerebral edema;

and psychiatric symptom, neurologic symptom, disorder in activities of daily living disability, amnesia, and dementia, which are based on those diseases.

[0027] (14) The pharmaceutical composition according to item (12), in which the cerebrovascular disorder is selected from the group consisting of: cerebral infarction and cerebral vasospasm; and a neurologic symptom and disorder in activities of daily living disability, which are based on those diseases.

[0028] (15) The pharmaceutical composition according to item (12), in which the cerebrovascular disorder is selected from the group consisting of: cerebral vasospasm developed after subarachnoid hemorrhage; and neurologic symptom and disorder in activities of daily living disability, which are associated with those diseases.

[0029] (16) The pharmaceutical composition according to item (3), which is provided for prevention or treatment of a cerebrovascular disorder.

[0030] (17) The pharmaceutical composition according to item (16) in which the cerebrovascular disorder is selected from the group consisting of: cerebral infarction, cerebral thrombosis, cerebral embolism, and transient ischemic attack; and neurologic symptom and disorder in activities of daily living disability, which are based on those diseases.

[0031] (18) The pharmaceutical composition according to item (4), which is provided for prevention or treatment of a cerebrovascular disorder.

[0032] (19) The pharmaceutical composition according to item (18), in which the cerebrovascular disorder is selected from the group consisting of: cerebral infarction, cerebral thrombosis, cerebral embolism, cerebral hemorrhage, cerebral vasospasm, subarachnoid hemorrhage, transient ischemic attack, cerebral arteriosclerosis, head trauma, and cerebral edema; and psychiatric symptom, neurologic symptom, disorder in activities of daily living disability, amnesia, and dementia, which are based on those diseases.

[0033] (20) The pharmaceutical composition according to item (1), which is provided for prevention or treatment of a cardiac disease.

[0034] (21) The pharmaceutical composition according to item (20), in which the cardiac disease is selected from the group consisting of: myocardial ischemia, angina pectoris, myocardial infarction, complication of myocardial infarction, reperfusion injury in treatment of myocardial infarction, and cardiac failure.

[0035] (22) The pharmaceutical composition according to item (20), in which the cardiac disease is angina pectoris.

[0036] (23) The pharmaceutical composition according to item (5), which is provided for prevention or treatment of a cardiac disease.

[0037] (24) The pharmaceutical composition according to item (23), in which the cardiac disease is selected from the group consisting of: myocardial ischemia, angina pectoris, myocardial infarction, complication of myocardial infarction, reperfusion injury in treatment of myocardial infarction, and cardiac failure.

[0038] (25) The pharmaceutical composition according to item (23), in which the cardiac disease is angina pectoris.

