



Industria y Comercio

SUPERINTENDENCIA

02 090225 00



PETITORIO

SUPERINDUSTRIA Y COMERCIO

Radicación: 02990225 00000000

Folios: 59 fón

Fecha (MM/AA): 2002-10-07 16:38:37

Trámite: 011 PCT-PATENT 379 FASE NACI 411 PRESENTA

Dependencia: 8020 DIVISION DE NUEVAS CREACIONES

FORMULARIO UNICO DE SOLICITUD DE PATENTE
PCT
ENTRADA EN FASE NACIONAL

1

SOLICITUD DE:

☒ Patente de Invención.☐ Patente de Modelo de Utilidad.☐ Capítulo I.☒ Capítulo II.

2

SOLICITANTE
(71)Nombre: **SANOFI-SYNTHELABO**
sociedad constituida y existente bajo las
leyes de Francia.Dirección: 174, avenue de France
F-75013, París
Francia.

Domicilio: París, Francia.

IDENTIFICACION

C.C. ☐ NIT ☐C.E. ☐ Otro ☐
Cual _____

Número: _____

3

REPRESENTANTE
O APODERADONombre: **EMILIO FERRERO**

Dirección: Carrera 4ª. No. 72-35

Teléfono: 347 36 11

Fax:: 217 92 11

E-mail: clientes@camyp.com

Domicilio: Bogotá, Colombia.

IDENTIFICACION

C.C. ☒ NIT ☐C.E. ☐ Otro ☐
Cual _____Número: 438.019 T.P. 31.929

4

INVENTOR (ES)
(72)1- István HERMECZ
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H-2146 Mogyoród,
Hungria.5- Benjamín PODÁNYI
Kazinczy u. 29,
H-2120 Dunakeszi,
Hungria.6- Kálmán SIMON
Ratkóc u. 9,
H-1118 Budapest
Hungria7- Judit SIPOS
Sáfrány u. 40,
H-1116 Budapest,
Hungria.8- Ágota SMELKÓNÉ ESEK
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Hungria.9- Anna SZABÓ
Berzeviczy G.u. 5/b
H-1042 Budapest,
Hungria.10- Árpádné VASVÁRI
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H-1122 Budapest,
Hungria

5

PCT (86)

Solicitud Internacional No. PCT/HU01/00039Fecha: 4 de abril de 2001Publicación Internacional No. WO 01/77108 A1Fecha: 18 de octubre 2001

6

Título (54) NUEVAS SALES TERAPEÚTICAS ÚTILES DE INHIBIDORES CCK,
PROCESO PARA LA PREPARACION DE ESTOS Y PREPARACIONES
FARMACEUTICAS QUE LOS CONTIENEN

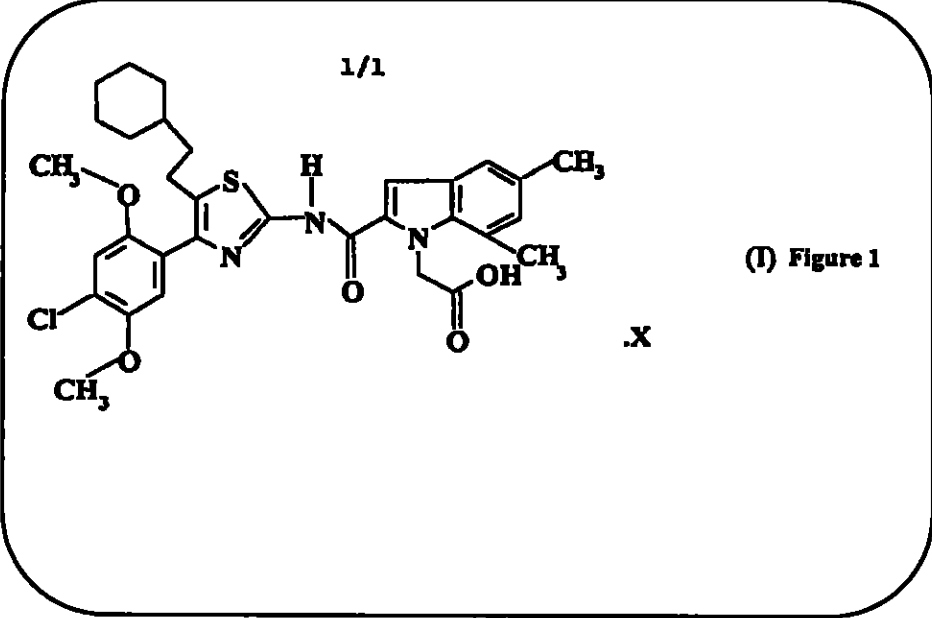
7

Clasificación Internacional (51) C07D 417/12.; A61K31/425

8	Prioridad SI ☒ NO ☐	(33) País de Origen <u>HU.</u>	(32) Fecha <u>7 de abril de 2000</u>	(31) Número de Solicitud <u>P0001417</u>
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9	Comprobante de pago No.: <u>02-65.104</u> Fecha: <u>30 de septiembre de 2002</u>
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10	Anexos: ☒ Comprobante de pago de la tasa de presentación de la solicitud por 378.000.00. ☐ Comprobante de pago por reivindicación de prioridad. ☒ Documento que acredita la existencia y representación legal cuando el solicitante sea persona jurídica. ☒ Poderes, si fuere el caso. ☐ Documento de cesión del inventor al solicitante o a su causante. ☐ Declaraciones. ☒ Copia de la solicitud internacional. (Resumen, descripción, reivindicaciones, dibujos) ☒ Traducción de la solicitud internacional al castellano. (Resumen, descripción, reivindicaciones, dibujos) ☒ Copia del examen preliminar efectuado por la IPEA. ☐ Traducción del examen preliminar efectuado por la IPEA. ☐ De ser el caso, copia del contrato de acceso. ☐ De ser el caso, documento que acredite la licencia o autorización de uso de conocimientos tradicionales de las comunidades indígenas. ☐ De ser el caso, certificado de depósito del material biológico. ☒ Arte final 12x12 ☐ De ser el caso, información sobre otras solicitudes de patente o títulos obtenidos en el extranjero por el mismo titular o su causante, relacionadas parcial o totalmente con la invención de esta solicitud. ☐ Otros
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11	FIGURA CARACTERISTICA:  (I) Figure 1
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Solicito la concesión de la patente,

NOMBRE: EMILIO FERRERO

FIRMA:

Emilio Ferrero

C.C. 438.019 de Usaquén T.P. 31.929

REPRESENTACION Y PODER

Pour brevets, modèles d'utilité, dessins industriels; marques de fabrique, de service, noms commerciaux, enseignes, slogans, licences.

Para patentes, modelos de utilidad, diseños industriales, marcas de fábrica y de servicio, nombres comerciales, enseñanzas, lemas comerciales, licencias.

REPRESENTATION ET POUVOIR

18555
2560

Je (nous) soussigné (s)/Yo (nosotros), abajo firmado (s)

SANOFI-SYNTHELABO

résidant (s) à/domiciliado (s) en 174 Avenue de France,
75013 Paris, FRANCE

por el presente nombramos a EMILIO FERRERO, tpa. 31929; GONZALO PERDOMO, tpa. 831; LUZ CLEMENCIA DE PAEZ, tpa. 23555 y GERMAN CAVELIER, tpa. 832, domiciliados en la Carrera 4ª N° 72-35, Bogotá, Colombia, en obediencia a lo dispuesto en el parágrafo 1º del Artículo 543 del Código de Comercio, el primero como principal y los demás como suplentes, en su orden, como mis (nuestros) representantes en todos los asuntos de propiedad industrial con facultad para recibir notificaciones y nombrar apoderados judiciales o extrajudiciales. El primer representante suplente reemplazará al principal en caso de ausencia o impedimento temporal o definitivo de aquél. La misma regla se aplicará cuando el segundo representante suplente haya de reemplazar al primero, o el tercero al segundo. En tales casos, el representante principal, o el primero, o segundo suplente, en su caso, o ambos, declararán su intención de no ejercer la representación mediante declaración autenticada por Notario Público en Colombia, o por Notario u otro Funcionario Público, o Cónsul de Colombia, en el extranjero; y si se tratare de impedimento, con el certificado respectivo. Si alguno de los nombrados faltare definitivamente, el siguiente tomará su lugar. Cuando cesare la ausencia o impedimento del representante principal, o de su primero o segundo suplentes, en su caso, podrán ejercer la representación, en su orden, uno u otros según el caso, asumiéndola por el solo hecho de ejercerla, cesando en ese momento el ejercicio de la representación por el primero, segundo o tercer suplente en su caso.

