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Tea. 11 PATENTEIVII Eve: 379 FASENACIONALU corn
Act. 538 PETICION Folios: 15
Seæor
SUPERINTENDENTE DE INDUSTRIA V COMERCIO DIVISION DE NUEVAS CREACIONES
E S. D.

Re: Pi-NESTEC S.A.-Patente de Invención en Fase Nacional PCT. para
"UN METODO V COMPOSICXÔN PARA ME)ORAW NLETRICXONALMENTE EL CONTROL DE LA GLUCOSA V LA
ACCIÔN DE LA INSULINA"-Clase A23L 1/29 A23L 1L305.-
Expediente nimero 07-104268.- S

1. Me refiero & memorial de 13 de Diciembre de 2007

2. De conformidad con lo dispuesto en el ArtIculo 5212 de la Circular Externa
No 03 de 28 de AbrU de 2003, y estando dentro del plazo de seis meses contados desde la fecha de la publlcación de la solicitud en la Gaceta de la Propiedad Industrial nümero 597 de 31 de Octubre de 2008, solicito a ese Despacho proceder a realizar el examen de patentabilidad de la presente invención.

3. De otro modo, par medlo del presente escrito me permito informar a ese
Despacho que la solicitud de la referenda fue presentada a nombre de la sociedad NOVARTXS AG. Sin embargo, recientemente Østa sociedad ha cedido todos sus derechos a la sociedad NESTEC S.A., quedando esta iltima como titular de la presente solicitud.

Por lo cual, atentamente solicito a ese Despacho que el Certificado de Patente correspondiente sea expedido a nombre de NESTEC S.A., sociedad organizada y existente de conformidad con las leyes de Suiza, dornicillada en Vevey, Suiza.

LLOREDA & CIA. S.A.

En cons cuenci, anexo me permito presentar el doc
traspaso de socied d solicitante NOVARTIS AG a Ia so i d debidamente a ostilla o y junto con sus Traducciones Ofici I s 150 y 077/09 debid mente legalizadas hasta por ei Minis
Exteriores baj los imeros 888443 y 888442 del, 18
respectivamen

4. Anexos e per Ito presentar:

(a) For ularlo nico de modificaciones y correcciones

(b) Reci o No 9-23.193, que acredita el pago de to
mod ficació causa; y

(c) Rec o nil ero 09-21.357, expedido por la
Inddi tria y Comercio, que acredita el pago d

exa en ca sa.

5. De la mis a ma ra, par media del presente escrtito m
a ese Despacho otocop, debidamente autenticada por ØI No ri
del Circulo de B gotª, I documento que acredita a (a suscr
y/o al doctor G4 TAVO AMAYO, y/o a la doctor IGNACO S doctor ENRIQU ALVA Z, en los tØrminos del PØrrafo 10 Decreto-Ley 410 e 197, como Representantes Legates en B
asuntos relacion dos c (a Propiedad Industrial de la socie
organizada y exi tente e conformidad con las (eyes de Sui Vevey, Suiza.

6. En conse encia, atentamente solicito a ese Desp
personerla, en este sunto, de conformidad con los
Representación L’ gal pa todos los asuntos de (a Propiecad I
de la sociedad NE TEC A., otorgados a favor de la suscita All
at doctor GUSTA 0 TAM VO y/o at doctor IGNACIO SAI’TAM
ENRIQUE AWARE de uerdo con las copias debidamnte
Notarlo Püblico e adj nto at presente expediente (ArtIcul Decision 486 de l Comu dad Andina de Naciones).

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LLOREDA & CIA. S. A.

7. Con el texto del documento mencionado presento fotocopias, debidamente autenticadas par el Notarlo Cuarenta y Uno del Circulo de Bogota, de:

(a) Certificado Notarial expedido el 11 de Agosto de 2004 que acredita la existencia y representación del solicitante, debidamente apostillado; y,

(b) Copia autØntica de la Traducción Oficial No. 283/04 correspondiente a
las partes pertinentes del documento anterior, tamblØn debidamente legalizada hasta por el Ministerlo de Relaciones Exteriores bajo el
nCimero 861229 de 2 de Septiembre de 2004.

8. Ruego a usted tomar atenta nota de 10 anterior y proceder de conformidad.

SeæorSuperintendente,

?I
AJUCIA LLOREDA RICAURTE T.P. 53.215

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Espacio reservado para el adhesivo de radicaciOn

Industria Cornercio

SUPERINTENDENaA

FORMULARIO UNICO DE CORRECCIONES Y MODIFICACIONES.
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Norc::re: NESTEC S.A., soedo existente Y IDENTIFICACION
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Suiz CE. Otro

Te efonc 26270 Fax: 6 06970 1 El
E-rnai: IIcco.cLhUrcdacamacho.com Ntmero

DoincTo: Vevey, Suiza

() Nombre: ALICIA LLOREDA RICAURTE

IDENTIFICACION

C.C. IILNIJ NIT R’FESENTANTE.DireccjOn: Gaile 72 No. 5-83 Piso 50, Bogota,
APODERADO Colombia C.E. Otro fl

TelØfono: 3 264270 Fax: 2 128426 Numero 39.690.713 TP 53.215 I E-mail: jllcco'ltoredacamacho.com

NUrnero de expediente:
07-104.268

OescripciOn de la corrección o modificación solicitada carnbiode nombre del solicitante de

NOVAR11S AG a NESTEC S.A.

Comprobante de pago No. 00-23.193 Fecha 2-03-2009

(7) Anexos:

Comprobante de pago de Ia tasa.
Poderes, si fuere el caso.
Certificado.de existencia representaciOn legal de las partes, cuando sean personas juridicas.

N OMBRE ALJCU\LLOREDARICAURTE FIRL (&
C.C. 39.690.713 T.P.53.215

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TRADUCCION OFICIAL No. 2009-03-13-150
DE UN DOCUMENTO ESCRITO EN INGLES -

TRASPASO DE PATENTE

l suscrito, NOVART1S AG, una sociedad constituida y existente bajo las leyes de
Suiza, domicHiada en Postfach 4002, Basilea, Suiza, propietaria de la Solicitud de Patents de Colombia No. 07-104.268, registrada el 4 de octubre de 2007, por el presente transfiere y traspasa completamente los derechos correspondientes a
dicha solicitud a NESTEC S.A.., una sociedad constituida y existente bajo las Ieyes de Suiza, domiciliada en Avenue NestlØ 55, CH-1800, Vevey, Suiza; siendo dicho Cesionarlo considerado de ahora en adelante como el dueæoy propietario Unico y legitimo del derecho sujeto.

NESTEC S.A. por el presente acepta dicha trarisferencia y Traspaso.

n testimonlo de to cuat, el presente documento es por el presente firmado el dia 4 del mes de diciembre del aæo 2008.

Cedente Cesionarto

(firmas: ilegibles) (firmas: ilegibles)
NOVARTIS AG

Signatarlo AUtorizado

NESTEC S.A.

Signatario Autorizado

LEGALIZACION

’1° el suscrito Notarlo Püblico, ho. lur. Beat BOrgin, residente en CH-4052 Basilea (Suiza), con oficina en Lautengartenstrasse 7, certifico como fieles y autØnticas las firmas colocadas sobre el presente por el SeæorDr. Dietz, ciudadano alemÆn, residente en AIJschwill BL, y la Seæora Susan Ilamada SueEvans, ciudadana de ran Bretafia, residente en Muttenz BL.

Estas dos personas estÆn autorizadas para representar como Signatarios 4utorizados a Novartis AG, una sociedad limitada par acciones legalmente domiciliada en Basilea, con firma conjunta.
H
onozco a las personas nombradas y sus firmas personalmente.

oasilea, este dia nueve (9) de diciembre de 2008 (dos mil ocho).

Qblea Notarial
tegReg-Nr. 2003/2008 (firma: ilegible) Beat BUrgin
Apoderado y Notarlo

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APOSTILLA

(ConvenciOndeLa Haya del 5 de octubre de 1961)

14 Pals: Suiza
Este documento oficial
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ha sido firmado por (ilegible)
actuando como (ilegible)
y certificado por el sello/estampilla de (ilegible) I
Certificado
an Basilea 6 el 10 do di’ -2008
por la Cancilleria do Estado del CantOn do la Ciudad de Basilea
No. 10’5521 (ilegible) ’090
SoIlo/Estampilla 10. Firma: (ilegible)
SeHo do La Cancilleria de Estado Heidi Fischer
de la Ciudad do Basilea

Traducido segun mi major saber y entender, este dla 13 ie m,o de 2009, ep la ciudad do Bogota, D.C., por Anita Escobar do Tamayo, Tradora Oficial, Fes. 2177 de 1989, Ministerio de Justicia, RepibIica do Colombia.

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TRADUCCION OFICIAL No. 077/09 DE UN DOCUMENTO ESCRITO EN FRANCES, EL CUAL PARA SU IDENTIFICACION SE SELLA CON EL SELLO DEL TRADUCTOR. ESTA ES UNA TRADUCCION OFICIAL EFECTUADA EL DIA 16 DE MARZO DE 2009 POR JEAN-JACQUES TURP1N, C.E. 193849 DE BOGOTA, TRADUCTOR E INTERPRETE OFICIAL SEGUN RESOLUCION N0.2680/91 DEL 19 DE DICIEMBRE DE 1991, EXPEDIDA POR EL MINISTERIO DE JUSTIdIA DE COLOMBIA.

ahzación NO 10.559. Con base en un cotejo de firma, el suscnto JEAN-DANIEL RUMPF, Notario en Vevey para el CantOn de Vaud, Suiza, certifica autØntica la firma puesta por el seæorCornelis SCHULLER, Sub-director de la companIa Nestec S.A., en Vevey, la cual compromete en forma vÆlida con su firmaindividual.
Dado en Vevey, el trece de febrero de dos mil nueve Firma Iegible del Notario Sello JEAN-DANIEL RUMPF, Notario

APOSTILLA

(Convenciôn de La Haya del 5 de octubre de 1961) Cu

1. Pals: Suiza
El presente documento püblico
2. ha sido firmado por Jean-Daniel RUMPF
3.- obrando en calidad de Notario en Vevey

4.- con sello de Jean-Daniel RUMPF, Notario Jo
CERTIFICADO
5.- En Lausana 6.- El 16 de febrero de 2009
7.- Por la Cancillerla del Estado del Canton de Vaud
8.- Bajo el nümero 1595
9.- Sello: Cancilleria del Consejo de Estado CantOn de Vaud
10.- Por el CanciHer do Estado, firma ilegible de Agron Ismaili.
Es traducción fiel y completa de la cual se deja copia en los archivos de esta oficina
para confrontaciOn y a la cual me remito.
Traducción oficial No. 077/09.

$mducCió Oig& M. 0 7/o5
JEN4 JA H. TURPIN
WOW e J,Mipr OficiaI
FKAtM - £SPA$1OL
Rei. WnWcla No. 26091

Traductor. Jean-Jacques Turpin. Bogota, D.C., 16 do marzo 2009.

TRADUCCION OFICIAL No.283104 DE UN DOCUMENTO ESCRITO EN FRANCES, EL CUAL PARA SU IDENTIFICACION SE SELLA CON EL SELLO DEL TRADUCTOR. ESTA ES UNA TRADUCCION OFICIAL EFECTUADA EL DIA 01 DE SEPTIEMBRE. DE 2004 POR JEAN-JACQUES TURPIN, C.E.: 193849 DE BOGOTA TRADUCTOR E INTERPRETE OFICIAL SEGUN RESOLUCION No. 1680/91 DEL 19 DE DICIEMBRE DE 1991, EXPEDIDA POR EL MINISTERIO DE
JUSTJC1A DE COLOMBIA.

Autenticaciones que se hallan a continuación de un documento de poder confendo en inglØs y espaæol por NESTEC SA, una sociedad organizada y existe de conformidad con las leyes de Suiza, domiciliada en Avenue NestlØ 55, CH-1800 Vevey, Suiza, y otorgado a los Doctores ALICIA LLOREDA y/o GUSTAVO TAMAYO y/o IGNACIO SANTAMARIA y/o ENRIQUE ALVAREZ, todos domiciliados en Bogota, Colombia, Calle 72 No. 5-83 (Piso 60).
Dado el 5 de agosto de 2004. Firma ilegible de la Seæora Paula Nelson, Vice-Presidente de Nester, S.A.