134

US 2004/0242565 A1

Dec. 2, 2004

4

olol, celiprolol, bopindolol, bevantolol, labetalol, alprenolol, amosulalol, arotinolol, befunolol, bucumolol, bufetolol, buferalol, buprandolol, butylidine, butofilolol, carazolol, cetamolol, cloranolol, dilevalol, epanolol, levobunolol, mepindolol, metipranolol, moprolol, nadoxolol, nevilolol, oxprenolol, practol, pronetalol, sotalol, sufinalol, talindolol, tertalol, toliprolol, and esmolol), α -receptor blocking drugs (such as amosulalol, prazosin, terazosin, doxazosin, bunazosin, urapidil, phenolamine, arotinolol, dapiprazole, fenspiride, indoramin, labetalol, naftopidil, nicergolone, tamsulosin, tolazoline, trimazosin, and yohimbine), sympathetic nerve inhibitors (such as clonidine, guanfacine, guanabenz, methyl dopa, and reserpine), hydralazine, tobradiazine, budralazine, and cadralazine. Examples of the antianginal drug include nitrate drugs (such as amyl nitrite, nitroglycerin, and isosorbide), β -adrenaline receptor blocking drugs (such as propranolol, pindolol, indenolol, carteolol, bunitrolol, atenolol, acebutolol, metoprolol, timolol, nipradilol, penbutolol, nadolol, tilisolol, carvedilol, bisoprolol, betaxolol, celiprolol, bopindolol, bevantolol, labetalol, alprenolol, amosulalol, arotinolol, befunolol, bucumolol, bufetolol, buferalol, buprandolol, butylidine, butofilolol, carazolol, cetamolol, cloranolol, dilevalol, epanolol, levobunolol, mepindolol, metipranolol, moprolol, nadoxolol, nevilolol, oxprenolol, practol, pronetalol, sotalol, sufinalol, talindolol, tertalol, toliprolol, and xybenolol), calciumchannel blocking drugs (such as amlodipine, felodipine, nicardipine, bamidipine, benidipine, manidipine, cilnidipine, nisoldipine, nitrendipine, nifedipine, nilvadipine, felodipine, amlodipine, diltiazem, bepridil, clemetiazem, phenidine, galopamil, mibefradil, prenylamine, semotiadil, terodiline, verapamil, cilnidipine, elgodipine, isradipine, lacidipine, lercanidipine, nimodipine, cinnarizine, flunarizine, lidoflazine, lomerizine, bencyclane, etafenone, and perhexiline) trimetazidine, dipyridamole, etafenone, dilazep, trapidil, nicorandil, enoxaparin, and aspirin. Examples of the diuretic include thiazide diuretics (such as hydrochlorothiazide, methyclothiazide, trichlormethiazide, benzylhydrochlorothiazide, and penflutizide), loop diuretics (such as furosemide, etacrynic acid, bumetanide, piretanide, azosemide, and torasemide), K^+ sparing diuretics (spironolactone, triamterene, and potassiumcanrenoate), osmotic diuretics (such as isosorbide, D-mannitol, and glycerin), nonthiazide diuretics (such as meticrane, triamide, chlorthalidone, and mefruside), and acetazolamide. Examples of the cardiotonic include digitalis formulations (such as digitoxin, digoxin, methyl digoxin, deslanoside, vesnarinone, lanatoside C, and proscillaridin), xanthine formulations (such as aminophylline, choline theophylline, diprophyllyline, and proxiphylline), catecholamine formulations (such as dopamine, dobutamine, and docapamine), PDE III inhibitors (such as amrinone, olprinone, and milrinone), denopamine, ubidecarenone, pimobendan, levosimendan, aminoethylsulfonic acid, vesnarinone, carperitide, and colforsin daropate. Examples of the antiarrhythmic drug include ajmaline, pirlmenol, procainamide, cibenzoline, disopyramide, quinidine, aprindine, mexiletine, lidocaine, phenylein, pilsicainide, propafenone, flecainide, atenolol, acebutolol, sotalol, propranolol, metoprolol, pindolol, amiodarone, nifekalant, diltiazem, bepridil, and verapamil. Examples of the antihyperlipidemic drug include atorvastatin, simvastatin, pravastatin sodium, fluvastatin sodium, cefinofibrate, clofibrate, simfibrate, fenofibrate, bezafibrate, colestumide, and colestyramine. Examples of the immuno-

suppressant include azathioprine, mizoribine, cyclosporine, tacrolimus, gusperimus, and methotrexate.

[0053] In addition, examples of the drugs of the present invention shown in (b) to be used together with the compound shown in (a) or pharmaceutically acceptable salts thereof include carperitide, eplerenone, vatanidipine, lemil-dipine, clevidipine, zofenopril, olmesartan, KR11-594, oma-patrilat, fasidotril, ccadotril, sampatrilat, MDL-100240, Z-13752A, xamoterol, molsidomine, ivabradine, cariporide, etomoxir, HMR-1098, eniporide, B111-890, SI-65.1708, triflusal, tinzaparin, pamicogrel, tirofiban, eptifibatide, abe-ximab, YM-33, BGC-728, CI-1031, NAp2, SB-249417, nesiritide, urotilatin, BG-9928, DTI-0017, monosialogan-glioside GM-1, tirilazad, nicaraven, EGB-761, ebselen, NXY-059, EPC-K1, sitaxsentan, tezosentan, ambrisentan, zonampanel, enrasentan, darusentan, J-104132, BMS-207940, BSF-302146, TBC-3711, ABT-546, Ro-61-1790, aliskiren, vepalimomab, VPA-985, SR-121463, toborinone, MCC-135, MCI-154, treprostinol, repinotan, SUN-N4057, dexanabinol, UK-315716, irampanel, DY-9760e, pexeli-zumab, UK-279276, and NS-7.