Además, confiero (conferimos) poder a los abogados arriba nombrados, para obtener la protección de mi (nuestra) propiedad industrial y contra la competencia desleal, a cuyo efecto autorizo (amos) a los dichos apoderados para que me (nos) representen ante cualesquiera entidades o personas, sean o no jurisdicción, especialmente ante las del orden administrativo, contencioso-administrativo y judicial, así como los tribunales de arbitramento, en todo lo concerniente a los siguientes asuntos: a) Obtención de patentes de invención, modelos de utilidad y diseños industriales; el registro de marcas de fábrica, colectivas, defensivas, de servicio, lemas comerciales, nombres comerciales, enseñanzas, variedades vegetales y denominaciones de origen; su renovación, traspaso, cambio de nombre o domicilio, cancelación voluntaria; y el registro de licencias de uso de esos derechos; b) Las acciones de competencia desleal, protección del consumidor, oposición, cancelación administrativa y judicial, nulidad, medidas cautelares, concesión de licencias, la tutela, la protección de secretos industriales, y en general los juicios civiles, penales, administrativos o contencioso-administrativos relacionados con estos derechos; acciones y procesos que promovamos o se nos promuevan. Y para que en todos los asuntos arriba determinados, puedan sustituir este mandato, transigir, conciliar, admitir los hechos del proceso, desistir, cancelar, recibir, renunciar, y ratificar los actos de agentes oficiales.

par cet instrument désigne (désignons) EMILIO FERRERO, tpa. 31929; GONZALO PERDOMO, tpa. 831; LUZ CLEMENCIA DE PAEZ, tpa. 23555 et GERMAN CAVELIER, tpa. 832, domiciliés à Bogota, Colombie, Carrera 4ª N° 72-35, conformément au paragraphe 1 de l'Article 543 du Code de Commerce, le premier comme principal et les autres comme suppléants, dans leur ordre, comme (mes) (nos) représentants dans toutes les affaires concernant la propriété industrielle ayant la faculté de recevoir les notifications et de nommer des mandataires judiciaires ou extrajudiciaires. Le premier représentant suppléant remplacera le principal en cas d'absence ou d'empêchement temporaire ou définitif de celui-ci. La même règle sera appliquée quand il faudra que le deuxième représentant suppléant remplace le premier, ou le troisième au deuxième. Dans ces cas, le représentant principal, ou le premier ou le deuxième suppléant dans leur cas, ou les deux, déclareront leur intention de ne pas exercer la représentation moyennant déclaration par devant Notaire Public en Colombie, ou par devant Notaire ou tout autre Fonctionnaire Public ou Consul de Colombie à l'étranger; et s'il s'agissait d'empêchement, avec le certificat respectif. Si l'un des nommés venait à manquer définitivement, le suivant prendrait sa place. Quand l'absence ou l'empêchement du représentant principal, ou de son premier ou second suppléant dans leur cas, aura cessé, ils pourront exercer leur représentation dans leur ordre, l'un ou les autres, suivant le cas, l'assumant par le seul fait de l'exercer, cessant à ce moment-là l'exercice de la représentation par le premier, deuxième ou troisième suppléant dans leur cas.

Par ailleurs, j'(nous), octroie (octroyons) pouvoir aux avocats ci-avant mentionnés pour obtenir la protection de ma (notre) propriété industrielle et contre la concurrence déloyale; à cet effet, autorise (ons) mes (nos) apoderados à me (nous) représenter devant toutes entités ou personnes, avec ou sans juridiction; notamment devant celles de l'ordre administratif, contentieux-administratif et judiciaire; ainsi que devant les Tribunaux d'Arbitrage, pour tout ce qui concerne les affaires suivantes: a) l'obtention de brevets d'invention, modèles d'utilité, dessins industriels; le dépôt de marques de fabrique, collectives, defensives, de service, lemas commerciaux, enseignes, variétés végétales et appellations d'origine; leur renouvellement, transfert, changement de nom ou de domicile, radiation volontaire, et l'enregistrement des contrats de licence; b) les actions de concurrence déloyale, protection du consommateur, opposition, radiation administrative ou judiciaire, annulation, contrefaçon, licences, tutelle, protection des secrets industriels, et les procès civils, pénaux, administratifs ou contentieux-administratifs ayant trait à ces droits; actions et procès établis par moi (nous) ou contre moi (nous); et c) afin que pour toutes les questions mentionnées ci-dessus, ils puissent substituer ce pouvoir, transiger, concilier, admettre les faits du procès, renoncer, et ratifier les actes des agents officiels ou personnes sans mandat.

Signé le/Dado y firmado hoy 07 JUN 2001

à/en

Signature

Elisabeth THOURET-LEMAITRE
Directeur Brevet / Patent Director

SANOFI-SYNTHELAB
174, Avenue de France
75013 PARIS
33 1 69 07 44 44 BCS Paris

Vu pour certification
matérielle de la signature
de Mme THOURET-LEMAITRE
opposée ci. 04/6

LEGALIZACION

Es necesaria la legalización con certificado consular sobre la existencia legal de la compañía, que éste ejerce su objeto social y que la persona que otorga el poder está autorizada para ello. A este efecto les solicitamos que muestren al Cónsul las pruebas que acreditan estos hechos.

LEGALISATION

La légalisation consulaire est nécessaire, le Consul certifiant l'existence légale des sociétés qui octroient le pouvoir, l'exercice d'une activité conforme à leur objet social et que la personne qui octroie le pouvoir est habilitée à le faire. A cet effet il faut présenter au Consul les documents qui prouvent les faits mentionnés ci-dessus.

Traducción Oficial No. 243/01
JEAN - JACQUES H. TURPIN
Traductor e Intérprete Oficial
FRANCOIS - ESPAROL
Reg. Ministerio No. 2480/91

APOSTILLE
(Convention de La Haye du 5 Octobre 1961)

1. - République Française
Le présent acte public
2. - a été signé par M^e KOENIG
3. - agissant en qualité de N. V. Van
4. - est revêtu du sceau de N. V. Van

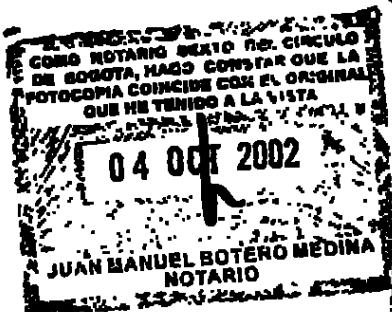
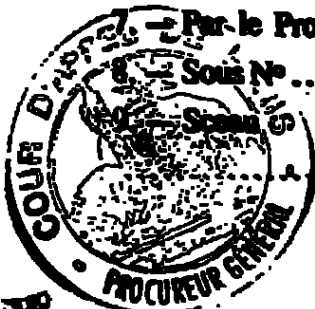
ATTESTE

5. - à Paris le 12 SEP. 2001

Par le Procureur G^{al} près la Cour d'Appel

Sous N^o 56961/02

Le signature



APOSTILLE
(Convention de La Haye du 5 Octobre 1961)

1. - République Française
Le présent acte public
2. - a été signé par
3. - agissant en qualité de
4. - est revêtu du sceau de

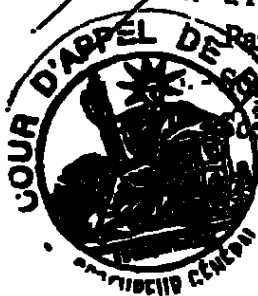
ATTESTE

5. - à Paris le 12 SEP. 2001

Par le Procureur G^{al} près la Cour d'Appel

Sous N^o

Le signature



NOTA PARA EL SEÑOR CONSUL DE COLOMBIA: Según los artículos 65 del C. de P.C. y 480 del C. de Co., si el poderdante es una sociedad, el Señor Cónsul debe certificar que tuvo a la vista las pruebas de su existencia, que ejerce su objeto social y que quien confiere el poder es su representante.

NOTA PARA EL SEÑOR CONSUL DE COLOMBIA

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TRADUCCIÓN OFICIAL No. 243/01 DE UN DOCUMENTO ESCRITO EN FRANCÉS, EL CUAL PARA SU IDENTIFICACIÓN SE SELLA CON EL SELLO DEL TRADUCTOR. ESTA ES UNA TRADUCCIÓN OFICIAL EFECTUADA EL DIA 06 DE NOVIEMBRE DEL AÑO 2001 POR JEAN-JACQUES TURPIN, C.E.: 193849 DE BOGOTÁ, TRADUCTOR OFICIAL SEGÚN RESOLUCIÓN No. 2680/91 DEL 19 DE DICIEMBRE DE 1991, EXPEDIDA POR EL MINISTERIO DE JUSTICIA DE COLOMBIA.

Autenticaciones que se hallan a continuación de un documento de representación y poder conferido en francés y español por **SANOFI-SYNTHELABO**, domiciliada en 174, Avenue de France, 75013, Paris, Francia y otorgado a los Doctores Emilio Ferrero TPA 31929, Gonzalo Perdomo TPA 831, Luz Clemencia de Paez TPA 23555 y Germán Cavalier TPA 832, todos domiciliados en Bogotá, Colombia, Carrera 4 No 72-35.

Dado y firmado el 07 de junio del 2001. Firma ilegible de Elizabeth THOURET-LEMAITRE (Directora patentes).

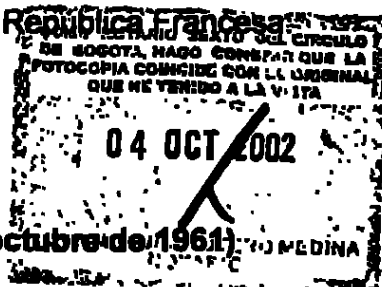
Sello: Sanofi-Synthelabo, 174, Avenue de France, 75013 Paris – 395 030 844 RCS PARIS.

Legalización de la firma de la Señora Elizabeth THOURET-LEMAITRE por el Señor Koenig, Notario en Paris. Firma ilegible del Notario.

Sello: Koenig - Notario en Paris – Tribunal Superior – República Francesa

APOSTILLA

(Convención de La Haya del 5 de octubre de 1961)



1. - República francesa

El presente acta público

Traducción Oficial No. **243/01**
JEAN - JACQUES H. TURPIN
Traductor e Interprete Oficial
FRANCOIS - ESPANOL
Res. Ministerio No. 2680/91

2. - Ha sido firmado por el Doctor Koenig
3. - Obrando en calidad de Notario
4. - Con sello de su Notaría

CERTIFICADO

5. - En Paris El 12 de septiembre del 2001
6. - Por el Procurador General ante el Tribunal Superior
7. - Bajo el número 56961/01 ✓
8. - Sello: Tribunal Superior de Paris – Procurador General.
9. - Firma ilegible.

Es traducción fiel y completa de la cual se deja copia en los archivos de esta oficina para confrontación y a la cual me remito.