CERT1FICADO NOTARIAL (SOCIEDAD)
Legalización por parte del suscnto Notaro de la firma de la Seæora Paula NELSON quien desempeæa el cargo de Vice-Presidente de la compaæIa NESTEC SA, una sociedad legalmenteconstituida y existente de acuerdo con las leyes de Suiza, domiciliada en Vevey (Suiza). AdemÆs, dichoNotano certifica que el sinatano, segn las leyes de Suiza, tiene facultad para otorgar el presente documento. Los hechos anteriores constan por haber examinado los documentos respectivos el 24 de marzo de 1997, y de tocj ello da fe.
Firma de Jean-Daniel RUMPF.
Sello: Jean-Daniel RUMPF - Notano. Estampilla de

In Ofidal No.

Tijr e In*pe. Ofidat
ł Mbnncie No. 26OJ9I

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TraducciOn oficial No. 283/04.
Traductor Jean-Jacques Turpin.
Bogota, D.C., 1 de septiembre de 2004.

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Leoalización No. 7.135. El Notarlo Jean-Daniel RUMPF, en Vevey, Distrito de Vevey, CantOn de Vaud, Suiza, certifica la firma puestà en la pÆginaanterior por la Seæora Paula Nelson, Directora adjunta de Nestec S.A, en Vevey, la cual omprornete en fqrma vâlida con su firma individual.
Dado en Vevey, el once de agosto de dos mil cuatro. Firma uJegibIedel:Fotanb.
il Sello: Jean-Daniel RUMPF -Notario. Estampilla de 4 Frs.

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(Convención de La Haya del 5 de octubre de 1961) .
1. - Pals: Suiza
El presente documento püblico
2. - ha sido firmado por el SeæorJean-Daniel RUMPF

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- obrando en calidad de Notario en Vevey
4. - con sello de Jean-Daniel RUMPF, Notano
CERTIFICADO

5. - En Lausana 6- El 12 de agosto de 2004
7.- Por la Cancillerla de Estado del Canton de Vaud
8. - Bajo el nmero 6705

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9.- Sello: Cancilleria del Consejo de Estado -Libertad y Patila -Emolumento

de 25 Fr.
10.- Por el Canciller de Estado, firma de P. Equey.
Es traducciôn fiel y completa de la cual se deja copia en los arctlivos de esta oficina pam confrontaciOn y a la cual me remito. S a

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Lâ.ajo,firmacos, NESTEC S.A., una sociedad ’organizada y existente de conformidad con las leyes
de Suiza

cart dor,iciIloen Avenue 55, CH-1800 Vevey, Suiza

nombramos par el presenfe a ALICIA LLOREDA yb GUSTAVO TAMAYO y10 IGNACIO SANTAMARIA y/o ENRIQUE ALVAREZ, domiciHados an Bogota, Colombia, con oficinas an dicha ciuciad, Calle 72 No. 5-83, iso 6o, nuestros representantes legales y verdaderos an Bogota, con facultades pare recibir notmcaciones y nombrar apoderados judiciales o extrajucicIales, con el fin de der cumpilmiento al parÆgrafo 10. del articulo 543 del decreto 410 de
1971.

Ls doctores ALICIA LLOREDA y/0 GUSTAVO TM4AYD y/o IGNACIO SANTAMARIA y/o ENRIQUE ALVARZ,o los apoderados quo cualquiera de ellos designe, quedan especialmente facultados pare repl:esek,tamos ante las autoridades colombianas, dminjstrativas, judiciales o de policla, on todos los râmlfes relativos a la propiedad industrial, a cuyo efecto les facultamos pare dar ante dichas autorldades todos los pesos necesarios al objeto indicadd; elevar solicitudes, dectaraclones, reclamos, recursos y presenter desistimientos; formular descripciores, enmiendas, limiter el alcance de las solicitudes, presenter oposiclones y apelaciones; instaurar cancelaciones, renunciar total o parcialrr!ente a los registros, abonar todos los impuestos y cuotas y efectuar tocto otro pago determifltado por la ley, recibir todos los documentos y valores, dando el descargo respectivo; Ilenar cualesqtiiera otros requisitos y tomar, an fin, todas las meddas qua creyeren conducentes al resguardo tie nuetros intereses; y an caso tie producirse oposiclóh, pasando los antecedentes a los tribunales, quedan facultados pare tomar intervenciOn coma demandantes a demanddos ante los jueces qua seen ctrnpetentes, pudiendo transar, someter a rbltros, desistir, peroibir y apelar, con todas las demÆs acultades qua resulteri necesarias, y por el presentq declaramos desde ahora vØlido y bueno cuanto dichos representantes y/o los apoderados qua cuaIqulea de ellos nombre hicieren an nuestro beneflcio

AimIsmo, facultamos a los doctores ALICIA LLOREDA y/o GUSTAVO TAMAYO ybo IGNACIO SANTAMARIA y/o ENRIQUE ALVAREZ,. pare solicitar la Oficina tie Propiedad Industrial la protocolización de este documento y de cualquier poder que: cualqulera de ellos otorgue a nombre
nuestro.

Dado y firrriado

P LLUP4

The undersigned, NESTEC S.A., a corporation organized and existing under the laws of Switzerland.

domiciled at Avenue NestlØ 55, CH-1 800
Vevey, Switzerland

hereby appoint, ALICIA LLOREDA and/or GUSTAVO TAMAYO and/or IGNACIO SANTAMARIA and/or ENRIQUE ALVAREZ, of Bogota, Colombia, with offices in said town, CaIle 72 No. 5-83, Sixth Floor, our true and legal representatives in Bogota, with power to receive notifications and to appoint judicial or extrajudicial agents, so as to comply with paragraph 10. of article. 543 of decree 410 of 1971.

Doctors ALICIA LLOREDA and/or GUSTAVO TAMAYO and/or IGNACIO SANTAMARIA and/or ENRIQUE ALVAREZ, or the agents by any one them appointed, are especially empowered to represent us before the administrative, judicial or police authorities of Colombia, in all proceedings pertaining to industrial property, for which purpose we authorize them to take before the said authorities all the necessary steps for the said end; to file petitions, declarations, claims, recourses and withdrawals, to draw up specifications; to file amendments, to limit the scope of applications, file oppositions; file cancellations total or partially waive registrations, to pay all installments and effect:all other payments prescribed by law; to receive proper receipts, to comply with all other requirements and, in short, to take all those measures which they may deem fit for the protection of our interests; and in case opposition, where the proceedings be passed over to the courts, we authorize said agents to act on our behalf, as complainants as as defendants, before the competent judges, with full powers to make arrangements, to submit to arbitrators, to desist, to collect, to appeal and, in short, with all such further powers as may be required, and we hereby declare from now on as valid and good all that said representatives and/or the agents by any one of them appointed may do for our benefit.

We also authorize doctors ALICIA LLOREDA and/or GUSTAVO TAMAYO and/or IGNACIO SANTAMARIA and/or ENRIQUE ALVAREZ, to apply for protocolization of this document and of any power of attorney by any one of them conferred In our name, before the Office of Industrial Property.

Given and signed this

Paula NELSON -Vice President

NOTARY SHOULD

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CERT1IICADO NOTARIAL (SOCIEDAD)

Suiza
Vevey {Ss

Hoy 44 de Aqk do 2004, compareclO I2PJL$, a quien conozco y
de quieri me consta quo firmó el anterior documento, y quien iebidamente juramentado dºclarO y do qua Øles ’i.) ie9(esde r’,4
de NESTEC S.A., Is
compaæa nombrada an el documentoqua antecede, una sociedad debidamente orgaAizada y existente conforms a las byes do Suiza, domiciliada an Is cludad de Vevey, Suiza legalmente constituida Para ur perlodo do duraclón qua ain no ha terminaco, quo ejerce su objeto social; conforme a
las leye do Suiza, quo el declarante estÆautorizado
por dicho Compaflla pars conferir este poder; quo el
J solo estmpado por el al pie do tal poder, an nombre

Wyan

repesentaciOn de Is expresada Compaflla, as el
eIlo ofiØial do ella; y qua el objeto pars of cual so c’-onflere este instrumento estÆ comprendido dentro
del do la;sociedad.
El suscito Notarlo ha visto los Estatutos do incorporthck5n firmados en Vevey, Suiza, con fecha 2L\ 1-k(L9 cl)-, y certifies quo de conforrriad con Is legislación de dicho Pals, (a anterior I declaración juramentada as prueba suflcient4 do quo los hechos sobre quo ells versa son ciertos o verdaderos. de to cual da fe.

Notary Pyblic (Notarlo POblico).

li_sation No 71135_
pe no
Vaud,
part

NOTARIAL CERTIFICATE (CORPORATION)

Switzerland

Vevey {ss

On this lltlUay of August , 2004, personally came
Paula NELSON
to me known, and known to me to be the person who signed the foregoing instrument, who being by me duly sworn did depose and say that he/she is the Vice President of NESTEC S.A., the company named within, a Corporation organized and existing under the laws of the Switzerland, domiciled at the City of Vevey, Switzerland legally constituted for a period of tenure not yet expired, which exercises its corporate purposes according to the laws of Switzerland, that the deponent is authorized by said Company to confer this power of attomey, that the seal affixed hereunto by the deponent in the name and on behalf of said Corporation is the corporate seal thereof; and that the purpose for which this instrument is granted is included within the corporate purposes of the Company.
The undersigned Notary Public has seen the articles of Incorporation of said Corporation executed at Vevey, Switzerland, under date of March 24 1997 and hereby certifies that under the laws of said County the foregoing acknowledgment is sufficient proof that the facts therein contained are true, which he attests.

de Vevey, Cant
apposØe d’autr
de la sociØtØ

par sa siqnat
indiviauelle. ____

re JEANDANIEL RUMPF, a. Vevey, District
isse, certifie authentique la signature
Paula NELSON, directriceadjointe
.A.., a Vevey, qu’.elle engage valablezuent

ONZE AOUT DEUX MILLE QUATRE. -----------------

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APOSTILL

(Co venlion do La Haye du 5 octobre 1961) II
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2, etô sign par Joan-Daniel Rumpf
3. glssant e qualitØ do notaire Vevey
4. at revtu u sceau/tlmbre do J.-D. Rumpf notairo

AttestØ
5. Lausant 6.19 12 aoOt 2004
7. ar La Ch cellerie d’Etat du Canton de Vaud
8.ousNo605 S

ceau/th re: 10. Signature
pr Ia Chancelier d’Etat:

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Industria y Comercio 4AP

SUPERNTENDENCIA

DIVISION DE NUEVAS CREACIONES

RADICACION EXPED1ENTE No. 07-104268

EL EXTRACTO DE LA PRESENTE SOLICITUD DE PATENTE DE INVENCION

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No 597 DE

FECHA 31 DE OCTUBRE DE 2008 EL TERMINO HABIL SENALADO POR LA

LEY EXPIRA EL 02 DE FEBRERO DE 2009

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de Is fecha de publicaciön en Is gacota de Propledad Industrial, deberØ solicitar y cancelar el examen de patentabilklacl so pena de que Is solicitud caiga en abandono, de acuerdo COfl 10 establecido an el ArtIculo 44 de Is Decisión 486/2000.

SE PRESENTARON OPOSICIONES PORPARTE DE TERCEROS.

Si NO

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1Eurowsch"Pat""

9) jEuropean Patent Office

Office europden des brevets (11) EP 0898900 A2

EUROPEAN PATENT APPUCATION

43) of publication:.---.
O3.03.1999 BulletIn 1999/09

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Composition and method for providing nutritfon to diabetics

A nutritional composition for diabetics. The
Iposition contains a protein source, a lipid source,
acarbohyd a-source. The composition includes a
mixture containing a viscous soluble fibre and mu-
a hydrolysate of inulin, or both. The fibre mixture
also contain insoluble fibre. When in liquid form, nutritional composition has it low viscosity and llent tube flow rates.