[0054] The pharmaceutical composition of the present invention includes not only a mixture in which at least one of the above-mentioned components (a) and at least one of the above-mentioned components (b) have been mixed previously, but also a nonmixed combination such as a form of a kit or a pharmaceutical package.

[0055] On preparing the pharmaceutical composition of the present invention as a formulation having a form suitable for administration, there may be mixed: the compound represented by the general formula (I) (wherein R1 represents a hydrogen atom or a hydroxyl group) provided as an active ingredient or an acid addition salt or hydrate thereof; at least one treatment agent of the drugs shown in (b) or a pharmaceutically acceptable salt thereof; and a pharmaceutically acceptable carrier which is known as a supplementary component. Examples of the carrier include: gelatin; saccharides such as lactose and glucose; starches such as wheat, rice, and corn starch; fatty acids such as stearic acid; fatty acid salts such as calcium stearate and magnesium stearate; talc; vegetable oils; alcohols such as stearic alcohol and benzyl alcohol; gum; and polyalkylene glycol.

[0056] Moreover, general examples of a liquid carrier include: water; physiological saline; a solution containing dextrose or a similar saccharide; and glycols such as ethylene glycol, propylene glycol, polyethylene glycol, and polypropylene glycol. When the pharmaceutical composition of the present invention is prepared as a capsule, typically, gelatin is preferably used.

[0057] The pharmaceutical composition of the present invention, which is composed of: the carrier provided as a supplementary component; the compound represented by the general formula (I) (wherein R1 represents a hydrogen atom or a hydroxyl group) provided as an active ingredient or an acid addition salt or hydrate thereof; and at least one treatment agent of the drugs shown in (b) or a pharmaceutically acceptable salt thereof, includes an active ingredient in an amount of, typically 0.01 wt % or more and 80 wt % or less, preferably 60 wt % or less, for example.

[0058] In addition, the present invention relates to a method of treating a cerebrovascular disorder or a cardiac



US 20040058896A1

(19) **United States**

(12) **Patent Application Publication**

Dietrich et al.

(10) **Pub. No.: US 2004/0058896 A1**

(43) **Pub. Date: Mar. 25, 2004**

(54) **PHARMACEUTICAL PREPARATION
COMPRISING AN ACTIVE DISPERSED ON A
MATRIX**

(76) **Inventors: Rango Dietrich, Konstanz (DE);
Rudolf Linder, Konstanz (DE);
Hartmut Ney, Konstanz (DE)**

**Correspondence Address:
NATH & ASSOCIATES PLLC
1030 FIFTEENTH STREET, N.W.
SIXTH FLOOR
WASHINGTON, DC 20005 (US)**

(21) **Appl. No.: 10/433,398**

(22) **PCT Filed: Dec. 6, 2001**

(86) **PCT No.: PCT/EP01/14307**

(30) **Foreign Application Priority Data**

Dec. 7, 2000 (EP) 00126847.3

Publication Classification

(51) **Int. Cl.⁷ A61K 31/56; A61K 31/4439**

(52) **U.S. Cl. 514/171; 514/179; 514/338**

(57) **ABSTRACT**

The present invention relates to the field of pharmaceutical technology and describes a novel advantageous preparation for an active ingredient. The novel preparation is suitable for producing a large number of pharmaceutical dosage forms. In the new preparation an active ingredient is present essentially uniformly dispersed in an excipient matrix composed of one or more excipients selected from the group of fatty alcohol, triglyceride, partial glyceride and fatty acid ester.

US 2004/0058896 A1

4

Mar. 25, 2004

quinazolin; RS-97078; proroquine; sertindole; SGB-1534; SL-89.0591; tamsulosin; tedisamil; terazosin; tibalosin; tiadiazosin; tolazoline; trimazosin; upidosin; urapidil; yohimbine; zolertine.