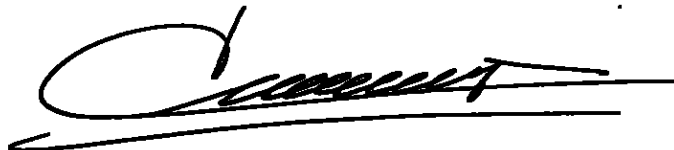
Traducción oficial No. 243/01

Colo: 12555-803-004-0

Traductor: Jean-Jacques Turpin.

Bogotá D.C. 06 de noviembre del año 2001.

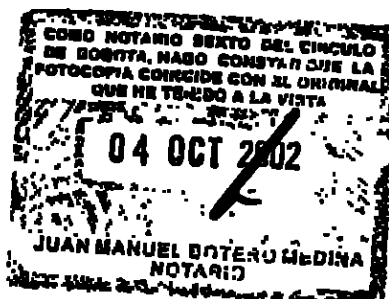
Traducción Oficial No. 243/01
JEAN - JACQUES H. TURPIN
Traductor e Intérprete Oficial
FRANCÉS - ESPAÑOL
Res. Minjusticia No. 2680/91



NO SE ASUME
RESPONSABILIDAD DEL TEXTO
2001 NOV 13 P 12:23
JEF. DE LEGALIZACIONES
SECRETARÍA DE BOGOTÁ D.C.

MINISTERIO DE RELACIONES
EXTERIORES

189410
Jean-Jacques Turpin
CUYA FIRMA APARECE EN EL
DOCUMENTO DESEMPEÑA
LAS FUNCIONES INDICADAS



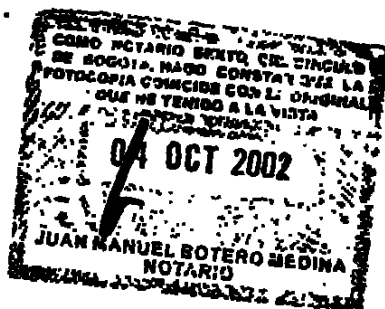
COMO NOTARIO SEXTO DEL CIRCULO DE SANTAFE DE BOGOTA, HAGO CONSTAR QUE LAS ANTERIORES FIRMAS PUESTAS POR

Lequer A. Vergara

IDENTIFICADOS CON C.C. No. (s)

ES(DON) AUTENTICA(S)

SANTAFE DE BOGOTA, 13 NOV. 2001



QUELLE QUE SOIT LA FORMALITE, LES RUBRIQUES SUR FOND ROUGE DOIVENT OBLIGATOIREMENT ETRE REMPLIES

DENOMINATION : SANOFI

SIGLE :

SIÈGE - ADRESSE y compris s'il y a lieu, l'IDENTITE DU DOMICILIAIRE (Nom, Prénoms ou Dénomination) :

174 AVENUE DE FRANCE

75013 PARIS

N° SIRET :

FORME JURIDIQUE : SA

PRINCIPALES ACTIVITES DE L'ENTREPRISE : PRISE DE PARTICIPATIONS DANS TOUTES SOCIETES

OU ENTREPRISES DANS LE DOMAINE DE LA SANTE

EFFECTIF SAUVAIE de l'entreprise : 175

CESSATION TOTALE D'ACTIVITE de l'entreprise, Indiquer la date : 18/05/1999

DISSOLUTION / DISPARITION à la suite d'une FUSION ☐ ou d'une SCISSION ☐ , Indiquer la date : 18/05/1999

Personnes Morales ayant participé à l'opération (Dénomination, Forme Juridique, Adresse du siège, n° RCS) : SANOFI - SYNTHELABO

174 AVENUE DE FRANCE 75013 PARIS RCS PARIS 395 030 844

Liste à suivre sur intercalaire(s) : OUI ☐ NON ☐

En cas de SUPPRESSION du SIÈGE de l'entreprise :

En cas de cessation totale d'emploi de tout salarié, préciser la date :

18/05/1999

DATE de fin d'exploitation

Préciser la DESTINATION : ☐ ☐ ☐ ☐ ☐ ☐ FUSION, ABSORPTION AVEC EFFET RETROACTIF AU

disparition

vente

apport

mise en location

reprise par le propriétaire

autres (préciser)

Identité du BÉNÉFICIAIRE : SANOFI - SYNTHELABO - 174 AVENUE DE FRANCE

75013 PARIS - RCS PARIS 395 030 844

01-01-1999

Lieu principal d'exploitation de l'entreprise :

Centre des impôts où ont été déposées les dernières déclarations de résultats et de TVA :

Le cas échéant, RÉFÉRENCES DES ÉTABLISSEMENTS (autres que le siège) SUPPRIMÉS À L'OCCASION DE CETTE DÉCLARATION :

ÉTABLISSEMENT : ADRESSE

N° SIRET :

Préciser la DESTINATION

En cas de cessation totale d'emploi de tout salarié, préciser la date :

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Identité du BÉNÉFICIAIRE :

Nom, Prénoms, Dénomination ou Dénomination, Adresse du Siège

ÉTABLISSEMENT, ADRESSE

N° SIRET :

Préciser la DESTINATION

disparition

vente

apport

mise en location

reprise par le propriétaire

autres (préciser)

Identité du BÉNÉFICIAIRE :

Nom, Prénoms, Dénomination ou Dénomination, Adresse du Siège

ÉTABLISSEMENT, ADRESSE

N° SIRET :

Préciser la DESTINATION

disparition

vente

apport

mise en location

reprise par le propriétaire

autres (préciser)

Identité du BÉNÉFICIAIRE :

Nom, Prénoms, Dénomination ou Dénomination, Adresse du Siège

ÉTABLISSEMENT, ADRESSE

ADRESSE PERMANENTE : 174 AVENUE DE FRANCE 75013 PARIS

pour la correspondance

tel, fax, e-mail, etc.

code postal

lieu d'habitation du gérant

tel.

LE SOUSSIGNÉ :

LES PETITES AFFICHES (102 RUE MONTESQUIEU 75001 PARIS

09/0909.254

demande que ce document constitue l'acte de description

MODIFICATIVE au RCS ☒ , au RM ☐ , au RSAC ☐ , au REBA ☐ , de RADIATION au RCS ☐ , au RM ☐ , au RSAC ☐ , au REBA ☐ ,

et déclaration aux Services Fiscaux, aux Organismes de Sécurité Sociale, à l'INSEE, et s'il y a lieu, à l'Inspection du Travail et à l'ASSEDIC.

Fait à :

le :

signature :

signature :

CHAMBRE DE MÉTIERS

Coté réservé à la Chambre de Métiers

Numéro de dossier

NUMÉRO D'IMMATRICULATION RM

REN

PM

NOM OU DÉNOMINATION :

DE :

RÉPERTOIRE DES MÉTIERS

- ☐ DEMANDE D'IMMATRICULATION
☐ INSCRIPTION DE MENTION DE CONJOINT COLLABORATEUR (Personnes Physiques uniquement)

☐ DÉCLARATION DE MODIFICATION

- ☐ DEMANDE DE RADIATION
☐ RADIATION DE MENTION DE CONJOINT COLLABORATEUR (Personnes Physiques uniquement)

STAGE D'INITIATION A LA GESTION

(Article 2 de la loi du 23/7/82)

Attestation - date de délivrance :

Dépense - motif de la dépense :

PIÈCES JUSTIFICATIVES :

en cas de DÉCISION du PRÉSIDENT de la CHAMBRE DE MÉTIERS

(Article 11 du décret du 10.08.83)

Date de dépôt de la demande :

Demande de renseignements complémentaires :

☐ NON DÉCISÉ

Production des renseignements demandés :

Date limite de la décision du Président :

DÉCISION DU PRÉSIDENT :

PM n° en date du :

☐ Accord

☐ Refus

en cas de PASSAGE en COMMISSION du RÉPERTOIRE DES MÉTIERS

(Articles 12 et 13 du décret du 10.08.83)

Date de la transmission

à la Commission de Répertoire

Date de la notification

Paiement de la redevance : en F

☐ espèces ☐ chèque bancaire ☐ chèque postal

Référence du Registre à souche :

Affichage du :

La conformité des déclarations ci-annexées avec les pièces justificatives produites en application des règlements a été vérifiée sous notre responsabilité

DATE DE L'INSCRIPTION :

Le Président de la Chambre de Métiers :

CADRE RÉSERVÉ

A L'INSTITUT

NATIONAL

DE LA PROPRIÉTÉ

INDUSTRIELLE

NUMÉRO D'IMMATRICULATION RCS :

NOM OU DÉNOMINATION :

Certifié, le Greffier

DATE DE L'INSCRIPTION :

La conformité des déclarations ci-annexées avec les pièces justificatives produites en application des règlements a été vérifiée

OBSERVATIONS du GREFFIER :

DATE DE DÉPÔT des STATUTS :

ACTES RÉGLEMENTAIRES :

PIÈCES JUSTIFICATIVES :

NOTA :

Les Greffiers et l'Institut National de la Propriété Industrielle sont astreints et seuls habilités à délivrer à toute personne qui en fait la demande des certificats, copies ou extraits des inscriptions portées au registre et actes déposés en annexe, sauf en ce qui concerne les inscriptions radiées, qui sont communiquées dans les conditions fixées par l'article 169 du 24 septembre 1984, prévu à l'article 86 (décret n° 84-408 du 30 mai 1984, art. 67)

Date d'arrivée au Greffe :

Nombre d'arrivée au Greffe :

IMMATRICULATION ☐ PRINCIPALE ☐ SECONDAIRE
INSCRIPTION ☐ COMPLÉMENTAIRE ☐ MODIFICATIVE
CORRECTION ☐ RADIATION

RÉGISTRE DU COMMERCE ET DES SOCIÉTÉS

GREFFE DU TRIBUNAL

CODE GREFFE :

Coté réservé au Greffier

8

TRADUCCIÓN OFICIAL No. 245/01 DE UN DOCUMENTO ESCRITO EN FRANCÉS,
EL CUAL PARA SU IDENTIFICACIÓN SE SELLA CON EL SELLO DEL TRADUCTOR.
ESTA ES UNA TRADUCCIÓN OFICIAL EFECTUADA EL DIA 06 DE NOVIEMBRE DEL
AÑO 2001 POR JEAN-JACQUES TURPIN, C.E.: 193849 DE BOGOTÁ, TRADUCTOR
OFICIAL SEGÚN RESOLUCIÓN No. 2680/91 DEL 19 DE DICIEMBRE DE 1991,
EXPEDIDA POR EL MINISTERIO DE JUSTICIA DE COLOMBIA.