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Discriptlon

Eiel&QttbeJnvention

[0001] This invention relates to a nutritional composition suitable for providing nutrition to diabetic patients. The inven-tion also relates to a method for providing nutrition to diabetic patients and to a method for the nutritional management of diabetic symptoms in patients.

Bpckaround of the Invention
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[0002] Diabetes is a general term for a group of metabolic disorders which are characterised by the inability to prop-erly metabolise glucose. This Inability is due either to a deficiency of the hormone insulin or to a resistance to the action of insulin. In either case, if untreated, the inability leads to hypeiIycaemia and its complications of morbidity and mor-tIity,
15 [0003] Diabetes Is usually classified into three clinical classes; diabetes mellitus, gestational diabetes, and impaired
glucose tolerance or glucose intolerance. Diabetes mellitus is generally broken down into two types; type I diabetes mellitus and type II diabetes mellitus, Type I diabetes mellitus occurs in individuals who produce little or no insulin and constitutes less than about 10% of the diabetic population. The onset of type I diabetes mellitus usually manifests itself diring youth. Type II diabetes mellitus, or non-insulin dependent diabetes mellitus, usually develops after the age of
20 about 30 years and constitutes more than about 90% of the diabetic population. Impaired glucose tolerance, in the din-
ial setting, often occurs as stress-induced hyperglycaemia.
160041 Often, especially in severe cases, diabetes is treated by the administration of exogenous Insulin or anthyper-giycaemic agents. However, nutritional management of diabetes is possible and the American Diabetes Association has published guidelines for the nutritional therapy of diabetes. These guidelines suggest that diabetic patients should
25 consume about 20 to 25 g of dietary fibre daily.
(0005] Dietary fibres maybe classified as soluble and insoluble. Insoluble fibres appear to have little influence on gly-cemic levels, However, the incorporation of soluble fibres into foods is known reduce postprandial glycaemia in diabet-is (Anderson, J.W. and Akanji, A.O.; 1993; "Treatment of Diabetes with High Fiber Diets, QRC Handbook tDietarv Elbefjn Humpo1i,dr.iti, CRC Press Inc, 2nd Edition, pages 443 to 470). Examples of soluble fibres which are believed
so to have this property are guar gum, pectin, xanthan gum, and p-glucan. This property makes soluble fibres ideal candi-
dates for incorporation into foods for diabetics.
[0006] However, to date, soluble fibres have not been widely used in food for diabetics. A common problem is that many soluble fibres are not very palatable. Also, in the field of clinical nutrition, the incorporation of soluble fibres into enterally administered compositions is extremely difficult since soluble fibres are thickening agents and greatly increase
ss viscosity. Consequently compositions which contain sufficient soluble fibre to significantly reduce postprandial glycae-
mis are usually too thick and viscous for enterally feeding; especially for patients requiring tube-feeding.
(0007] One nutritional composition which offers a solution to the problem is described in US patent 5,292,723. The nutritional composition described in this patent has a carbohydrate component made up of glucose polymers, modified starch, and soluble fibre. Pectin is suggested as a suitable soluble fibre. The nutritional composition has a viscosity of
40 lssthan 0.05 kglms when measured at about 200. Further the nutrition composition, when consumed, results in lower
gtycemic response in patients as compared to glucose of the same energy content.
(0008] However there is still a need for a nutritional composition which is suitable for diabetic patients and which has gbod flow characteristics.

45urnrpary of the invention

(0009] Accordingly, in one aspect, this invention provides anutritional composition for diabetic patients, the composi-tion containing a protein source, a lipid source, and a carbohydrate source, the carbohydrate source including a fibre mixture comprising a viscous soluble fibre and inulin or ahydrolysate of inulin, or both.
50 (0010] It is surprisingly found that the use of a fibre mixture of a viscous soluble fibre and inulin, a hydrolysate of inulin,
or both, results in an adequately reduced glycemic response while retaining reasonably low viscosity. Therefore, due to the excellent flow properties, the nutritional composition is ideally suited to be tube-fed to patients. Further, the use of inulin or its hydrolysates provides a substrate for lactic acid bacteria in the gastro-intestinal tract; leading to beneficial effects in the general health of the patient.
ss (00113 The nutritional composition maybe in liquid form or in the form of a soluble powder which is reconstituteable
In an aqueous liquid to provide a liquid nutritional composition.
(Q012] Preferably, the protein source provides about 10% to about 20% of energy, the lipid source provides about 30% to about 50% of energy, and the carbohydrate source provides about 35% to about 55% of energy.

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(0013] In another aspect, this invention provides a method for the nutritional management of the symptom of diabetes, the method comprising orally administering to a patient an effective amount of a liquid nutritional composition for dia-betic patients, the composition comprising a protein source, a lipid source, a carbohydrate source, and a fibre mixture including a viscous soluble fibre and inulin, a hydrolysate of inulin, or both.
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Detailed Description of the Preferred Embodiments

(0014] Embodiments of the invention are now described byway of example only. This invention provides a nutritional composition for diabetic patients. The composition contains a protein source, a lipid source, and a carbohydrate source.
10 The carbohydrate source Includes a fibre mixture comprising a viscous soluble fibre and inulin. In this specification, the
term soluble fibre’ means those dietary fibres which are characterised as soluble using the method of Prosky at at; 1988; J. Assoc. Off. Anal. Chem. 70,5 1017. This is the official method of the Association of Official Analytical Chem-lets. The term viscous soluble fibres means a soluble fibre which is able to increase the viscosity of the contents of the stomach and the small Intestine and slow gastric emptying rates.
10 (0015] The viscous soluble fibre maybe any suitable soluble fibre which is We to increase the viscosity of the con-
tents of the stomach and the small intestine. Examples of suitable soluble fibres are gums such as guar gum, xanthan gum, and gum arabic, pectin, and -glucan, or mixtures of these. Pectin and gum arabic are particularly preferred.
(001 6J The inulln maybe provided in the form of a natural extract which is suitable for human consumption. Extracts from chicory are particularly suitable. The extract preferably contains at least 80% by weight of inulin or a hydrolysate
20 of inulin; more preferably at least 90% by weight of inulin or a hydrolysate of inulin. The inulin preferably has a degree
of polymerisation of at least about 8; for example about 10 to about 25. Suitable inulin extracts may be obtained from Orafti $A of Tirlemont 3300, Belgium under the trade mark "Raftiline. For example, the inulin may be provided In the form of RaftilinefiST which is a fine white powder which contains about 90 to about 94% by weight of inulin, up to about 4% by weight of glucose and fructose, and about 4 to 976 by weight of sucrose. The average degree of polymerisation
25 of the inulin is about 10 to about 12. The inulin may also be in the form of inulin hydrolysates or mixtures of inulin and
inulin hydrolysates. Inulin hydrolysates are commonly known as fructooligosaccahrides or FOS.
(00171 lnulirr and its hydrolysates are reported to promote the growth of bitidobacteria in the gastro-intestinal tract and,
in certain circumstances prevent or decrease the growth of pathogens such as Clostrid!ae. Further, promoting the growth of bitidobacteria is reported to have various other beneficial effects. Moreover, inulin and its hydrolysates may
30 reduce blood glucose levels.
100181 The fibre mixture may also contain a source of insoluble dietary fibre. Suitable sources of insoluble dietary
fibres are hull fibres from legumes and grains; for example pea hull fibre, oat hull fibre, barley hull fibre, and soy hull fibre. Pea hull fibre is especially preferred. However any suitable source of insoluble dietary fibre may be used. These sources may also contain some soluble fibre.
35 [0019] The ratio of soluble fibre, including inulin, to insoluble fibre is preferably about 1:3 to about 3:1; more preferably
about 1:1 to about 2:1. For example, ratio of soluble fibre, including inulin, to insoluble fibre is preferably about 2:1. Fur-ther, the fibre mixture may be present in an amount of about 1.0 g/l 00m1 to about 2.0 g/l OOml; for example about 1.3 gIlOOml to about 1.7 gllOOml; for example about 1.5 g1100 ml. In a preferred example, the fibre mixture comprises about 0.5 g/100 ml inulin, about 0.5 g/100 ml pectin or gum arabic, and about 0.5 g/100 ml outer pea fibre.
40 (0020] The protein source is preferably a high quality protein source; for example milk protein, whey protein, casein
protein, or soy protein, or mixtures of these proteins. The protein source may be in the form of intact protein or may be hydrolyzed. Other protein sources such as rice, pea and oat protein, or mixtures thereof, may also be used. Further, if desired, the protein source may include free amino acids.
[0021] The protein source preferably provides about 10% to about 20% of the energy ofthe composition. For example,
45 the protein source may provide about 12% to about 18% of the energy of the composition; preferably about 15% of the
energy of the composition.
(0022] The carbohydrate source may be any suitable carbohydrate or carbohydrate mixtures. For example, the car-bohydrate source maybe maltodextrin, modified starch, amylose starch, topioca starch, cornstarch, or fructose, or mix-tures thereof. Modified starch is preferred; especially modified topioca and corn starches. If the carbohydrate source
so includes maltodextrin maltodextnn with a low DE is preferred, for example maltodextrin with a DE of 3 or less Prefer-
ably the composition is low in or free from mono- and di-saccharides such as fructose and other exchange sugars, and lactose, For example the composition contains less than about 3 g/l of lactose.
100231 The carbohydrate source, including the viscous soluble fibre and inulin, provides about 35% to about 550/6 of
the energy of the composition; preferably about 40% to about 50% of the energy. For example, the carbohydrate source
so may provide about 45% of the energy of the composition. The amount of energy provided to the patient by the viscous
soluble fibre and inulin is very small.
100241 The lipid source is preferably rich in monounsaturated fatty acids; for example monounsaturated fatty acids
may provide at least 50% of energy of the lipid source. Preferably, monounsaturated fat acids provide about 25% to

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about 35% of the energy of the composition; for example about 29 to 30%. The lipid source may contain polyunsatu-rated fatty acids (omega-3 and omega-6 fatty acids); preferably these polyunsaturated fatty acids provide up to about 10%of the energy of the composition. For example these polyunsaturated fatty adds may provide about 3% to about 10% of the energy of the composition. The lipid profile of the enteral composition is preferably designed to have a pol-yunsaturated fatty acid omega-6 (ri-6) to omega-3 (n-3) ratio of about 4:1 to about 10:1. Saturated fatty acids preferably provide less than 100/9 of the energy of the composition; for example less than about 7%.
[0025] The lipid source may provide about 30% to about 50% of the energy of the composition; preferably about 35% to about 45%., For example, the lipid source may provide about 40% of the energy of the composition.
(0026] If desired, the lipid source may include-medium Chain triglycerides. For example, medium chain triglycerides
to may make up about 10% to about 50% by weight of the lipid source.
[0027] Suitable sources of monounsaturated fatty acids are olive oil, sunflower oil rich in oleic acid, rapeseed oil rich
ir oleic acid, hazelnut oil, safflower oil, and the like. If medium chain triglycerides are included In the lipid source, frac-tionated coconut oils are a suitable source of medium chain triglycerides. A mixture of sunflower oil, rapeseed oil and olive oil Is preferred.
15 (0028] The enteral composition preferably includes a complete vitamin and mineral profile. For example, sufficient
vitamins and minerals may be provided to supply about 750/6 to about 250% of the recommended daily allowance of the vitamins and minerals per 1000 calories of the nutritional composition.
(0029) The nutritional composition conveniently has an osmolarity of about 180 mOsm/i to about 300 mosm/i; for example about 190 mOsmll to about 210 mOsnl.

20 (0030] The viscosity of the nutritional composition, when measured at room temperature, is preferably less than about
004 kg/me; especially less than about 0.035 kg/ms. For example, the viscosity of the nutritional composition, when measured at room temperature, may be about 0.015 to about 0.03 kg/ms. Further, the flow rate of the nutritional corn-psition through a standard feeding tube is preferably less than about 150 minutes/I; for example less than about 100
minutes/l.

26 [0031] The energy density of the nutritional composition is preferably about 700 kcal/l to about 1500 kcaUl; for example
about 1000 kcal/l.