[0053] ACE inhibitors:

[0054] alacepril; benazepril; benazeprilat; BMS-189921; BRL-36378; captopril; ceronapril; CGS-13928C; cilazapril; cilazaprilat; dehydrocaptopril; delapril; enalapril; enalaprilat; EU4867; EXP-7711; fasidotril; fosinopril; fosinoprilat; idrapril; imidapril; imidaprilat; indolapril; libenzapril; lisinopril; mixanpril; moexipril; moexiprilat; moveltipril; omapatrilat; orbutopril; pentopril; perindopril; perindoprilat; pivopril; quinapril; quinaprilat; ramipril; rentiapril; sampatrilat; SCH-54470; spirapril; spiraprilat; temocapril; temocaprilat; teprotide; trandolapril; trandolaprilat; utibapril; utibaprilat; Z-13752A; zabicipril; zofenopril; zofenoprilat.

[0055] Renin antagonists

[0056] CGP-38560; ciprokiren; CP-108671; enalkiren; ES-6864; FK-906; remikiren; terlakiren; zankiren.

[0057] Antiallergics such as PDE inhibitors:

[0058] arofilline; atizoram, AWD-12-281 (N-(3,5-dichloro-4-pyridinyl)-2-[1-(4-fluorobenzyl)-5-hydroxy-1H-indol-3-yl]-2-oxoacetamide); BAY-19-8004 (ethanesulfonic acid 2-(2,4-dichlorophenylcarbonyl)-3-ureidobenzofuran-6-yl ester); benafentrine; CC-1088; CDC-801 (β -[3-(cyclopentylloxy)-4-methoxyphenyl]-1,3-dihydro-1,3-dioxo-2H-isindole-2-propanamide); CDC-998; CI-1018; cilomilast (cis-[4-cyano-4-(3-cyclopentylloxy-4-methoxyphenyl)cyclohexane-1-carboxylic acid]; cilostazol; ciprofylline (8-amino-1,3-bis(cyclopropylmethyl)xanthine); D-4396; D-4418 [N-(2,5-dichloro-3-pyridinyl)-8-methoxy-5-quinolinecarboxamide]; darbufelone; denbufylline; ER-21355; flaminast; ibudilast; IC-485; indolidan; laprafylline; lixazinone; MESOPRAM [(+)-(R)-5-(4-methoxy-3-propoxyphenyl)-5-methyloxazolidin-2-one]; nitraquazone; NM-702; olprinone; ORG-20241 (4-(3,4-dimethoxyphenyl)-N2-hydroxythiazole-2-carboxamide); piclamilast; pumafentrine ((-)-cis-9-ethoxy-8-methoxy-2-methyl-1,2,3,4,4a,10-Ob-hexahydro-6-(4-diisopropylaminocarbonylphenyl)benzo[c][1,6]-naphthyridine); quazinone; RO-15-2041; roflumilast (3-(cyclopropylmethoxy)-N-(3,5-dichloro-pyridyl)-4-(difluoromethoxy)-benzamide); rolipram; SCH-351591; SH-636; tibencast (5,6-diethoxybenzo[b]thiophene-2-carboxylic acid); tolafrine; trequinsin; V-11294A (3-{[3-(cyclopentylloxy)-4-methoxyphenyl]methyl}-N-ethyl-8-(1-methylethyl)-3H-purin-6-amine); YM-58997 (4-(3-bromophenyl)-1-ethyl-7-methyl-1,8-naphthyridin-2(1H)-one); YM-976 (4-(3-chlorophenyl)-1,7-diethylpyrido[2,3-d]pyrimidin-2(1H)-one); zardaverine.

[0059] Other antiallergics for asthma treatment:

[0060] ablukast; atreleuton; bunaprolast; cinalukast; cromitrite; cromolyn; FPI-55712; iralukast; isamox-

ole; ketoufen; L-648051; leveromakalim; lodoxamide ethyl; lodoxamide tromethamine; montelukast; oxarbazole; piriprost; pirolate; pobilukast; pranlukast; ritolukast; sulukast; tiaramide; Ubenelast; tomelukast; verlukast; verofylline; zafirlukast; zileuton.