SECRETARIADO DEL TRIBUNAL DE PARIS

Código del Secretariado: 7501

Número de referencia : (en blanco)

Número de matrícula RCS : 73 B 5933

Nombre o denominación : (en blanco)

Sigla : (en blanco)

Espacio reservado para el secretariado del Tribunal: (en blanco)

REGISTRO DEL COMERCIO Y SOCIEDADES

Matrícula: Principal _____

segundaria _____

Inscripción Complementaria _____

modificativa _____

Corrección _____

Cancelación _____

Fecha de radicación en el Secretariado del Tribunal _____

Número de radicación en el Secretariado del Tribunal _____

04 OCT/2002

(en blanco)

JUAN MANUEL SERRA MEDINA
NOTARIO

: (en blanco)

NTA: Los Secretarios de los Tribunales y el Instituto de la Propiedad Industrial están obligados, y son los únicos habilitados, a expedir a cualquier persona que lo solicite certificaciones, copias o certificados de las inscripciones llevadas en el registro y actas depositados en anexo, salvo lo relacionado con las inscripciones canceladas, las cuales se comunican de acuerdo con las condiciones establecidas por la resolución (del 24 de Septiembre de 1984), prevista en el artículo 88 (decreto No. 84-406 del 30 de mayo de 1984, art.67)

Traducción Oficial No. 245/01
JEAN - JACQUES H. TURPIN
Traductor e Intérprete Oficial
FRANCÉS - ESPAÑOL
Res. Ministerio No. 2680/91

DOCUMENTOS DE PRUEBA : (en blanco)

ACTIVIDADES REGLAMENTADAS (doc. No. 24) : (en blanco)

FECHA de PRESENTACIÓN de los ESTATUTOS : (en blanco)

OBSERVACIONES del SECRETARIO DEL TRIBUNAL : (en blanco)

Sello: Tribunal de Comercio de Paris con fecha del 16 de junio de 1999, No. de radicación 118.

La conformidad de las declaraciones adjuntas con los documentos justificativos presentados en aplicación de los reglamentos ha sido verificada por el suscrito Secretario del Tribunal quien luego procedió a la inscripción antes señalada.

FECHA DE LA INSCRIPCIÓN : (en blanco)

Certificado por el Secretario del Tribunal : (en blanco)

Espacio reservado para el Registro Nacional del Comercio y Sociedades: (en blanco).

CÁMARA OFICIAL DE ARTESANOS DE: (en blanco)

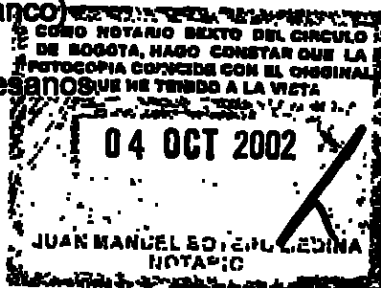
Espacio reservado para la Cámara Oficial de Artesanos

NÚMERO DE GESTIÓN : (en blanco)

NÚMERO DE MATRÍCULA RM : (en blanco)

NOMBRE O DENOMINACIÓN : (en blanco)

Siren : (en blanco)



REPERTORIO DE LAS PROFESIONES

- _____ SOLICITUD DE MATRICULA
- _____ INSCRIPCIÓN DE MENCIÓN DE CÓNYUGE COLABORADOR (únicamente para personas naturales)
- _____ DECLARACIÓN DE MODIFICACIÓN
- _____ SOLICITUD DE CANCELACIÓN
- _____ CANCELACIÓN DE MENCIÓN DE CÓNYUGE COLABORADOR (únicamente para personas naturales)

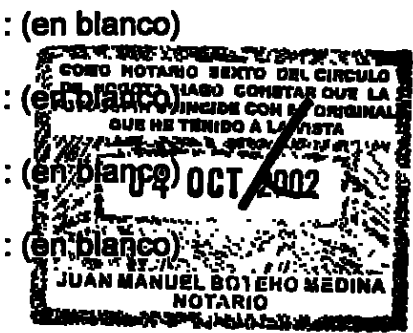
CURSO DE INICIACIÓN A LA GESTIÓN (artículo 2 de la ley del 23/12/82)

- Certificación - fecha de expedición : (en blanco)
- Dispensa - motivo de la dispensa : (en blanco)

DOCUMENTOS DE PRUEBA : (en blanco)

en caso de DECISIÓN del PRESIDENTE de la CÁMARA OFICIAL DE ARTESANOS (artículo 11 del Decreto del 10/06/83)

- Fecha de presentación de la solicitud
- Solicitud de informaciones adicionales
- Presentación de las informaciones solicitadas
- Fecha límite de la decisión del Presidente



Inscripción Oficial No. 245/91
JEAN - JACQUES H. TURPIN
Traductor e Intérprete Oficial
FRANCO - ESPAÑOL
Reg. Minjisterio No. 2480/91

DECISIÓN DEL PRESIDENTE:

Acta No.: (en blanco), con fecha del (en blanco)

_____ Acordado _____ Negado

en caso de PRESENTACIÓN en COMISIÓN del REPERTORIO DE LAS PROFESIONES (artículos 12 y 13 del Decreto del 10/06/83)

Fecha de transmisión a la Comisión de Repertorio : (en blanco)

Fecha de la notificación : (en blanco)

Pago del impuesto : (en blanco) en F.

_____ efectivo _____ cheque bancario _____ cheque postal

Referencia del Registro con talonario : (en blanco)

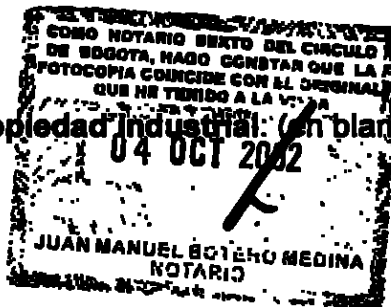
Fijación en cartelera: del (en blanco) al (en blanco)

Se verificó bajo nuestra responsabilidad la conformidad de las declaraciones adjuntas con base en los documentos justificativos presentados en aplicación de los reglamentos.

FECHA DE LA INSCRIPCIÓN : (en blanco)

El Presidente de la Cámara Oficial de Artesanos : (en blanco)

Espacio reservado al Instituto Nacional de la Propiedad Industrial: (en blanco)



Introducción Oficial No. **245/01**
JEAN - JACQUES H. TURPIN
Traductor e Intérprete Oficial
FRANCOIS - ESPAROL
Res. Minjusticia No. 2680/91

12

Declaración presentada en el CFE el: (en blanco)

DECLARACIÓN DE CESACIÓN TOTAL DE ACTIVIDAD _____

CIERRE DE LA LIQUIDACIÓN _____

C N X o SIN _____ SOLICITUD DE CANCELACIÓN EN EL RCS

NÚMERO(S) DE LA MATRÍCULA PRINCIPAL

RCS 732 059 332 R.C.S. PARIS (1973B5933)

73 B 5933

PERSONA JURÍDICA: G7550 974563 7

M GUIDABEFHJKT

Nº de páginas adicionales adjuntas: (en blanco)

DENOMINACIÓN: SANOFI SIGLA : (en blanco)

SEDE: DIRECCIÓN incluyendo si hay lugar LA IDENTIDAD DEL DOMICILIARIO:

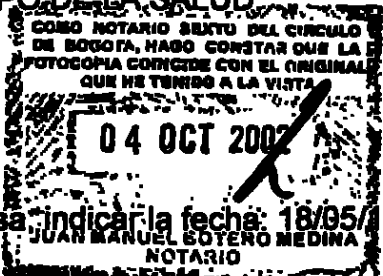
174, AVENUE DE FRANCE 75013 PARIS

Nº SIRET: (en blanco)

FORMA JURÍDICA: SA

PRINCIPALES ACTIVIDADES DE LA EMPRESA: TOMA DE PARTICIPACIONES EN CUALQUIER SOCIEDAD O EMPRESA EN EL CAMPO DE LA SALUD

NÚMERO DE ASALARIADOS: 1176



CESACIÓN TOTAL DE LA ACTIVIDAD de la empresa, indicar la fecha: 18/05/1999

DISOLUCIÓN / DESAPARICIÓN a consecuencia de una FUSIÓN X o ESCISIÓN

_____, indicar la fecha: 18/05/1999

Si es el caso, REFERENCIAS DE LOS ESTABLECIMIENTOS (diferentes a la sede)

SUPRIMIDOS CON OCASIÓN DE ESTA DECLARACIÓN:

ESTABLECIMIENTO: DIRECCIÓN: (en blanco)

N° de SIRET: (en blanco)

En caso de cesación total de empleo de cualquier asalariado, indicar la fecha: (en blanco)

Indicar el DESTINO:

☐ Desaparición
 ☐ venta
 ☐ aportación

☐ puesta en alquiler gerencia
 ☐ retoma por parte del propietario

☐ Otros (precisar)

Identidad del BENEFICIARIO: (en blanco)

**DIRECCIÓN PERMANENTE para la correspondencia: 174, AVENUE DE FRANCE
75013 PARIS**

**EL SUSCRITO "LES PETITES AFFICHES" (LM) 2, RUE MONTESQUIEU, 75001
PARIS solicita que el presente documento constituya una solicitud de INSCRIPCIÓN:**

- MODIFICATIVA en el RCS X, en el RM 1 en el RSAC 1 en el

- de **CANCELACIÓN** en el RCS _____ RM _____ RSAC _____ REBA _____

y una declaración a los Servicios Fiscales, Organismos del Seguro Social, INSEE y si

es o deja de ser **EMPLEADOR**, en la Inspección del Trabajo y en el ASSEDIC.