(0032] The nutritional composition is preferably in the form of a ready-to-use formulation. In this form, the composition May be fed to a patient via a nasogastric tube, jejunum tube or by having the patient drink it. As such, the nutritional composition may be in a variety of forms; for example as a fruit juice-type beverage, a milk shake-type beverage and
so the like. However, the nutritional composition may be in soluble powder form to be reconstituted prior to use.
(00333 Various flavours, sweeteners and other additives maybe present. Artificial sweeteners such as acetosulfame and L-aspartyl based sweeteners may be used; for example aspartame.
(0034] The nutritional composition maybe produced as is conventional; for example, by blending together the protein source, the carbohydrate source, and the lipid source. If used, the emulsifiers may be included in the blend. The vita-
35 mine and minerals may be added at this point but are usually added later to avoid thermal degradation. Any Iipophilic
vitamins, emulsifiers and the like may be dissolved into the lipid source prior to blending. Water, preferably water which h00 been subjected to reverse osmosis, may then be mixed in to form a liquid mixture. The temperature of the water is conveniently about 50°C to about 80°C to aid dispersal of the ingredients. Commercially available liquefiers may be
used to form the liquid mixture.
40 [00353 The liquid mixture may then be thermally treated to reduce bacterial loads. For example, the liquid mixture may
be rapidly heated to a temperature in the range of about 80°C to about 110°C for about 5 seconds to about 5 minutes.
This may be carried out by steam injection or by host exchanger; for example a plate heat exchanger.
[0036] The liquid mixture may then be cooled to about 60°C to about 85°C; for example by flash cooling. The liquid amixtureis then homogenised; for example in two stages at about 7 MPa to about 40 MPa in the first stage and about 2
45 MPa to about 14 MPa in the second stage. The homogenised mixture may then be further cooled to add any heat Sen-
sitive components; such as vitamins and minerals. The pH and solids content of the homogenised mixture is conven-
intIy standardised at this point
(0037] For a product in liquid form, the homogenised mixture is preferably aseptically filled into suitable containers.
Aseptic filling of the containers may be carried out by pre-heating the homogenised mixture (for example to about 75 to
so 85°C) and then injecting steam into the hofliogenised mixture to raise the temperature to about 140 to 160°C; for exam-
ple at about 150°C. The homogenised mixture may then be cooled, for example by flash cooling, to a temperature of about 75 to 85°C. The homogenised mixture may then be further homogenised, cooled to about room temperature and filled into containers. Suitable apparatus for carrying out aseptic filling of this nature is commercially available.
10)381 For a product in powder form, the homogenised mixture is dried to powder; for example by spray drying. Con-
es v*titional procedures may be used.
(0039] The nutritional composition maybe used as a nutritional support for patients suffering from metabolic anoma-which make them susceptible to hypo- or hyperglycaemia. For example, the nutritional composition may be used as anutrltional support for patients suffering from type I diabetes mellitus, type 11 diabetes mellitus, or intolerance to glu-

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se. Further, the nutritional composition may be used as a nutritional support for patients who are at risk of a recur-rence of hypo- or hypergiycaemla. The nutritional composition may also be used as nutritional support for post operative patients. The nutritional composition is particularly useful for the nutritional management of diabetic symp-toms of diabetic patients.
5 [040 The amount of the nu1rIPicn1 composition required to be fed to a patient will vary depending upon factors such al the patient’s condition, the patient’s body weight, the age of the patient, arid whether the nutritional composition Is
t sofa source of nutrition. However the required amount may be readily set by a medical practitioner. In general, suf-nt of the nutritional composition Is administered to provide the patient with about 1 g protein to about 4.0 g protein
kg of body weight per day. For example, an adult patient may be administered about 1.5 g protein to about 2.0 g
10 ein per kg of body weight per day,Further, sufficient of the nutritional composition is administered to provide the Ipatient with up to about 40 g of dietary fibre (Insoluble and soluble) per day; for example about 259 to about 350 of detary fibre per day. If the nutritional formula is used as a supplement to other foods, the amount ofthe nutritional corn-pOsition that is administered daily may be decreased accordingly,
100411 The nutritional composition may be taken In multiple doses, for example 2 to 5 times, to make up the required 15 401y amount or may taken in a single dose. The nutritional composition may also be fed continuously over a desired

I t0042] A ready-to-use nutritional composition is prepared. The nutritional composition Includes the following compo-

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Conponent Cone (IlOOml) Energy (%)
Prgteln 3.8g 15
CaeiWSoy Protein (1:1)
abohydmte 11.2g 45
Mltodextrin (law DE) 1.0 g
Modified Starch 10.29
3ouble fibre Including InulIn 1.0 g
Insoluble fibre 0.59
.Upds? 4.49 40
Raeseed oil, Sunflower oil, Olive oil, Glyceryl stearate, Soya lecithin
"mine
itrninA 1501U

Vitamin 10 Mg
!ttmin 0 10 lU
rrtmInE 1.0 mg
fltrnInK 3.0 gg
hismln 0.1 mg
Riboflavine 0.12mg
Partitotheflic S 0.50 mg
min 86 0.14 mg.
vitamin 812 0.30g
icin 1.2 mg
cic.acid 18 A
liotin 10.rg
Alflerals

nc, Iron, Copper Magnesium, Manganese Selenium, Iodine, Potassium, Cal-
m Phosphorous, Chloride

043) The composition has an osmolarity of 210 mOsnl and an osmolafity of 240 mOsm/kg. The viscosity is 0.023 kbmns and the free flow rate is less than 70 minutes per 500 ml through standard enteral tubing
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()4] Eight healthy volunteers, of both sexes, are used in the study. The volunteers are between 20 and 45 years of
a e and have fasting blood glucose levels of about 70 to about 110 mgkfl Any volunteer exhibiting the symptoms of so d abates mellitus type I or, liar fructose intolerance are excluded
)451 The study is carried out In two stages each stage comprising two study days separated by a wash out period
at least 7 days The stages are also separated by a wash out period of at least 7 days Prior to each study day, each lunteer consumes an evening meal of pizza, salad and an apple No alcohol is taken Then from 10 pm, each volun-
t r505 rundergoes an overnight fast In the morning of the study day, an indwelling catheter is placed on each volunteer. A b sample Is then taken A meal is then consumed within 10 minutes of the taking of the sample Further blood sam
re taken at 15 30 45 80 90, 120 and 180 minutes after meal intake The blood glucose for each sample isana
I by the glucose O,ddass method using a 000AS analyser (Hoffmann-La Roche). The insulin level for each sample i masuredby radicimmune assay (Pharmacia).

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irate stand at the same height. An enteral feeding tube is connected to each container and the time required to
ret 500 ml through the enteral feeding tube is determined. An open reservoir is then connected to each stand and zmposifion of example I poured into one reservoir and the Fresubin DFN Plus product poured into the other. An feeding tube is connected to each reservoir and the time required to deliver 500 ml through the enteral feeding
Is determined.

Property Composition of exam- Fresubin DFN Plus
pie 1 product
Viscosity (kg/me) 0.023 0.035
Free Flow Rate
(minl500ml)
Original Container 66 158
Open reservoir 60 129

The results indicate that the composition of example 1 has a superior flow rate.

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()06] A ready-to-use nutritional composition is prepared. The nutritional composition includes the following compo-

Component Cone (110am)) Energy (%)
Prptsln 341 15
Casein/Soy Protein (1:1)
Carbohydrate -11.2 g 45
Maltodextrin (’ow DE) 1.0 g
Modified topioca and corn starch 10.2 g
Soluble fibre including lnulin 1.0 g
Insoluble fibre 0.5 g
Upids 4.4g 40
Ràpºseed oil, Sunflower oil, Olive oil, Mono- and di-glycerides (E471)
Vitamins and minerals as in example I

(0071 The composition has an osmotarity of 190 mOsm/l. The viscosity is about 0.023 kg/ms and the free flow rate
1$ less than about 70 minutes per 500 ml through standard enteral tubing. Monounsaturated fatty acids provide about 2% of ensrgy, polyunsaturated fatty acids provide about 6% of energy, and saturated fatty acids provide about 5% of eiergy.
so [)058] It be understood that numerous modifications may be made to the specific embodiments described above without departing from the scope of the invention as defined in the claims.

661 nufr,bonaiOomposWon for diabetic patients, the-composition comprising a protein source providing about 10% to about 20% Of ener9 a lipid source providing-about 30%rtoabout 50% of energy, a carbohydrate source providing
about 3%to. about 55 of energy, and a fibre mixture including a viscous soluble fibre and inulin, àhydrolysate of lnulin,Orboth.

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2 A liquid nutritional composition for diabetic patients, the composition comprising a protein source, a lipid source, a
carbohydrate source, and a fibre mixture including a viscous soluble fibre and inulin, a hydrolysate of inulin, or both,

3. A nutritional composition according to claim 2 which has a viscosity, when measured at room temperature, of 0.015
5 to0.03kgM’s.

4. A powdered nutritional composition for diabetic patients, the composition comprising a protein source, a lipid
source, a carbohydrate source, and a fibre mixture including a viscous soluble fibre and inulin, a hydrolysate of inu-
lin, or both; the powdered nutritional composition being reconstitutabla in an aqueous liquid for providing a liquid
10 nutritional composition.

S. A nutritional composition according to any of claims ito 4 in which the fibre mixture further includes a source of
insoluble dietary fibre.

15 6. A nutritional composition according to claim 5 in which the source of insoluble dietary fibre is pea hull fibre.

7. A nutritional composition according to claim 5 or claim 6 in which the ratio of soluble fibre, including inulin, to insol-
uble fibre is 1:3to3:1.

20 S. A nutritional composition according to any of claims 1t4 in which the fibre mixture comprises about 0.5 g1100 ml
inulin, about 0.5 g/100 ml pectin or gum arabic, and about 0.5 g/100 ml pea hull fibre.

9. A nutritional composition according to any of claims 1t8 in which the lipid source Includes monounsaturated fatty
$ acids which provide about 25% to about 35% of the energy of the composition.
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10. A nutritional composition according to claim 9 in which the lipid source further includes saturated fatty acids provid-ing less than 10% of the energy of the composition.

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nited States Patent [19]

METHOD OF AND NUTRITIONAL AND - PHARMACEUTICAL COMPOSITIONS F0I, REDUCTION OF HYPERINSUUNEMIA

Inventor: Barry ft Sears, Swampscott, Mass.

Assignee: Elcotech Corporation, Boston, Mass.

[2.J Appi. No.: 07/996,797

[2] Filed: Dec. 24, 1992

Related U.S. Application Data

[63] Continuation-in of application No. 07/771,058, Oct. 2,
1991, abandoned, and application No. 07/771,402, Oct. 2, 1991, abandoned, each is a continuation-la-part of applica-
tion No.07/539,384, Jun. 18, 1990, Pat. V. 5,059,622,
which is a division of application No, 07/400,288, Aug. 29, 1989, abandoned, which is a continuation-in-part of appli-cation No. 07/251,139, Sep. 28, 1988, abandoned.

[51] hit. C1.7..........................A6IK 38/00; A61K 31170;
A61K 31/22; A61K 31/23; A61K 31/20

[5] U.S. CI.................................. 514/2; 514/23; 514/549;
514/552; 514/560

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(11]!atent Number:

[45] Date of Patent:

- 691409304

Oct. 34 2000

[58] Field of Search..................................... 514/549, 552, 514/560, 866, 2, 23

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Primary ExaminerRaymond Henley, III
A#anwy, Agent) or FlrmDechert Price & Rhoads

[57] ABSTRACT

A method and nutritional and pharmaceutical compositions are provided for the reduction of byperinsulinemia and the improvement of disease conditions related to byperinsuline-mia by administering a nutritional composition to modify hormonal response.

16 Claims, S Drawing Sheets

6,140,304

METHOD OF AND NUTRITIONAL AND PHARMACEUTICAL COMPOSITIONS FOR REDUCTION OF HYPERINSULINEMIA

REFERENCE TO PRIOR APPLICATIONS

This application is a continuation-in-part application of
U.S. patent applications Ser. No. 07/771,058 filed Oct. 2, 1991, now abandoned, and Ser. No. 07/771,402, filed Oct. 2, 1991, now abandoned, which applications are both continuation-in-part applications of U.S. Ser. No. 07/539, 384, filed Jun. 18, 1990, now U.S. Pat. No. 5,059,622, issued Oct. 22, 1991, which application is a divisional of U.S. Ser. No. 07/400,288, filedAug. 29, 1989, now abandoned, which application is a continuation-in-part of U.S. Ser. No. 07/251, 19, filed Sep. 28, 1988, now abandoned. All are incorpo-rated by reference herein.