[0061] Other antiallergics (for example leukotriene antagonists):

[0062] acitazanolast; acrivastine; alinastine; altoqualine; amlexanox; andolast; astemizole; ataquimast; azatadine; azelastine; bamipine; barmastine; batebustast; BAY-X-1005; BAY-X-7195; bepiastine; bepotaastine; BIL-284; bilastine; binizolast; buclizine; bunaprolast; cabastine; carebastine; cetirizine; CI-959; ciproxifan; clemastine; CMI-977; cromoglicic acid; cromolyn sodium; dametralast; desloratadine; dlmenhydrinate; diphenhydramine; doqualast; dorastine; E-4704; efetirizine; emedastine; enofelast; enoxamast; ebastine; eclazolast; epinastine; fexofenadine; flezelastine; HSR-609; KCA-757; levocabastine; levocetirizine; linetastine; loratadine; LY-293111; mapinastine; mequitamium iodide; mequitazin; minocromil; mizolastine; MK-886; moxastine; moxilubant; nedocromil; nedocromil calcium; nedocromil sodium; nivimdone; noberastine; norastemizole; octastine; ONO-4057; ontazolast; oxatomide; pemirolast; pentigetide; perastine; piclopastine; picumast; pirquinozol; poisonoak extract; probicromil; proxicromil; quazolast; quifenadine; quinotolast; raxofelast; repirinast; REV-5901-A; rocastine; rupatadine; SKF-S-106203; sequifenadine; setastine; sudexanox; tagorizine; talastine; tanzolast; tazifylline; temelastine; terfenadine; tetrazolast; texacromil; thiazinamium chloride; tiacrilast; tiprinast meglumine; tixanox; tranilast; WY-50295; ZD-3523; zepastine.

[0063] Amebicides:

[0064] 1B-bisamidine; berythromycin; bialamicol; carbarsone; chloroquine; chloroquine; clamoxyquin; ciloquinol; dehydrocmetine; difetarsone; diloxanide; emetine; etofamide; iodoquinol; lachnumon; lirolidine; paromomycin sulfate; pinafide; quinfamide; satranidazole; stevaldil; stirimazole; symetine; teclozan; tetracycline; tilbroquinol.

[0065] Antiandrogens:

[0066] abiraterone; benorterone; cioterone; cyprotone; delanterone; delmadinone; drospirenone; epitostanol; inocoterone; L-654066; minamestane; norgestimate; osaterone; oxendolone; progesterone; rosterelone; topterone; zanoterone.

[0067] Antianemics:

[0068] ancestim; diciferron; epoetin alfa; epoetin beta; epoetin epsilon; epoetin gamma; epoetin omega; ferrous sulfate, FK-352; folic acid; gleptoferron; glutathione monoisopropyl ester; leucovorin calcium; tucaresol; TYB-5220; velaresol;

[0069] Antianginals:

[0070] alinidine; amiodarone; amlodipine besylate; amlodipine maleate; azaclozine; bamidipine; ber-

**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCIÓN DE NUEVAS CREACIONES**

2020
Bogotá, D.C.,

Abogado:
JUAN MANUEL SERRANO CASTILLO

ASUNTO:	Radicación No.	06 01 27403
	Trámite	002
	Evento	001
	Actuación	430
	Oficio	
	Folios	14804

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

Documentos estudiados:

Descripción:	Folios 32 a 41 como se radicó inicialmente.
Reivindicaciones:	Folios 42 a 43 como se radicó inicialmente.
Prioridad:	FR 05.13006 (21.12.2005)

Objeto de la Invención

Título de la invención: "Nueva asociación de un inhibidor de la corriente sinusoidal y de un inhibidor de la enzima de conversión y las composiciones farmacéuticas que la contienen"

Problema Técnico Planteado: "Necesidad de un tratamiento alternativo para el tratamiento de la hipertensión arterial"

Solución: "Proporcionar tratamientos alternativos para la hipertensión arterial que contienen la asociación de un inhibidor selectivo y de un agente inhibidor de la enzima de angiotensina"

IPC: A61K 31/55

Reivindicaciones relativas a un uso o a un segundo uso (Art 14 y 21 D 486)

La reivindicación 10 se refiere al uso de la asociación según una de las reivindicaciones 1 a 6 para elaborar composiciones farmacéuticas destinadas al tratamiento de la hipertensión arterial, al respecto se anota que esta debe ser eliminada del capítulo reivindicatorio ya que hace referencia a un uso.