Dado en (ilegible), el (ilegible). Firma ilegible.

7

Traducción Oficial No. 4
JEAN - JACQUES H. TURPIN
Traductor e Interprete Oficial
FRANCOIS - ESPAROL
Reg. Minisrancia No. 2680/91

245/01

Sello: Copia certificada en el RNCS de Lille, con fecha del 31/07/01. Por el Director General del INPI, firma ilegible del Jefe de Departamento.

Sello: Instituto Nacional de la Propiedad Industrial - República Francesa.

Sello: Ministerio de Economía, Hacienda e Industria - Instituto Nacional de la Propiedad Industrial - República Francesa.

APOSTILLA

(Convención de La Haya del 5 de octubre de 1961)

1. República Francesa
El presente acta público
2. Ha sido firmado por el funcionario encargado
3. Actuando en calidad funcionario encargado
4. Con sello del INPI

Certificado

5. En Paris
6. El 12 de septiembre del 2001
7. Por el Procurador General ante el Tribunal Superior
8. Bajo el número 56831/01 ✓
9. Sello / estampilla: Tribunal Superior de París, Francia, República Francesa.
10. Firma ilegible.

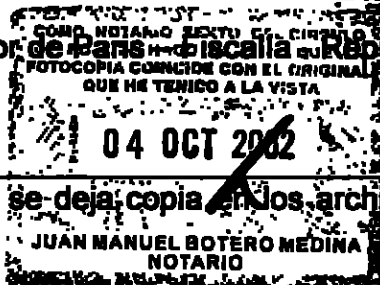
Es traducción fiel y completa de la cual se deja copia en los archivos de esta oficina para confrontación y a la cual me remito.

Traducción oficial No. 245/01

COLO: 12555-803-004-0

Traductor: Jean-Jacques Turpin.

Bogotá, D.C., 06 de noviembre del 2001



Traducción Oficial No.
JEAN - JACQUES H. TURPIN
Traductor e Interprete Oficial
FRANCOIS - ESPANOL
Res. Minjencia No. 2680/91

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
18 October 2001 (18.10.2001)

PCT

(10) International Publication Number
WO 01/77108 A1

(51) International Patent Classification⁷: C07D 417/12.
A61K 31/425, A61P 1/00, 25/00

(21) International Application Number: PCT/HU01/00039

(22) International Filing Date: 4 April 2001 (04.04.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
P 0001417 7 April 2000 (07.04.2000) HU

(71) Applicant (for all designated States except US):
SANOFI-SYNTHELABO [FR/FR]: 174, avenue de
France, F-75013 Paris (FR).

(72) Inventors; and

(75) Inventors/Applicants (for US only): HERMECZ,
István [HU/HU]: Molnár u. 52, H-1056 Budapest (HU).
HORVÁTH, Ágnes [HU/HU]: Budenz u. 30/a, H-1021
Budapest (HU). KISS, Gyuláné [HU/HU]: Ajtósi Dürer
sor 33/b, H-1146 Budapest (HU). MORVAI, Mik-
lós [HU/HU]: Zsák u. 11., H-2146 Mogyoród (HU).
PODÁNYI, Benjámin [HU/HU]: Kazinczy u. 29, H-2120
Dunakeszi (HU). SIMON, Miklós [HU/HU]: Raskóc
u. 9, H-1118 Budapest (HU). SIPOS, Judit [HU/HU]:
Sáfrány u. 40, H-1116 Budapest (HU). SMELKÓÉ

ESEK, Ágota [HU/HU]: Batakegyi u. 9/a, H-1028
Budapest (HU). SZABÓ, Anna [HU/HU]: Berzeviczy
G. u. 5/B, H-1042 Budapest (HU). VASVÁRI, Árpádné
[HU/HU]: Goldmark K. u. 33, H-1122 Budapest (HU).

(74) Agent: SANOFI-SYNTHELABO; Dr. György Mihályi
and Katalin Mármárosi, Tó u. 1-5., H-1045 Budapest (HU).

(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM,
HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK,
LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX,
MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL,
TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

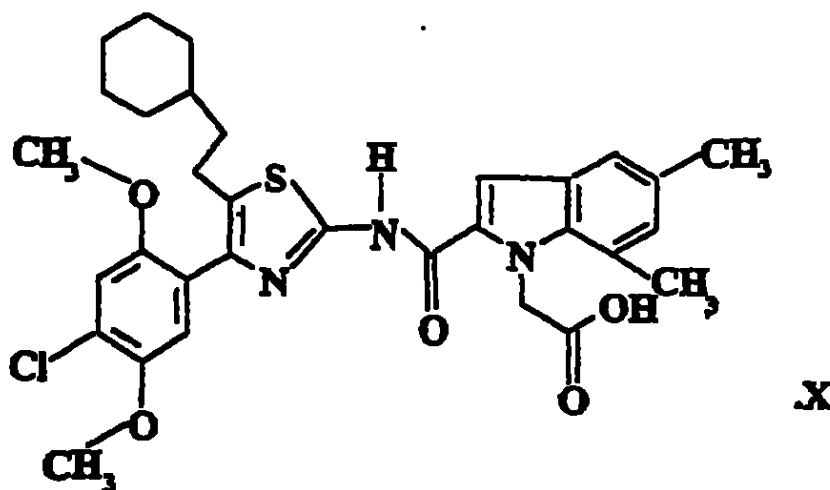
(84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF,
CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

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

(54) Title: THERAPEUTICALLY USEFUL NEW SALTS OF CCK INHIBITORS, PROCESS FOR THE PREPARATION
THEREOF AND PHARMACEUTICAL PREPARATIONS CONTAINING THEM



(57) Abstract: New salts of the general formula (I), their solvates, polymorphs and pseudo polymorphs wherein X stands for
ethanolamine, diethanolamine or diethylamine.



WO 01/77108 A1

INTERNATIONAL SEARCH REPORT

Int. Application No
PCT/HU 01/00039

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07D417/12 A61K31/425 A61P1/00 A61P25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99 15525 A (SANOFI) 1 April 1999 (1999-04-01) cited in the application claims; example 5	1-11

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E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

26 June 2001

Date of mailing of the international search report

06/07/2001

Name and mailing address of the ISA

European Patent Office, P.O. Box 5818 Patentkan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 851 epo nl
Fax (+31-70) 340-3018

Authorized officer

Helps, I

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/HU 01/00039

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9915525 A	01-04-1999	FR 2768737 A	26-03-1999
		FR 2777887 A	29-10-1999
		AU 9170598 A	12-04-1999
		BR 9812653 A	22-08-2000
		CN 1276790 T	13-12-2000
		EP 1017693 A	12-07-2000
		HR 20000153 A	30-04-2001
		NO 20001409 A	16-05-2000
		PL 339292 A	04-12-2000
		ZA 9807961 A	07-04-1999

INTERNATIONAL SEARCH REPORT

Int. Application No
PCT/HU 01/00039

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07D417/12 A61K31/425 A61P1/00 A61P25/00

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Minimum documentation searched (classification system followed by classification symbols)

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

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Further documents are listed in the continuation of box C.



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- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *&* document member of the same patent family

Date of the actual completion of the international search

26 June 2001

Date of mailing of the international search report

06/07/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentkan 2
NL - 2260 HV Rijswijk
Tel. (+31-70) 340-2040. Tx. 31 651 epo nl
Fax (+31-70) 340-3018

Authorized officer

Helps, I

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/HU 01/00039

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9915525 A	01-04-1999	FR 2768737 A	26-03-1999
		FR 2777887 A	29-10-1999
		AU 9170598 A	12-04-1999
		BR 9812653 A	22-08-2000
		CN 1276790 T	13-12-2000
		EP 1017693 A	12-07-2000
		HR 20000153 A	30-04-2001
		NO 20001409 A	16-05-2000
		PL 339292 A	04-12-2000
		ZA 9807961 A	07-04-1999

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
18 October 2001 (18.10.2001)

PCT

(10) International Publication Number
WO 01/77108 A1

(51) International Patent Classification⁷: C07D 417/12.
A61K 31/425, A61P 1/00, 25/00

ESEK, Ágota [HU/HU]; Patakhgyi u. 9/a, H-1028
Budapest (HU). SZABÓ, Anna [HU/HU]; Berzeviczy
G. u. 5/B, H-1042 Budapest (HU). VASVÁRI, Árpádné
[HU/HU]; Goldmark K. u. 33, H-1122 Budapest (HU).

(21) International Application Number: PCT/HU01/00039

(22) International Filing Date: 4 April 2001 (04.04.2001)

(74) Agent: SANOFI-SYNTHELABO; Dr. György Mihályi
and Katalin Mármárosi, Tó u. 1-5., H-1045 Budapest (HU).

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
P 0001417 7 April 2000 (07.04.2000) HU

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM,
HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK,
LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX,
MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL,
TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(71) Applicant (*for all designated States except US*):
SANOFI-SYNTHELABO [FR/FR]; 174, avenue de
France, F-75013 Paris (FR).