FIELD OF TIM INVENTION

Thepresent invention relates to both,, nutritional and pharmaceutical compositions containing specified activated Omega 6 essential fatty acids, such as.gamma linolenic acid (GLA) and/or dihomo gamma linolenic acid (DGLA), com-bined with the activated Omega 3 essential fatty acids, such as eicosapentaeuoic acid (EPA), for the modulation of prostaglandin levels in order to reduce hyperinsulinemia. Although certain ratios of activated Omega 6 essential fatty acids and Omega 3 essential fatty acids can achieve this result, the modulation of prostaglandin levels can be enhanced when the appropriate ratio of activated essential fatty acids are combined with the appropriate ratios of protein and carbohydrate to control the postprandial secre-tion of insulin and glucagon. This invention can provide effective treatment for existing disease conditions which are related to hyperinsulinemia.

BACKGROUND OF THE INVENTION

Prostaglandins are a group of hormone-like substances which are known to play a critical role in virtually all body functions, including the control of the endocrine system, including insulin secretion. Elevated levels of insulin (i.e. hyperinsulinemia) are known to be strongly correlated with cardiovascular conditions such as hypertension, hyperlipidemia, Type II diabetes, and obesity [Reaven, G. M. Diabetes 37 1595-1607 (1988)]. The reduction of hyper-insulinemia results in a significant reduction of symptoms associated with any of these associated cardiovascular con-ditions.

Prostaglandins are directly effected by the diet. The role of diet in prostaglandin production is critical since the precursors of prostaglandins, known as essential fatty acids, cannot be made by humans and therefore must be supplied in the diet. Essential fatty acids are classified as either Omega 6 or Omega 3 depending on the positioning of their unsaturated double bonds within the fatty acid molecule. The typical essential fatty acids found in the diet are linoleic acid, (an Omega 6 essential fatty acid), and alpha linolenic acid (an Omega 3 essential fatty acid). However, the essen-tial fatty acids normally found in the diet are not the actual precursors to prostaglandins. The body must further metabo-lize these commonly available essential fatty acids into more metabolically activated essential fatty acids. The rate limit-ing step in this further metabolism is controlled by the enzyme delta 6 desaturase. Once an essential fatty acid has progressed beyond this enzymatic rate determining step, it has a far greater impact on prostaglandin metabolism. We term essential fatty acids beyond this enzymatic step as "activated essential fatty acids".

U.S. Pat. No. 5,059,622 discloses that the ratio of acti-vated Omega 6 essential fatty acids [such as gamma lino-lenic acid (GLA) or dihomo gamma linolenic acid (DGLA)] and activated Omega 3 essential fatty acids, such as eicosa-
s pentaenoic acid (EPA), will have a significant impact on the
production of prostaglandins of the one series or production ofprostaglandins ofthe two series. Prostaglandins of the one series(derived from DGLA) such as PGE1, have a beneficial impact on the cardiovascular system, whereas prostaglan-dies of the two series (derived from arachidonie acid [AA]) such as thromboxane Ac often have an adverse impact on the cardiovascular system. it is the dynamic balance of these two classes of prostaglandins, which is controlled by the diet, which will be a major factor in determining cardiovas-15 cular function.

The importance of maintaining an appropriate balance of prostaglandins of the one and two series is ultimately controlled by maintaining an optimal ratio of DGLA to AA. The ratio of DGLA to AA can be controlled through the 20 dietary intake of the ratio of activated Omega 3 and Omega 6 essential fatty acids was disclosed in U.S. Pat. No. 5,059,622. It has been disclosed in U.S. Pat. No. 5,059,622 that the balance of activated Omega 3 essential fatty acids (in particular eicosapentaenoic acid or EPA) and activated 25 Omega 6 essential fatty acids (either GLAor DGLA) has an impact on prostaglandin formation and the resulting reduc-tion of hypertension. The appropriate ratio of EPA combined with gamma linolenic acid (GLA) or dihomo gamma

linoleic acid (DGLA) would increase the amount of pros- 30 taglandins of the one series (such as POE,) which are
vasodilators while decreasing the relative amounts of pros-taglandins ofthe two series (such as thromboxane A1) which are vasoconstrictors. The end result of this prostaglandin modulation would be reflected in the reduction of hyperten-35 sion.

SUMMARY OF THE INVENTION

This invention comprises a method of and nutritional and
, pharmaceutical compositions for the treatment of hyperin-
sulinemia by altering the hormonal response caused by dietary factors. In particular, this invention relates to the reduction of byperinsulinemia, and therefore the control of resulting disease conditions that are strongly associated with 45 hyperinsulinemia.
Although prostaglandins are the primary regulators of the cardiovascular system, the also play a significant role in the regulation of other hormonal systems. An example of these effects on the endocrine system is that prostaglandins have
so a significant effect on the release of insulin from the pan-
creas. Thus reduction of hyperinsulinemia can be achieved by the appropriate modulation of prostaglandins, and in particular by increasing the prostaglandins of the one series while simultaneously decreasing those of the two series. This is because prostaglandins of the one series, and in particular PGE, have an inhibitory effect on the release of insulin [Sacca, Let. al., Acta Endocrieoiogica 79 266-274 (1975)].
This modulation of prostaglandins can be accomplished
60 by the supplementation of the diet with the appropriate ratio of activated Omega 6 essential fatty acids and the activated Omega 3 essential fatty acids. This modulation of prostag-landins can be further enhanced by the simultaneous inges-tion of the appropriate combination of protein to carbohy-65 drate in a solid food format to control the postprandial ratio of insulin to glucagon. The control of the postprandial ratio of insulin to glucagon will further enhance the production of

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stearidonic acid (which can be elongated into EPA), eicosa-pentaenoic acid (EPA), or docosahexaenoic acid (which can
be retroconverted into EPA). If activated Omega 6 essential
fatty acids (GLA or DGLA) are a constituent of the solid
food format, then the amount of activated Omega 3 essential
fatty acids should be at least equal to, if not greater than, the amount of activated Omega 6 essential fatty acids since the postprandial secretion of insulin and glucagon is being controlled by the solid food format. The reduced need for activated Omega 3 essential fatty acids such as EPA com-pared to U.S. Pat. No. 5,059,622 is due to the postprandial control of the insulin to glucagon balance using the appro-priate protein to carbohydrate ratio in a solid format which will have a greater inhibition on delta 5 desaturase activity thereby reducing the need for increased levels of EPA to control the activity of the same enzyme.
Since the solid food enhancement of the invention can be used as a meal replacement, it is also desirable to include necessary vitamins and minerals. The levels of these vita-mins and minerals should be greater than 25% of the RDA of vitamins and minerals in order to maintain relatively constant blood levels when the invention is being used as a meal replacement.
Although U.S. Pat. No. 4,920,098 discusses nutritional support for cardiovascular impaired individuals, this inven-tion relates to a more defined nutritional compositions which are designed to modulate the production ofprostaglandins of the one series. As an example, U.S. Pat, No. 4,920,098 teaches the use of hydrolyzed protein as a component ofthat invention. Furthermore, U.S. Pat. No. 4,920,098 teaches the use of a liquid formulation which would provide the maxi-mum surface area for the digestive process. In either situation, the control of the postprandial balance of insulin and glucagon would not be achieved and subsequently the modulation of the physiological fate of the activated essen-tial fatty acids could not be controlled.
To obtain optimal postprandial modulation of insulin and glucagon, the protein source of the solid food format should consist of between about 20% and 401/16 of total calories. Most preferably the protein source comprises approximately 30% of the total calories. The carbohydrate sources should contain approximately 30 to 50% of total calories. Most preferably, the carbohydrate source should contain approxi-nately 40% of the total calories. The ratio of protein to carbohydrate should not be greater than 1:1 nor less than 0.4:1. The fat component should contain 20 to 40% of the total calories with the most preferable amount approxi-mately being 30% of total calories. The most preferred balance of protein, carbohydrate, and fat (30%, 40%, and 30% of total calories respectively) in the solid food format enhancement of this invention is quite different than the preferred balance (20%, 50%, and 30% of total calories) taught in U.S. Pat. No. 4,920,098. The preferred ratio of protein to carbohydrate taught in U.S. Pat. No. 4,920,098 is too low to effect positively the postprandial insulin to glucagon ratio. Furthermore, as noted above, a liquid format for both enteral and parenteral formulations described in U.S. Pat. No. 4,920,098 will also prevent that nutritional composition from controlling insulin and glucagon levels because it is not in a solid format to slow digestion and subsequent rnacronutrient absorption. Also the use of hydro-lyzed protein in the liquid format as taught in U.S. Pat. No. 4,920,098 would be contraindicated since it would cause an increase in insulin levels compared to this invention. These increased insulin levels would decrease the desired modu-lation of prostaglandins and would not reduce hyperinsulinentia, and in fact may even increase it.

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If activated Omega 6 essential fatty acids are included in
the fat component of the solid food format, then the ratio of activated Omega 3 essential fatty to the total activated Omega 6 essential fatty acids should be at least greater than
s 1:1. 11 the solid food format consisting of protein and
carbohydrate is not used with the activated essential fatty acids, then the ratio of activated Omega 3 essential fatty acids to activated Omega 6 essential fatty acids should be greater that 2:1 as taught in U.S. Pat. No. 5,059,622.
10 The cardiovascular disease conditions that can be treated

by the invention by way of example and illustration, and not limitation, include the following: diabetes (Type I and Type II), hypertension, hyperlipidemia, obesity, congestive heart failure, angina, increased platelet aggregation, and obesity. 1-5 Examples will now be given. However, it is recognized that various changes and modifications to the illustrated examples can be made by those persons skilled in the art, all falling within the spirit and scope of the invention.

20 EXAMPLE

Asoft gelatin capsule containing 40mg. ofrefined borage
oil, 333 mg. of refined marine oil, and 120 mg. of olive oil would contains 80 mg. of EPA and 10 mg. of GLA. This soft 25 gelatin capsule can be given orally for the reduction of hyperinsulinemia.

EXAMPLE 2

Asoft gelatin capsule containing 10 mg. of the ethyl ester
30 of DGLA and 333 rug, of refined marine oil would contain
10 mg. of DGLA and 80 rug. of EPA. This soft gelatin capsules can be given orally for the reduction of hyperin-sulinemia.

35 EXAMPLE 3

A solid food format in a bar form containing 14 grams of --protein consisting ofsoy protein, calcium casineate, peanuts (31% of calories), 18 grams of carbohydrate consisting of
40 high fructose corn syrup, honey, sucrose, and fructose (40%
of calories), and fat consisting of olive oil, borage oil (a sàurce of GLA), marine oil (a source of EPA) and palm kernel oil (29% of calories). The amount of GLA(5 rug.) and of EPA (5 rug.) in the bar gives a 1:1 ratio. The bar also
45 containsthe following vitamin and mineral contents with the
per cent U.S. Recommended Daily Allowance (RDA) in parenthesis: A(50), B1(48), B2 (46), B3 (100), B6 (200), B12 (33), C (200),. D (34),E (200), Folic acid (33),
- D-pauto.tbenic acid (33), Biotin (30), Calcium (32), Phos-
phorus (28), Iron (33), Zinc (50),-Magnesium (35), Iodine (40), Copper (43),,chrothium..(100 ug*), Manganese (13 mg.*). The asterisk means..that noU.S. RDA has been established.