Determinación del Estado de la Técnica

El Estado de la Técnica se determinó con base en la fecha de presentación 2005.12.21 y se encontraron los siguientes documentos que anticipan el objeto de esta solicitud:

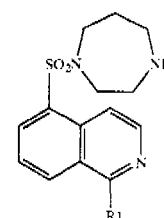
Item	Documento	Título	Fecha de Publicación
D1	US 2004/0242565	<i>Medicinal composition for prevention of or treatment for cerebrovascular disorder and cardiopathy</i>	Dec. 02, 2004
D2	US 2004/0058896	<i>Pharmaceutical preparation comprising an active dispersed on a matrix</i>	Mar. 25, 2004

Análisis de Patentabilidad (Art 14 D486)

Nivel Inventivo (Art18 D486)

La reivindicación independiente 1 dice: "Asociación de un inhibidor selectivo y específico de la corriente sinusal If y de un agente inhibidor de la enzima de conversión de la angiotensina.", y la reivindicación independiente 7 dice: "Composiciones farmacéuticas que contienen como principio activo un inhibidor selectivo y específico de la corriente sinusal If en asociación con un agente inhibidor de la enzima de conversión de la angiotensina según una de las reivindicaciones 1 a 6, solos o en combinación con uno o varios excipientes farmacéuticamente aceptables."

D1 presenta una composición farmacéutica capaz de tratar trastornos cerebrovasculares y enfermedad cardíaca (párrafo 1), la cual incluye (a) un compuesto representado por la fórmula I (derecha) y al menos uno de los componentes (b), dentro de este grupo (b) están fármacos antihipertensivos y diuréticos entre otros, y los ejemplos de los fármacos antihipertensivos incluyen inhibidores de la enzima convertidora de la angiotensina como el perindopril y antagonistas de la angiotensina II como losartán (párrafo 52). Además de los ejemplos mencionados se incluyen agentes antianginosos como la ivabradina (párrafo 53). La composición farmacéutica de la presente invención está compuesta por: el compuesto representado por la fórmula I y al menos un agente activo del grupo (b) o una sal farmacéuticamente aceptable del mismo (párrafo 57).



La solicitud se diferencia de D1 en que la asociación y composición farmacéutica reveladas por la presente solicitud carecen de los compuestos derivados de la fórmula I revelados por la anterioridad.

El Efecto Técnico que logra la diferencia es proporcionar tratamientos alternativos para la hipertensión arterial que contienen la asociación de un inhibidor selectivo y de un agente inhibidor de la enzima de angiotensina

El Problema Técnico Objetivo de esta solicitud es la necesidad de un tratamiento alternativo para el tratamiento de la hipertensión arterial.

D2 se refiere a una preparación en la que un ingrediente activo es uniformemente disperso en una matriz de excipientes seleccionados (párrafo 1), los ingredientes activos pueden ser inhibidores de la ECA: como por ejemplo: perindopril y fármacos antianginosos como ivabradina (párrafo 60).

El experto en la materia habría sido motivado por D2 a asociar de perindopril e ivabridina y a su vez a incluir en la composición farmacéutica de D1 dicha asociación de IECAs como perindopril y antianginosos como ivabridina.

Se concluye que las reivindicaciones 1 y 7 y sus dependientes carecen de nivel inventivo.

Conclusión

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

Nº	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	US 2004/0242565	1-9	Nivel inventivo
D2	US 2004/0058896	1-9	Nivel inventivo

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de 60 días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

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



JESUS FERNEL GARCIA GARCIA
Director de Nuevas Creaciones (E)

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

CONCEPTO TECNICO NUMERO: 4169	EXAMINADOR TÉCNICO Código:202092
----------------------------------	-------------------------------------