(84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF,
CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

(72) Inventors; and

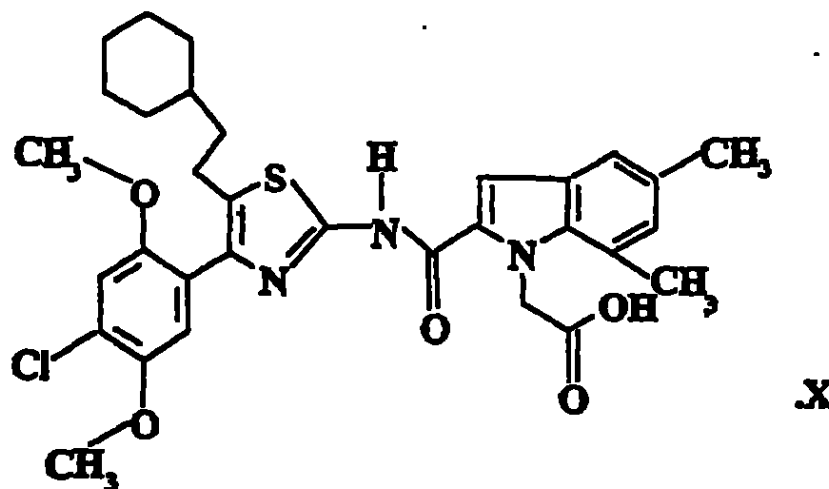
(75) Inventors/Applicants (*for US only*): HERMECZ,
István [HU/HU]; Molnár u. 52, H-1056 Budapest (HU).
HORVÁTH, Ágnes [HU/HU]; Budenz u. 30/a, H-1021
Budapest (HU). KISS, Gyuláné [HU/HU]; Ajtósi Dürer
sor 33/b, H-1146 Budapest (HU). MORVAI, Mik-
lós [HU/HU]; Zsák u. 11., H-2146 Mogyoród (HU).
PODÁNYI, Benjámin [HU/HU]; Kazinczy u. 29, H-2120
Dunakeszi (HU). SIMON, Kálmán [HU/HU]; Ratkóc
u. 9, H-1118 Budapest (HU). SIPOS, Judit [HU/HU];
Sáfrány u. 40, H-1116 Budapest (HU). SMELKÓNÉ

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guid-
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(54) Title: THERAPEUTICALLY USEFUL NEW SALTS OF CCK INHIBITORS, PROCESS FOR THE PREPARATION
THEREOF AND PHARMACEUTICAL PREPARATIONS CONTAINING THEM



(57) Abstract: New salts of the general formula (I), their solvates, polymorphs and pseudo polymorphs wherein X stands for
ethanolamine, diethanolamine or diethylamine.

WO 01/77108 A1

20

THERAPEUTICALLY USEFUL NEW SALTS OF CCK INHIBITORS. PROCESS FOR THE PREPARATION THEREOF AND PHARMACEUTICAL PREPARATIONS CONTAINING THEM

The invention relates to the therapeutically useful new salts of the general formula
5 (I) (Figure 1), their solvates, polymorphs and pseudopolymorphs, to the process for the preparation thereof and to the pharmaceutical preparations containing them, wherein in the formula

X means ethanolamine, diethanolamine or diethylamine.

The compound of the formula (II) (Figure 2) is a cholecystokinin A (CCK-
10 A) agonist, which can be used for the treatment of the disorders of the gastrointestinal system, and of the central nervous system.

The following salts of the compound of the formula (II) and the processes for their preparation are described in publication WO 99/15525: salt with trifluoroacetic acid, salt with hydrochloric acid, mono- and di-sodium salts, mono-
15 and di-potassium salts. The salt with trifluoroacetic acid and its hydrate, because of the strong toxicity of the trifluoroacetic acid, are not suitable for therapeutic use. The composition of the salt with hydrochloric acid is not stoichiometric, it is not reproducible.

The mono- and di-sodium salts, as well as the mono- and di-potassium salts
20 and their hydrates are highly hygroscopic and chemically not stable compounds, namely the compound of the formula (II) decomposes at the amide bond giving rise to decomposition products of formulae (IV) (Figure 6) and (V) (Figure 7).

The subjects of the present invention, the therapeutically applicable new salts of the general formula (I) and their solvates, polymorphs and pseudopolymorphs,
25 wherein in the formula X has the meaning as given above, with special regards to the ethanolamine salt and its solvates, are chemically stable, non-hygroscopic and their preparation is well reproducible.

Preparation of the subjects of the present invention, the therapeutically
30 applicable new salts of the general formula (I) and their solvates, polymorphs and pseudopolymorphs is carried out by reacting the 2-[[[4-(4-chloro-2,5-

dimethoxyphenyl)-5-(2-cyclohexylethyl)-2-thiazolyl]amino]carbonyl]-5,7-dimethyl-1*H*-indol-1-acetic acid of the formula (II) with the ethanolamine of the formula (IIIa) (Figure 3) or the diethanolamine of the formula (IIIb) (Figure 4) or the diethylamine of the formula (IIIc) (Figure 5).

5 The compounds (IIIa), (IIIb) or (IIIc) are preferably applied in an excess of 1,2-1,5 equivalents. The reaction is preferably carried out in protic solvents, at a temperature between 40-100°C, preferably at the boiling point of the solvent. As for protic solvents preferably ethanol, acetonitrile or ethanol-water mixture can be applied.

10 The therapeutically applicable new salts of the general formula (I) and their solvates, polymorphs and pseudopolymorphs of the present invention are cholecystokinin A (CCK-A) agonists, which can be used for the treatment of the disorders of the gastrointestinal system, and of the central nervous system.

15 The agonistic effect of the compound according to the present invention was investigated as described in the publication WO/99/15525 by investigating its effect on emptying the stomach, on rat, p.o. We have found that the ED₅₀ value, 34 µg/kg p.o, is in the same order as the ED₅₀ value of the trifluoroacetic acid salt and of the potassium salt.

20 A further subject of the present invention are pharmaceutical preparations containing the salts of the general formula (I), their solvates, polymorphs and pseudopolymorphs, as active ingredients.

25 The pharmaceutical preparations according to the present invention, beside the active ingredients, may contain the usual pharmaceutical excipients and may be formulated as oral, sublingual, subcutan, intramuscular, intravenous, topical, intratracheal, intra-vasal, transdermal, rectal, intraocular, etc drug products.

 The daily dose may be 0.01-50 mg bodyweight kg/day depending on the severity of the illness, on the sex and weight of the patient.

30 Further details of the invention are demonstrated by the following examples without limiting the invention to the examples.

3

EXAMPLES

1. Preparation of 2-[[[4-(4-chloro-2,5-dimethoxyphenyl)-5-(2-cyclohexylethyl)-2-thiazolyl]amino]carbonyl]-5,7-dimethyl-1*H*-indol-1-acetic acid ethanolamine salt

647.4 g (1.060 mol) of 2-[[[4-(4-chloro-2,5-dimethoxyphenyl)-5-(2-cyclohexylethyl)-2-thiazolyl]amino]carbonyl]-5,7-dimethyl-1*H*-indol-1-acetic acid and 7000 cm³ of ethanol are mixed and the resulting suspension is heated to 72 °C. Then 95.3 cm³ (97.2 g = 1.592 mol) of 2-aminoethanol are added to the suspension. The reaction mixture is heated to reflux temperature and refluxed for 30 minutes. The resulting pale yellow suspension is allowed to cool to room temperature, under stirring. The crystals are filtered off, washed with ethanol, dried in vacuum drying cupboard at 60-65 °C.

Product: 694.6 g white crystals of the title compound, mp: 208-210 °C.

2. Preparation of 2-[[[4-(4-chloro-2,5-dimethoxyphenyl)-5-(2-cyclohexylethyl)-2-thiazolyl]amino]carbonyl]-5,7-dimethyl-1*H*-indol-1-acetic acid diethanolamine salt

1.22 g (2 mmol) of 2-[[[4-(4-chloro-2,5-dimethoxyphenyl)-5-(2-cyclohexylethyl)-2-thiazolyl]amino]carbonyl]-5,7-dimethyl-1*H*-indol-1-acetic acid and 18 cm³ of ethanol are mixed and the resulting suspension is heated to 70-75 °C and 0.4 cm³ (4 mmol) of diethanolamine are added to the suspension. The mixture is refluxed for 20 minutes. The resulting pale yellow suspension is allowed to cool to room temperature, under stirring. After cooling the crystals are filtered off, washed with ethanol, then with di-isopropyl ether.

Product: 1.29 g white crystals of the title compound, mp: 215.5-216.5 °C.

3. Preparation of 2-⁴[[[4-(4-chloro-2,5-dimethoxyphenyl)-5-(2-cyclohexylethyl)-2-thiazolyl]amino]carbonyl]-5,7-dimethyl-1*H*-indol-1-acetic acid diethylamine salt

1.22 g (2 mmol) of 2-[[[4-(4-chloro-2,5-dimethoxyphenyl)-5-(2-cyclohexylethyl)-2-thiazolyl]amino]carbonyl]-5,7-dimethyl-1*H*-indol-1-acetic acid and 12 cm³ of acetonitrile are mixed, the resulting suspension is heated to 50 °C and 0.62 cm³ (4 mmol) of diethylamine are added to it. The mixture is stirred at 50 °C for 20 minutes. The pale yellow suspension is allowed to cool to room temperature, under stirring. After cooling the crystals are filtered off, washed with acetonitrile, then with di-isopropyl ether.

Product: 1.28 g white crystals of the title compound, mp: 209.4 - 210.7 °C.