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EXAMPLE

A solid food format in a bar form containing 14 grªms. of protein consisting of toasted soy beans, soybean isolate, whey protein concentrate, and calcium caseinate. (31% of calories), 18 grams of carbohydrate consisting of raisin 60 paste, honey, high fructose corn syrup, and high maltose corn syrup (40% of calories), and fat consisting of sesame oil, marine oil (source of EPA), black currant Oil (source of GLA), and palm kernel oil (29% of calories). The amount EPA (80 rug.) and GLA (5 mg.) in the bar gives a 16:1 ratio. 65 The bar also contains the following vitamin and mineral contents with the per cent U.S. Recommended Daily Allow-ance (RDA) in parenthesis: A(50), B1(48), B2 (46), B3

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(100), 136 (200), 1312 (33), C (200), 1) (34),E (200), Folic
acid (33), D-pantothenic acid (33), lotili (30), Calcium
(32), Phosphorus (28), Iron (33). Zinc (50), Magnesium
(35), Iodine (40), Copper (43) Chromium (100 u.g*), Man-giaese (1.3 mg.*). The asterisk means that no U.S. RDAhas
been established.

EXAMPLE 5

A solid food format in a bar form containing 14 g. of protein consisting of soy protein, calcium casineate, peanuts (31% of calories), 18 grams of carbohydrate consisting of high fructose corn syrup, honey, sucrose, and fructose (40% of calories), and fat consisting of olive oil and palm kernel oil (29% of calories). This bar contains no activated Omega 3 or Omega 6 essential fatty acids. The bar also contains the following vitamin and mineral contents with the per cent U.S. Recommended DailyAllowance (RDA) in parenthesis: A(50), 131(48), 132 (46), 133 (100), B6 (200), B12 (33), C (200), 1) (34),E (200), Folic acid (33), 1)-pantothenic acid (33), Biotin (30), Calcium (32), Phosphorus (28), Iron (33), Zinc (50), Magnesium (35), Iodine (40), Copper (43).Chr-11um.100.ug*), Manganese (1.3 mg.*). The asterisk eans that no U.S. RDA has been established.

EXAMPLE 6

Elevated triglyceride levels are strongly associated with .byperbasuiinemia (see Reaven, G. M.). This is because the a key enzyme (acetyl-CoAcarboxylase) that is the firststep of fatty acid biosynthesis in the liver is activated by insulin (Mabrouk, G. M., et al. J. EIoL Chem. 265 6330-6338 (1990). Apatient with triglycerides levels of 467 mg./dl was put on a dietary regime of two solid food bars per day as a meal replacement using a composition found in Example 5. With each bar two soft gelatin capsules containing activated essential fatty acids were taken. The capsules, each contain-ing 60 mg. EPA and 15 mg. of GLA., were consumed with each bar.

After six weeks, the triglyceride level of the patient had decreased to 167 mg./dl. The patient was taken off the bars and capsules containing the activated essential fatty acids, and her triglyceride levels after 6 weeks rose to 432 mg./dl. The reduction of elevated triglycerides levels is consistent with a lowering of hyperinsulinemia.

EXAMPLE 7

Hypertension is strongly associated with hyperinsuline-mia (see Reaven, G. M.). A patient had a blood pressure of 180/110. Using the composition described in Example 3 given twice per day as a meal replacement along with two soft gelatin capsules, each capsule containing 80 mg. EPA and 10 mg. GLA, with each bar. The total intake of EPA and GLA per day was 170 mg. and 30 rug. GLA respectively, The blood pressure was reduced to 110170 within six weeks. The reduction of hypertension is consistent with a reduction the associated hyperinsulinemia.

EXAMPLE 8

1)’pe II diabetes is strongly associated with hyperinsuline-mia (see Reaven, G. M.). Using the composition in Table 3, a bar along a single soft gelatin capsules containing a total o 80mg. EPA and 5mg. GLAwere consumed twice per day as a meal replacement. The patient with ’Ipe II diabetes was able to reduce her fasting blood sugar from 150 mg./dl. to 107 mg./dl. after 5 weeks. The reduction of fasting blood sugar is consistent with a reduction of the associated hyper-insulinemia.

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EXAMPLE 9

Hyperinsulinemia results in insulin resistance (see Reaven, G. M.). The two primary serum indicators ofinsulin resistance is fasting serum glucose and fasting serum trig-lycerides. A two week study was conducted with the com-position of Example 4 using six males. The composition was taken twice per day. At the end of two weeks, the average serum glucose had decreased from 99.5–5.3 to 82.5–4.9.

10 This represents a 17% decrease in fasting glucose levels which had a statistical significance of p4).005. Serum triglycerides decreased from 189.3–54.7 to 138.2–37.9 in the same time period. This represents a 30% decrease in fasting triglyceride levels with a statistical significance of 15 p40.05. The reductions in fasting glucose and fasting trig-lycerides levels are consistent with a reduction in elevated insulin levels.

EXAMPLE 10

20 The development of hyperinsulinemia often leads to increases in platelet aggregation [Winocour, P. D. Diabetes 4126-31 (1992)]. To determine the effect on platelet aggre-gation of individuals without existing cardiovascular disease, ten normal individuals consumed eight soft gelatin capsules containing 80 rug. EPA and 10 mg. GLA per day (640 mg. EPA and 80 mg. GLA per day) for a two week period. Platelet aggregation times of each subject were determined prior to and after dietary intervention with the invention. The platelet aggregation was initiated with expo-30 sure to collagen or with the throxnboxane A2 agonist U46619. Platelet aggregation initiated by U46619 was decreased by 24% (p’eO.Ol) compared to the starting values, and the lag time for the onset of platelet aggregation by exposure to collagen was increased by 20% (p>O.OS). The s reduction of platelet aggregation is consistent with a reduc-tion in the circulating levels of insulin.

EXAMPLE 11

Excess body fat is highly correlated with hyperinsuline- 40 Ten males with an average per cent body fat of
33.4–1.2% used the composition listed in Example 5 plus two soft gelatin capsules, each containing 80 mg. EPA and 10 rug. of GLA, twice a day as a meal replacement. After a

total of 8 weeks, their average per cent body fat had ’ decreased to 26.4–1.4%. This represents a 21% decrease in
body fat with a statistical significance of p.cz0.005. The decrease in per cent body fat is consistent with a reduction of hyperinsulinemia.

50 EXAMPLE 12

Twenty women with an average per cent body fat of 36.8–3.2% using the composition in Example 2 twice per day as a meal replacement. After 8 weeks, their average per 55 cent body fat had decreased to 29.5–4.1. This represented a 19% decrease in their body fat with a statistical significance of p<0.005. The reduction in the body fat is consistent with
a reduction in hyperinsulinemia.

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EXAMPLE 13

Insulin resistance due to hyperinsulinemia is commonly associated with increased glycosation of hemoglobin (HbMc) due to increased serum glucose levels. Hyperin-sulinemia is also associated with increased triglycerides, 65 decreased HDL cholesterol levels, and elevated percent body fat (see Reaven, G. M.). Amale subject with a body fat percentage of 34.8%, a triglyceride level of 450 mg./dl, a

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13 HbAZC level of 6.8% of total hemoglobin, and HDL choles-

terol level of 24 mg./dl used two capsules, each capsule contained 80 mg. EPA and 10 mg. GLA, twice a day. The capsules were taken with the composition described in Example 5 as a meal replacement to enhance the action of
the activated essential fatty acids. After five weeks of treatment, his body fat had decreased to 30%, his triglycer-ides levels had decreased to 168 mg./dl., his Hbj, level decreased to 5.3% oftotal hemoglobin, and HDLcholesterol increased to 30 mg./dl. These changes in body fat and these blood parameters is consistent with a reduction in byperin-sülinemia.

EXAMPLE 14

Fatigue is a common result from cardiovascular deterio-ration especially in congestive heart failure. It is also com-mon as a consequence of postviral infection such as viral I myocarditis. To demonstrate the ability of the invention to treat fatigue, we used HIV infected patients who had devel-oped chronic fatigue. The patients self rated their fatigue using a five level score to determine changes in fatigue levels with treatment. These levels ranged from +2 (significant reduction of fatigue) to -.2 (significant increase in fatigue), with a level of 0 indicating no change in fatigue
status.

Patients in each group received soft gelatin capsules containing 80 mg. EPA and 10 mg. GLA (active) or placebo capsules containing olive oil. Each group took 10 capsules per day. After six months those taking the active capsules had a fatigue rating of (+1.1), whereas those on the placebo capsules had a fatigue rating of (-0.5). The differences between the two groups was statistically significant. When the patients taking the placebo capsules were switched to the active capsules, their fatigue rating changed from 0.5 to +0.8. This result was also statistically significant. This example indicates that cardiovascular fatigue can be allevi-ated by the invention.

EXAMPLE 15

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EXAMPLE 17

Beta blockers are often used to treat hypertension. An appropriate example of a pharmaceutical composition would
5 be the following: 5 mg. of propranodol is formulated in a
soft gelatin capsule containing 60 mg. EPA and 15 mg. of GLA. This formulation would then be used with or without the bar composition described in Example 5 to treat a patient with hypertension.
10

EXAMPLE 18

Fatigue is a result of congestive heart failure. Angiotensin

15 converting enzyme inhibitors such as captopril are used to
treat such heart failure. An appropriate example of pharma-ceutical composition would be the following: 5 mg. of captopril included in a solid food format similar to that described in Example 4 but which containing 30 mg. EPA
20 and 5mg. of GLAfor use with patients with congestive heart
failure.

What is claimed is:
1. A method for the reduction of hyperinsulinemia in a person by the control of insulin and glucagon levels, which
25 method comprises:

30

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Another example of the benefits of the invention, would
be for patients who are taking medication, which as a side 40 effect, will increase their fatigue. An example of such medication isAZTwhich causes anemia when taken by HIV positive individuals at a dosage of 1500 mg. AZT per day. The active group took 10 soft gelatin capsules per day. Each capsule of the active contained 60 mg. EPA and 15 mg. of 45 GLA. The control group took 10 capsules per day consisting of olive oil as a placebo. Fatigue ratings were as discussed in Example 14, After six months, those on the active had a fatigue rating of +1.0 whereas those on the placebo had a fatigue rating of 0.4. The differences between the two 50 groups was statistically significant. Those in the placebo group were then placed on the active capsules for 5 mouths. At the end of five months, their fatigue rating had changed from 0.4 to +0.5. These results indicate that the invention

can alleviate drug induced fatigue. 55

EXAMPLE 16

An example of a pharmaceutical composition is the addition of an existing drug to the invention. Aspirin is a known anti-platelet aggregation drug. Since the invention has been shown to reduce platelet aggregation (see Example
1 10, the addition of aspirin would be synergistic. An appro-priate pharmaceutical composition is the addition of 50 mg.
I of aspirin to a soft gelatin capsule containing 80 mg. of EPA and 10 nag. of GLA. These capsules can, be combined with or; without the solid food format to reduce platelet aggrega-tion.

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a) providing for the oral introduction into the person of a therapeutic, effective amount of a solid food product having a total calorie value, which solid food product comprises:
1) a protein source of high biological value having
about 20 to 40% of total calorie value;
ii) a carbohydrate source composed primarily of a low glycemic index having about 30 to 50% of. total calorie value;
iii) a fat source having about 20 to 40% of total calorie value wherein the fat source comprises a combina-tion of activated Omega 6 essential fatty acids and activated Omega 3 essential fatty acids in a ratio of Omega 3 acids to Omega 6 acids of greater than 2:1;
and

iv) the protein source to carbohydrate source ratio Water than 0.4:1, but less than 1:1, to control the insulin and glucagon levels of the person.
2. The method of claim 1 which includes incorporating all or a portion of the fat source in a separate form for the introduction with the solid food product.
3. The method of claim 1 wherein the fatsource comprises a ratio of Omega 3 acids to Omega 6 acids from 2:1 to 8:1.
4. The method of claim 1 wherein the Omega 6 fatty acids are selected from the group consisting of gamma linolenic acid, dihomo gamma linolenic acid and their alkyl esters.
5. The method of claim 1 wherein the Omega 3 fatty acids are selected from the group consisting of eicosapentaenoic acid and its alkyl esters.
6. The method of claim 1 which includes reducing the blood pressure of a hypertensive person.
7. The method of claim 1 which includes providing for the oral ingestation by the person of the fat source in an emulsion, microencapsulated or capsule form.
S. The method of claim 1 wherein the carbohydrate source comprises fructose or a fructose source.
9. The method of claim 1 wherein the activated Omega 6 essential fatty acid comprises gamma linolenic acid (GLA) or dihmo gamma linolenic acid (DGLA) in the form of triglycerides, diglycerides, monoglycerides, free fatty acids or their alkyl esters.