4. Preparation of 2-[[[4-(4-chloro-2,5-dimethoxyphenyl)-5-(2-cyclohexylethyl)-2-thiazolyl]amino]carbonyl]-5,7-dimethyl-1*H*-indol-1-acetic acid ethanolamine monohydrate salt

5 g (8.2 mmol) of 2-[[[4-(4-chloro-2,5-dimethoxyphenyl)-5-(2-cyclohexylethyl)-2-thiazolyl]amino]carbonyl]-5,7-dimethyl-1*H*-indol-1-acetic acid are added to the mixture of 45 cm³ of 96 % ethanol and 30 cm³ of water. The resulting suspension is heated to 82 °C, then 0.74 cm³ (13.2 mmol) of ethanolamine are added to it. The mixture is refluxed for 15 minutes. The pale yellow suspension is allowed to cool to room temperature, under stirring. The crystals are filtered off, washed with 96 % ethanol.

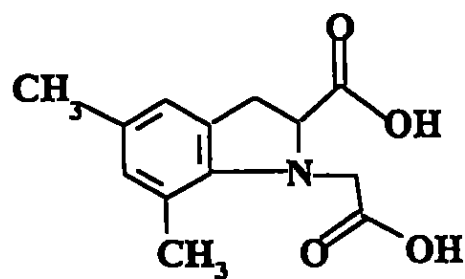
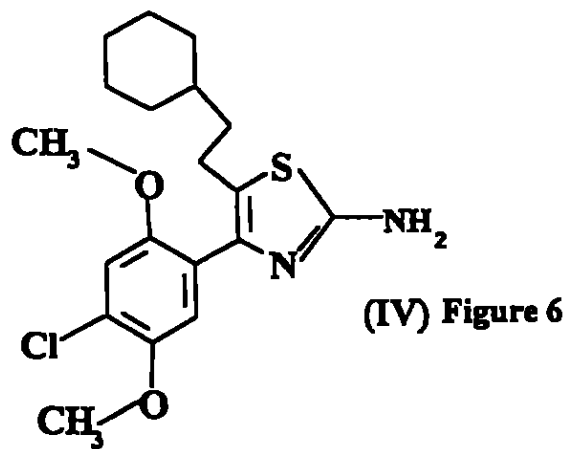
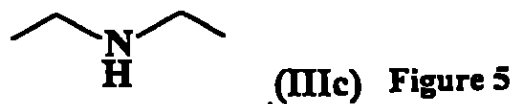
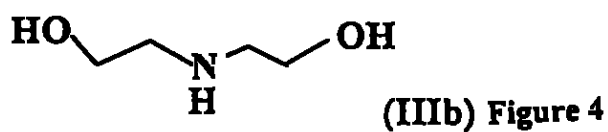
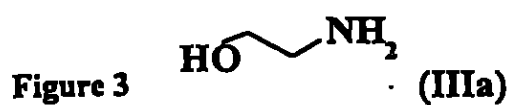
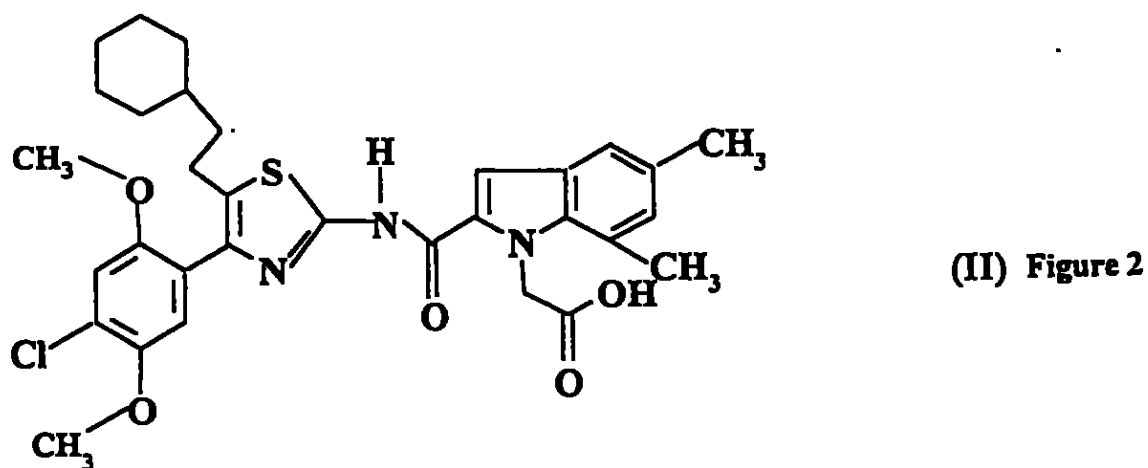
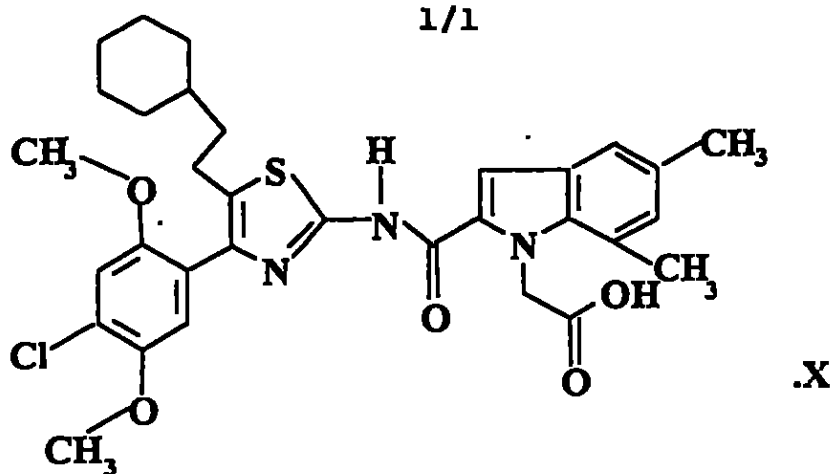
Product: 5 g white crystals of the title compound, mp: 166-167 / 198-201 °C.

What we claim is:

- 1) New salts of the general formula (I), their solvates, polymorphs and pseudo polymorphs
5 —wherein X stands for ethanolamine, diethanolamine or diethylamine —.
- 2) 2-[[[4-(4-chloro-2,5-dimethoxy-phenyl)-5-(2-cyclohexyl-ethyl)-2-thiazolyl]amino]carbonyl]-5,7-diethyl-1*H*-indol-1-acetic acid ethanolamine salt, its solvates, polymorphs and pseudopolymorphs.
- 3) Process for the preparation of the new salts of the general formula (I), their
10 solvates, polymorphs and pseudopolymorphs —wherein X stands for ethanolamine, diethanolamine or diethylamine —, characterized by reacting 2-[[[4-(4-chloro-2,5-dimethoxy-phenyl)-5-(2-cyclohexyl-ethyl)-2-thiazolyl]amino]carbonyl]-5,7-diethyl-1*H*-indol-1-acetic acid of the formula (II) with ethanolamine of the formula (IIIa), or diethanolamine of the formula (IIIb)
15 or diethylamine of the formula (IIIc).
- 4) Process according to claim 3 characterized by using the compounds of the formulae (IIIa), (IIIb) or (IIIc) in an excess of 1,2-1,5.
- 5) Process according to claims 3 and 4 characterized by carrying out the reaction in a protic solvent.
- 20 6) Process according to claim 5 characterized by using as protic solvent ethanol, acetonitrile or an ethanol-water mixture.
- 7) Process according to claims 3 to 6 characterized by carrying out the reaction at the boiling point of the solvent.
- 8) Pharmaceutical composition containing as active ingredient a new salt of the
25 general formula (I), its solvates, polymorphs or pseudopolymorphs —wherein X stands for ethanolamine, diethanolamine or diethylamine —.
- 9) Pharmaceutical composition according to claim 8 containing as active ingredient 2-[[[4-(4-chloro-2,5-dimethoxy-phenyl)-5-(2-cyclohexyl-ethyl)-2-thiazolyl]amino]carbonyl]-5,7-diethyl-1*H*-indol-1-acetic acid ethanolamine salt,
30 its solvates, polymorphs or pseudopolymorphs.

- 10) Use of the pharmaceutically acceptable new salts of the general formula (I), its solvates, polymorphs or pseudopolymorphs -wherein X stands for ethanolamine, diethanolamine or diethylamine -for the preparation of pharmaceutical compositions suitable for the treatment of the disorders of the gastrointestinal or central nervous systems.
- 11) Method of treatment of the disorders of the gastrointestinal or central nervous systems using an effective amount of a new salt of the general formula (I), its solvates, polymorphs or pseudopolymorphs -wherein X stands for ethanolamine, diethanolamine or diethylamine-.

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INTERNATIONAL SEARCH REPORT

24

International Application No

PCT/HU 01/00039

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07D417/12 A61K31/425 A61P1/00 A61P25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99 15525 A (SANOFI) 1 April 1999 (1999-04-01) cited in the application claims; example 5	1-11

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *S* document member of the same patent family

Date of the actual completion of the international search

26 June 2001

Date of mailing of the international search report

06/07/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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Fax (+31-70) 340-3018

Authorized officer

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/HU 01/00039

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9915525 A	01-04-1999	FR 2768737 A	26-03-1999
		FR 2777887 A	29-10-1999
		AU 9170598 A	12-04-1999
		BR 9812653 A	22-08-2000
		CN 1276790 T	13-12-2000
		EP 1017693 A	12-07-2000
		HR 20000153 A	30-04-2001
		NO 20001409 A	16-05-2000
		PL 339292 A	04-12-2000
		ZA 9807961 A	07-04-1999

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference Case 875/PCT	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, Item 5 below.	
International application No. PCT/HU 01/ 00039	International filing date (day/month/year) 04/04/2001	(Earliest) Priority Date (day/month/year) 07/04/2000
Applicant SANOFI-SYNTHELABO et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ Certain claims were found unsearchable (See Box I). ✓

3. ☐ Unity of invention is lacking (see Box II).