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO DIRECCION DE NUEVAS CREACIONES

2020
Bogota, D.C.,

4 Abogado ALICIA LLOREDA RICAURTE

ASUNTO Radicación 07-104268
TrÆmite 011
Evento 378
ActuaciOn 519.

Oficic U b
Folios 015

Patente de Invenciôn Patente de Modelo de Utilidad
Via Nacional
Via PCT (Fase Nacional) I.. Cap.I Cap. II

No. Solicitud Internacional PCT/US2006/01 2576
Fecha de Presentaciôn Internacional 04 Abut 2006

Fw-

Como resuttado del Examen de Fondo realizado, con fundamento en el ArtIcuto 45 de la Decision 486 de la Comisión de la Comunidad Andina, se comunica:

1. Documentos estudiados

Descripciôn:
Reivindicaciones:
Dibujos:
Prioridad:

2. Objeto de la invención

Folios 187 a 343 como se radicó inicialmente.
Folios 344 a 363 como se radicó inicialmente Folios 365 a 382 como se radicô inicialmente
US 60688633 Abril 06 2005

Titulo de la soUcitud:"Un mØtodo y composición para mejorar nutricionalmente el control de (a glucosa y (a acciOn de la insulina"

El problema planteado en esta solicitud es la necesidad de composiciones para aumentar la sensibilidad a (a insulina, reducir la resistencia a la insulina, aumentar la eliminaciôn de grasa postprandial, demorar la apariciôn de glucosa en sangre, yb reducir los niveles de insulina en plasma post-prandialmente.

Para resolver este problema tØcnico la solicitud en estudio proporciona una formulación nutricional que comprende una fuente de proteina, una fuente de grasa y una fuente de carbohidratos.

El objeto de (a presente Solicitud se re(aciona con la ClasificaciOn Internacional de Patentes (CIP): A231-1/29; A231-1/30; A231-1 /305; A61 K31/201; A61 P3/02; A61 P3/I0

3. Excepción a (a Patentabilidad (Art 20 D 486 literal (d))

El objeto de las reivindicaciones 49 a 95 no es patentable de acuerdo con el Art citado.

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4. De la Solicitud de Patente

Reivindicaciones (Art 30 D 486, Art 22 PCT)

Claridad

Las Reivindicaciones 21 a 24 no son claras porque contienen los tØrminos "aproximadamente, cuanto menos uno" que son imprecisos, por Ia cual no permite distinguir la invención del estado de la tØcnica. Se sugiere sustituirlos por un tØrmino
preciso o un rango concreto.

Las reivindicaciones 25 a 48 hacen referenda a regimen dietØtico sin embargo no es
claro Si este se refiere a un producto a una formulación. Se sugiere hacer la
aclaraciôn correspondiente y reivindicar tat como se hizo en la reivindicaciOn 1.

ConcisiOn

sLasreivindicaciones 8 a 16 y 20 a 24 hacen referenda a la proporciôn de la fuente do grasa como acido linoleico (18:2), sin embargo so presentan para cada una de las reivindicaciones diversas proporciones que varlan entre 2y 10 porciento. Se sugiere
at solicitante reivindicar de manera que sea conciso un rango de valores y no se
reivinclique uno par uno los vafores de las diferentes realizaciones.

S. Determinaclôn del Estado de la TØcnlca

El Estado de la TØcnica se determinó con base en la fecha do presentaciOn de la Solicitud de Prioridad (Abril 06 2005) y se encontraron los siguientes documentos que anticipan el objeto de esta solicitud:

Item Pocumento Tituto Fecha de

Publicación*

Dl EP0898900 Composition and method for providing 1999-03-03 nutrition_to_diabetes

Method of and nutritional and
D2 US6140304 pharmaceutical compositions for reduction 2000-10-31
of hyperinsulinemia

Dl divulga una composiciôn alimenticia para diabØticos. La composiciôn contiene una fuente do la prot&na, una fuente del lipidos, y una fuente del carbohidrato. La composicion incluye una mezcta de la fibra quo contiene una fibra y una inulina soluble viscose, un hidrolizado do La inulina, o ambos.

D2 divulga composiciones alimenticias y farmacØuticas para la reducciOn do la hiperinsulinemia y La mejora de (as condiciories de la enfermedad relacionadas esta, administrando una composiciOn alimenticia para modificar respuesta hormonal.

6. Examen de Patentabilidad (Art 14 D486)

Novedad (Art 16 D486)

La reivindicación I consiste en una formulaciOn nutricionat, (a cual comprende: a. Una fuente do proteins;
b. Una fuente de grasa; y
C. una fuente do carbohidratos.

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En donde la fuente de protelna y la fuente de grasa estÆn en unaproporc6n4 aproximadamente 1:1, cada una comprendiendo entre aproximadamente el 15 % aproximadamente el 45% de las calorlas totales de Is composiciôn, con la condiciOn que Is fuente de protelna, la fuente do grasa, y la fuente de carbohidratos no estØn en una proporciOn de 30:30:40.

Comparacion do las caracterIsticas tØcnicas esenciales, con (as del Estado de Is TØcnica:

Caracteristicas esenciales Di D2
Formulación nutricional

Fuente deppteina (entre 15-45% de calorias)
Fuente dØ grasa (entre 15-45% de calorlas)
Fuente de carbohidratos (entre 15-45% do calorlas)

Las caracterIsticas esenciales de la composick5n de la reivindicaciôn 1 habian sido divulgadas previamente en Dl, el cual enseæa una formulación nutricional que
contiene:

a.

una fuente do proteina que provee 15% de energia (calorlas) (ReivindicaciOn
1, ejemplos I y4);
b. una fuente do grasa que provee entre el 30 y el 40% do energia (calorias) (Reivindicación 1, ejemplos I y 4); y
C. una fuente do carbohidratos que provee 40% de energia (calorias)
(ReivindicaciOn 1, ejemplos I y 4)
y en donde la fuente de protelna y (a fuente de grasa estØn en una proporciOn de aproximadamente 1:1 (ejemplos I y 4).

En consecuencia, la reivindicación I carece do novedad, segün Jo divulgado en el documento Dl.

Las reivindicaciones dependientes 2 a 16 y 25 a 41 no mencionan alguna caracteristica que haga nueva a la composición de (a reivindicaciOn 1, con respecto a to divulgado por Dl, por Jo cual se considera que no son nuevas.

La reivindicación 18 consiste en una formulación nutricional, la cual comprende: d. Una fuente do proteina;
e. Una fuente do grasa; y
f. una fuente de carbohidratos.
En donde Ia fuente do protelna, la fuente de grasa y (a fuente de carbohidratos estÆn en una proporción de aproximadamente 1:1:1, cada una comprendiendo entre aproximadamente una tercera parte do las calorlas totales de la composición

Comparación do las caracteristicas tØcnicas esenciales, con las del Estado de Is TØcnica:

CaracterIsticas esenciales Dl D2
Formulación nutricional
Fuente de proteina (tercera parte de calorias)
Fuente do grasa (tercera parte de calorIasj
Fuente do carbohidratos tercera parte de calorias)

Las caracteristicas esenciales de la cornposición de (a reivindicación I habIan sido divulgadas previamente en D2, el cual enseæa una formulaciôn nutricional que contiene:

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d. una fuente de proteina que provee entre el 20 y 40% de calorlas
(Reivindicaciôn 1, ejemplos 3 a 4);
e. una fuente de grasa que provee entre et 20y 40% de calorlas (ReMndicaciOn
1, ejemplos 3 a 4); y
f. una fuente de carbohidratos que provee entre el 30 y 40% de calorias
(Reivindicación 1, ejemplos 3 a 4);
y en donde la fuente de proteina, la fuente de grasa y la fuente de carbohidratos estÆnen una proporciôn de aproximadamente 1:1:1 (ejemplos 3 a 5).

En consecuencia, la reivindicación 18 carece de novedad, segün 10 divulgado en et documento 02.

Las reivinthcaciones dependientes 19 a 24 y 42 a 48 no mencionan alguna caracterfstica que haga nueva a la composiciOn de la reivindicaciôn 1, con respecto a to divulgado por D2, par to cual se considera que no son nuevas.

7. Conclusion

Los requisitos de PatentabUidad de la presente Soticitud estÆn afectadosas[:

L Item DocumentoReivindicaciones afectadas Reguisito que afecta
L Dl EP0898900 I a 16 25 a 41 Novedad
D2 1JS6140304 18a24 y42a48 Novedad

En cumplimiento del artIculo 45 de la DecisiOn 486 de la ComisiOn de la Comunidad Andina, se le indica que debe dar respuesta dentro del tØrmino de sesenta (60) dIas contados a partir de la fecha de notificación de la presente comunicaciOn. En caso de no dar respuesta at presente requerimiento, o Si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegarà la patente.

Notifiquese el presente oficio conforme a to dispuesto en el numeral 5.2, literal e), del capituto quinto del tItulo primero de la Circular Unica No. 10 de 2001.

JOSÉ LUIS SALAZAR LOPEZ
Director de Nuevas Creaciones (C)

El anterior requerimiento fue notificado por faciOn en lista, de fecha

CONCEPTO TECNICO I EXAMINADOR TECNICO
No.0505 L Côdigo No.202093

Primer Artculo 45 - Expediente 07-104268

SUPRINTEN DEN CIA

Seæcr(a)(es)
AUCIA LLOREDA RICAURTE CALLE 72 NO.5-83 P180 5
BOGOTA D.C.

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CORREO CERTIFICADO

Radicaclón: 7-104268- -6.0 Fecha: 2011-09-0‘11&io’:28
Trmite: 11 PATENTEIYII
Evento: 379 FA$ENACIONAUI
Aotuación: 432 COMUNICACTOADM
Destinatario: ALICIA LLOREDA RICAURTE Folios I

Referenda RESOLUCION: 47265
Fecha: 31/08/2011
Expediente: 7-104268
TrÆmite: 11 PCT-PATENTE DE INVENCION CAPITULOS I Y II
Evento: 379 FASE NACIONAL INCLUIDO CAPITULO II
Actuación: 432 COMUNICACION ACTO ADMINISTRATIVO

Conedidamente 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 do) tØrmino do cinco (5) dlas hâbiles contados a partir dol envio de la presente citación, en horarlo de 8:00 a.m. a 4:30 . p.m. jornada continua, con el fin de notificarle personalmente el contenido de la resoluciôn de la referenda proferida dentro del expediente tramitado con el nimero de radicaciOn citdo en el asunto.

De no hacerse presente en el tOrmino indicado anteriormente, la providencia en mención se notificarª por edicto, el cual so fijarØ por el tØrmino de diez (10) dias en el Centro de DqcumentaciOn e lnformaciOn.

Para su comodidad el texto completo do la resoluciôn se encontrarâ disponible en la pÆgina web do la Entidad desde el dia hØbil siguiente al de su notificación, Pa cual podrØ ser consuItada desde un computador con acceso a Internet, en la pÆgina www.sic.gov.co,con et nUmero de resoluciôn a travØs do la opcion trÆmites y servicios - do carÆcter general transversal - corisulta actos administrativos y providencias.

SEn case de que se haya notificado, haga case omiso do este aviso.

Secretarla General

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

Soda Centro: Carrera 13 No. 27-00 plsos 3, 5, 7y 10 PBX: 5870000
Al contester favor indique all nOmero de Soda CAN: Av. Carrera 50 No. 26-55 mt. 2 Tel 5880070
radicaciôri consignado an el sticker Call Center 5920400. Linea 018000-910165
Web: www.slc.gov.co e-mail: lnfosio.gov.co
Bogota D.C. Colombia

Industria yComerc
SUPERINT-EN DENCIA

REPUBLICA DE COLOMBIA SUPER1NTENDENCIA DE INDUSTRIA V COMERCIO

RESOLUCIÔN L.:. 1
Por ía cuel se deniega una patente de invenciOn

Rad. PCT/07-104268

EL SUPERINTENDENTE DE INDUSTRIA Y COMERCIO

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

CONSIDERANDO:

FRIMERO: Que mediante escrito radicado en esta Superintendencia el dia 4 de octubre ç le 2007 con el N° 07-104268-00000-0000, la doctora Alicia Lioreda Ricaurte, en su calidad de apoderada de NESTEC S.A., presentO la solicitud de patente de invención titulada "UN METODO Y COMPOSICION PARA MEJORAR NUTR1CIONALMENTE EL CONTROL DE LA GLUCOSA Y LA ACCION DE LA INSULINA", corresponthente a La $olicitud internacional PCT/ US2006/ 012576 de fecha 4 de abril de 2006, para que se iniciara (a fase nacional en virtud del Tratado de Cooperación en Materia de Patentes (PCT).

$EGUNDO: Que de conformidad COfl 10 dispuesto en et articulo 27 del Tratado de Cooperación en Materia de Patentes (PCT).y la regla 5 Ibis del Reglamento, que facultan La Superintendencia sabre la aplicación de la Decision 486 de la Comisión de la Comunidad Andina, se efectuô el examen de forma a la solicitud, de acuerdo con Ia previsto en el articulo 38 de la mencionada Decision andina.

TERCERO: Que efectuado el examen de forma en cuanto a los requisitos que debe lienar la solicitud y cumplidas las exigencias legates, se ordenO pubticar el extracto sin que se hubieran presentado oposiciones por parte do terceros.

CUARTO: Quo mediante escrito radicado en esta Superintendencia el dia 26 de marzo de 2009, el solicitante presentó petición de examen de patentabilidad, en los tØrminos establecidos en el articulo 44 de la DecisiOn 486 do (a Comisión de la Comunidad Andina.

QUINTO: Que el articulo 45 de (a DecisiOn 486 de (a Comisión de (a Comunidad Andina establece quo: "Si ía oficina nacional competente encontrara quo ía invenciOn no es patentable o que no cumpie con alguno de los requisitos establecidos en esta DecisiOn para Ia concesiOn do ía patente, Jo notificarÆ a! solicitante. Este doberØ responder a la notificaciOn dentro del plazo de sesenta dies contados a partir de la fecha do la notificaciOn. Este plazo podrª ser prorrogado por una sole vez por an perlodo de treinta dias adiciona/es. (...) Si ci solicitante no rospondiora a la notificaciOn dontro del plazo senaiado, o si a poser do la respuesta subsistieran los impodimentos para ía concesiOn, Ia oficina nacional competente donegarO ía patente".

SEXTO: Quo de conformidad con lo dispuesto en el articulo 45 antes mencionado, se realizó el examen de fonda y se requiriO al solicitante mediante Oficlo No. 6135,

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: www.stc.aov.co e-mail: infosic.goy.co
Bogota D.C. - Colombia

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Industria y ComerciA’
SUPERNTENDENCIA

REPUBLICA DE COLOMBIA SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

RESOLUCIÔN

Por ía cual se deniega una patente de invención

Fad. PCT/07-104268

ificado el 8 de abril de 2011, para que se pronunciara sobre las objeciones ctuadas a la solicitud en cuanto a claridad y concision de las reivindicacior,es, :epciones a la patentabilidad y carencia de novedad, de acuerdo con las exigencias los arUculos 16, 20 d) y 30 de la Decision 486,

nscurrido el plazo establecido no se dio respuesta at requerimiento y sugerencias ba indicados.

RESUELVE:

FTiCULO PRIMERO: Denegar la patente de invericiOn titulada "UN METODO Y OMPOSICION PARA MEJORAR NUTRICIONALMENTE EL CONTROL DE LA

LUCOSA Y LA ACCION DE LA INSULINA", que entrO en fase nacional en virtuci del ratado de Cooperación en Materia de Patentes (PCT).

RT1CULO SEGUNDO: Notificarpersonatmente el contenido de la presente resoluciôn a a doctora Alicia Lioreda Ricaurte, en su calidad de apoderada de NESTEC S.A., o a uien haga sus veces, entregndoIe copia de Ia misma y advirtlØndole que contra ella rcede el recurso dereposiciOn, ante et Superintendente de Industria y Comercio, el cual QdrÆser interpuesto en el memento de la notificaciOn o dentro de los cinco 5 das hÆbiles iuientes a ella.

NOTJFQUESE V CI)MPLASE.
H Dada en Bogota, D.C., a los

lSUPER1NTENDENTEDEINDUSTRIAYCO R 0,

jo E MIGUEL D LA ALLE RESTREPO

Dcctora
ALiCIA LLOREDA RICAURTE
Calle 72 No. 5-83, P1cc 5.
otŒ D.C.

Juan Carlos Chaparr V.
Doris Elena Polo C.
Jose Luis Salazar
Jose Luis Londoæo F.

2de2 Sede Centro: Carrara 13 No. 27-00 Pisos 3, 4, 5 y 10, Sede CAN: Av. Carrara 50 No. 27-55, mt. 2.
Conmutadores: 5870000 y 5880234
Fax: 5870284. Linea 0180000-910165
Web: wwwsic.Qov.co e-mail: infotsic.ov.co
Bogota D.C. - Colombia

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S $UPERFNTENDENCA

REPUBLICA DE COLOMBIA
SUPERINTENDENCIA DE INDUSTRIA V COMERCIO

RESOLUCION No: 63686
Por ía cual Se dcclara ía caduc!dad de una patente

Rid. PCT I 07-104271

EL SUPERINTENDENTE DE INDUSTR1A Y COMERCO

On ejerciclo de sus facultades legates, en especial de las conferidas en el numeral 26 del articulo 30 del Decreto 4886 de 2011, y

CONSIDERANDO:

PRIMERO: Que mediante Resolución NO 4311 del 31 de enero de 2012, la Superintendencia do Industria y Comercio concediO una patente a la invenciOn titulada "COMPUESTO (3-CLORO-4-FLUOROBENClL)-(3-METlL-3-AZA-BlCICLO3i.0]HEX-6.ILMETIL) AMIDA DEL.AtDO 1 METIL -1H-1M1DAZOL-4-CARBOXIL1CO COMO IIJHJBIDOR DEL TRANS.PORTE DE GLICINA DE TWO I Y COMPOSICIONES FARMACEUTICAS QUE LO CONTIENEN", a nombre de la sociedad Pfizer Products Inc., con vigencia desde el 27 do marzo de 2006 hasta el 27 de marzo do 2026. La ResoluciOn NO. 4311 quedO en firme el 5 do marzo de 2012,

EGUNDO: Que el articulo 80 de la Decision 486 de la ComisiOn de la Comunidad Andina establece:

Para mantener vigente ía patente 0, en su caso, Ia solicitud do patente en lrØjnite,
deberÆ pagarse las was anuaies, de conformidad con las disposiciones do la
oficina naciona! competente. Las anuaiidadØs deberÆn pagarse par aæos
adelantados.

La foci-ia do vencimiento do cede anualidad serÆ elüitimo dia del mŁs enquo fue presentada ía solicitud. PodrÆnpagarse dos a mÆs tases anusiespar adelantado.

Una tasa anus.lpodia pagarse dentro do un plaza do grade do seis meses contado
desde.Ia fechà do inicio del per(odo anus.l correspondiente, pagando conjuntamente
of recargo establecido. Dua.nte el plaza do grade, Ia patente o ía solicitud do
patente mantendrÆ su vigencia plenà.

La faita de pago do una tasa anus.l conforme a este artIculo producirÆdo pleno
derecho Ia caducidad do Ia patente a do Ia soilcitud do patente".

ItRCERO: Que el interesado no acreditO el pago de los derechos legates porrespondientes a la primera anualidad comprendida entre el 27 de marzo de 2012 y el.27 do marzo de 2013,

CUARTO: Oue el tØrmino de aracia de 6 meses, a aue hace referenda la norma en nenciOn, venciO el dIa 27 de septiembre de 2012.

Pagina ide 2

Al contestar favor indique el nOmero S Sede Centro: Carrera 13 No. 27-00 pisos 2, 5, 7 y 10 PBX: 5870000
do radicaoiôn clue se indica a continuaoiOn: Sede CAN: Av, Carrera 50 No, 26-55 mt. 2 Tel 5737020
Cod Veriflcación: 311592710 Call Center 5920400. L1neagratuita Nacional 01800-910165
Web: ow,sic.gozea e-mail: coacte0os(sic4ov.co
Bogota D.C. Colombia

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IndusWa y Comm?,*
SUPERiNTENOENCA

REPUBLICA DE COLOMBIA
SUPERINTENDENCIA DE INDLJSTRIA V COMERC1O

RESOLUCION No: 63686
PoT ía cual se declara Ia caduc!dad de una patente PCT / 07-104271

LO PRIMERO: Declarar la caducidad de la patente de invenciOn titulada

ESTO (3-CLORQ-4-FLUOROBENCIL)-(3-METIL-3-AZA-BICICLO[3.1.O]HEX-6-ILMETIL) DEL ACIDO 1 METIL -1H-1MIDAZOL-4-CARBOXILICO COMO INHIBIDOR DEL
ORTE DE GLICINA DE TIPO I V COMPOSICIONES FARMACEUTIcAS QUE LO
lEN", concedida dentro del tràrnite del expediente Rad. PCT I 07-104271.

ARTICULO SEGUNDO: Notificar el contenido de la presente resoluciOn a! doctor Carlos Reinaldo Olarte, en su calidad. de. apoderado de la sociedad Pfizer Products Inc., o a quien haga sus veces, entregÆndole copia de la misma, advirtiØndole que contra ella ptocede el recurso do reposiciOn ante el Superintendente de Industria y Comercio, el cual podrÆ sØrinterpuesto en el momento de la notificación o dentro do los cinco (5) dlas hàbiles siguientes a ella.

ARTICULO TERCERO: Una vez quede en firme esta providencia, hacer las anotaciones crrespondientes en los libros de registro de Propiedad Industrial y archivar el expediente.

NOTIFIQUESE V CUMPLASE
Dada en Bogota, D.C., a los 29 Oct 2012

EL SUPERINTENDENTE DE INDUSTRIA V COMERC!O,

PABILO

doctor
CARLOS REINALDO OLARTE GARCtA

ffice@o!artemoure.com b. c’

laboró; Hasbleydi Lizbeth CaWo Rojas

evisO: Carlos Daniel Lemus Giraldo M m Revisô: Jose Luis Salazar Lopez S

probO: Jose Luis Londoo Fernandez

Ægina2deZ

Al contester favor Indique el nOmero S Sede Centro: Carrera 13 No. 27-00 pisos 2, 5, 7 10 PBX:J7lP0
de radicaclOn que se Indica a contlnuaciOn: Sede CAN: Av. Carrera 50 No. 26-55 mt. 2 Tel 57370

Cod VeriflcaciOn: 311592710 Call Center 5920400. Linea gratuita Nacional 01800-910165 C.) Web: w\MN.sic.gov.co e-mail: cOntactenoSic.g.ov.CO 0 m
Bogota D.C. Colombia rn

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I.: Expedlente N°.. 07-104.268
licitud de Patente de Invenelón titulada: "UN METODO Y COMPOSICION PARA EJORAR NUTRICIONALMENTE EL CONTROL DE LA GLUCOSA Y LA ACCION
LA INSULINA".
licitante: NOVARTIS A.G.

SPUJSTA AL OFICIO N°. 14666 NOWICADO POR FUAC!ON EN LISTA No.420, DE FECRA 16 DE NOVIEMBRE DE 2007, IEXAMEN DE FORMA)

CRLOS R. OLARTE, mayor de edad y vecino do Bogota, identificado tal como aparece al pie mi:Anna, en mi catheter do apoderado de la soviedad en referenda, me permito dar respuesta al auto emanadc, do.cse Despacho, dentro del tØrmino legal previsto en ci artIcuio 39 de la Deisión 486, en- los siguientes tØrminos:

1, En respuesta a la (mica observaciôn del Examinador, me permito aclarar al despacho que la presente 1ii1I Capitulo H como imciahnente se prsentO. Para tal efecto, adjuato copia del Reporte Preliminar Internacional de Patentabilidad, el ci.al, vaiga la pena aclarar, no contiene anexos. S

c,N0.79.78E!Bogot
T.P. 74.295

Aiexós: Copia del Reportede Examen Preliminar InternacionaL