4. With regard to the title,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

THERAPEUTICALLY USEFUL NEW SALTS OF CCK INHIBITORS, PROCESS FOR THE PREPARATION THEREOF AND PHARMACEUTICAL PREPARATIONS CONTAINING THEM

5. With regard to the abstract,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07D417/12 A61K31/425 A61P1/00 A61P25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99 15525 A (SANOFI) 1 April 1999 (1999-04-01) cited in the application claims; example 5 -----	1-11

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"A" document member of the same patent family

Date of the actual completion of the international search

26 June 2001

Date of mailing of the international search report

06/07/2001

Name and mailing address of the ISA

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Fax: (+31-70) 340-3016

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/HU 01/00039

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Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claim 11 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 8.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/HU 01/00039

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9915525 A	01-04-1999	FR 2768737 A	26-03-1999
		FR 2777887 A	29-10-1999
		AU 9170598 A	12-04-1999
		BR 9812653 A	22-08-2000
		CN 1276790 T	13-12-2000
		EP 1017693 A	12-07-2000
		HR 20000153 A	30-04-2001
		NO 20001409 A	16-05-2000
		PL 339292 A	04-12-2000
		ZA 9807961 A	07-04-1999

PATENT COOPERATION TREATY

29
2002 MARC 04

80001/553

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

To:

SANOFI-SYNTHELABO c/o
Dr. György Mihályi and
Katalin Mármárosi
To u. 1-6.
H-1045 Budapest
HONGRIE

→ C. 875/01

Date of mailing
(day/month/year) 28/02/2002

Applicant's or agent's file reference
Case 875/PCT

IMPORTANT NOTIFICATION

International application No. PCT/HU 01/ 00039	International filing date (day/month/year) 04/04/2001	Priority date (day/month/year) 07/04/2000
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Applicant

SANOFI-SYNTHELABO et al.

- The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
- REMINDER
The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/  European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer AIMALE MURILLO J Tel. (+49-89) 2399 2828
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Form PCT/IPEA/416 (July 1992) P20473



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference Case 875/PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/HU 01/ 00039	International filing date (day/month/year) 04/04/2001	Priority date (day/month/year) 07/04/2000
International Patent Classification (IPC) or national classification and IPC G07D417/12		
Applicant SANOFI-SYNTHELABO et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 2 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consists of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 16/10/2001	Date of completion of this report 25/02/2002
Name and mailing address of the IPEA/  European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer TZSCHOPPE D A Tel. (+49-89) 2399 2828



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

Internation application No. PCT/HU 01/ 00039

I. Basis of report

1. The basis of international preliminary examination report is the application as originally filed.

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

2. The question of whether the claimed invention appears to be novel, to involve an inventive step, or to be industrially applicable has not been and will not be the subject of the international preliminary examination (Article 34 (4) (a) (i) (ii) PCT; see also international search report) in respect of:

- 2.1 Applications having an unnecessary plurality of independent claims (generally not more than 1 independent claim in the same category is necessary; Article 6 PCT);

- 2.2 unsearched subject-matter (Article 17 (2) (a), Rule 66.1 (e) PCT).

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

3. To the extent that the international preliminary examination has been carried out (see item III above), the following is pointed out (Article 35 (2) and (3) (b) and Rule 70.7 and 70.8 (ii) PCT):

In light of the documents cited in the international search report, it is considered that the invention as claimed in the independent claims meets the criteria mentioned in Article 33 (1) PCT, i.e. it appears to be novel, to involve an inventive step and to be industrially applicable.

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference (if desired) (12 characters maximum) Case 875/PCT

Box No. I TITLE OF INVENTION THERAPEUTICALLY USEFUL NEW SALTS, PROCESS FOR THE PREPARATION THEREOF AND PHARMACEUTICAL PREPARATIONS CONTAINING THEM	
Box No. II APPLICANT ☐ This person is also inventor	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) SANOFI-SYNTHELABO 174, avenue de France F-75013 Paris FRANCE	Telephone No. +33 1 41 24 12 37 Facsimile No. +33 1 41 24 12 66 Teleprinter No. Applicant's registration No. with the Office
State (that is, country) of nationality: FRANCE	State (that is, country) of residence: FRANCE
This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box	
Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) HERMECZ, István Budapest, Molnár u. 53. H-1056 HUNGARY	This person is: ☐ applicant only ☒ applicant and inventor ☐ inventor only (If this check-box is marked, do not fill in below.) Applicant's registration No. with the Office
State (that is, country) of nationality: HUNGARY	State (that is, country) of residence: HUNGARY
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box	
☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.	
Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE	
The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) SANOFI-SYNTHELABO c/o Dr. György Mihályi and Katalin Mármárosi Budapest, Tó u. 1-5., H-1045 HUNGARY	Telephone No. +36 1 369 5706 Facsimile No. +36 1 369 5706 Teleprinter No. Agent's registration No. with the Office
☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.	

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this box is the applicant's State (that is, country) of residence (if no State of residence is indicated below.)

HORVÁTH, Ágnes
Budapest, Budenz u. 30/a
H-1021 HUNGARY.

This person is:

- ☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

Applicant's registration No. with the Office

State (that is, country) of nationality:
HUNGARY

State (that is, country) of residence:
HUNGARY

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this box is the applicant's State (that is, country) of residence (if no State of residence is indicated below.)

KISS, Gyuláné
Budapest, Ajtósi Dürer sor 33/b
H-1146 HUNGARY

This person is:

- ☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

Applicant's registration No. with the Office

State (that is, country) of nationality:
HUNGARY

State (that is, country) of residence:
HUNGARY

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this box is the applicant's State (that is, country) of residence (if no State of residence is indicated below.)

MORVAI, Miklós
Mogyoród, Zsák u. 11.
H-2146 HUNGARY

This person is:

- ☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

Applicant's registration No. with the Office

State (that is, country) of nationality:
HUNGARY

State (that is, country) of residence:
HUNGARY

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this box is the applicant's State (that is, country) of residence (if no State of residence is indicated below.)

PODÁNYI, Benjámín
Dunakeszi, Kazinczy u. 29.
H-2120 HUNGARY

This person is:

- ☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

Applicant's registration No. with the Office

State (that is, country) of nationality:
HUNGARY

State (that is, country) of residence:
HUNGARY

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box



Further applicants and/or (further) inventors are indicated on another continuation sheet.

Supplemental Box

If the Supplemental Box is not used, this sheet should not be included in the request.

1. If, in any of the Boxes, except Boxes Nos. VIII(i) to (v) for which a special continuation box is provided, the space is insufficient to furnish all the information: in such case, write "Continuation of Box No." (Indicate the number of the Box) and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient, in particular:

(i) If more than two persons are to be indicated as applicants and/or inventors and no "continuation sheet" is available: in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below:

(ii) If, in Box No. II or in any of the sub-boxes of Box No. III, the indication "the States indicated in the Supplemental Box" is checked: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant;

(iii) If, in Box No. II or in any of the sub-boxes of Box No. III, the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor;

(iv) If, in addition to the agent(s) indicated in Box No. IV, there are further agents: in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;

(v) If, in Box No. V, the name of any State (or OAPI) is accompanied by the indication "parent of addition," or "certificate of addition," or if, in Box No. V, the name of the United States of America is accompanied by an indication "continuation" or "continuation-in-part": in such case, write "Continuation of Box No. V" and the name of each State involved (or OAPI), and after the name of each such State (or OAPI), the number of the parent title or parent application and the date of grant of the parent title or filing of the parent application;

(vi) If, in Box No. VI, there are more than five earlier applications whose priority is claimed: in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI.

2. If, with regard to the precautionary designation statement contained in Box No. V, the applicant wishes to exclude any State(s) from the scope of that statement: in such case, write "Designation(s) excluded from precautionary designation statement" and indicate the name or two-letter code of each State so excluded.

Continuation of Box N X:

Hermez István
HERMECZ, István

HORVÁTH Ágnes
HORVÁTH, Ágnes

KISS Gyuláné
KISS, Gyuláné

MORVAI Miklós
MORVAI, Miklós

PODÁNYI Benjámin
PODÁNYI, Benjámin

SIMON Kálmán
SIMON, Kálmán

SIPOS Judit
SIPOS, Judit

SMELKÓNÉ ESEK Ágota
SMELKÓNÉ ESEK, Ágota

SZABÓ Anna
SZABÓ, Anna

VASVÁRI Árpádné
VASVÁRI, Árpádné

Continuation of Box No IV:

For further applicants the address written in Box No IV is the special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)	
<i>If none of the following sub-boxes is used, this sheet should not be included in the request.</i>	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) SIMON, Kálmán Budapest, Ratkóc u. 9. H-1118 HUNGARY	This person is: ☐ applicant only ☒ applicant and inventor ☐ inventor only (If this check-box is marked, do not fill in below.) Applicant's registration No. with the Office
State (that is, country) of nationality: HUNGARY	State (that is, country) of residence: HUNGARY
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) SIPOS, Judit Budapest, Sáfrány u. 40. H-1116 HUNGARY	This person is: ☐ applicant only ☒ applicant and inventor ☐ inventor only (If this check-box is marked, do not fill in below.) Applicant's registration No. with the Office
State (that is, country) of nationality: HUNGARY	State (that is, country) of residence: HUNGARY
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) SMELKÓNÉ ESEK, Ágota Budapest, Patakegyi u. 9/a H-1028 HUNGARY	This person is: ☐ applicant only ☒ applicant and inventor ☐ inventor only (If this check-box is marked, do not fill in below.) Applicant's registration No. with the Office
State (that is, country) of nationality: HUNGARY	State (that is, country) of residence: HUNGARY
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) SZABÓ, Anna Budapest, Berzeviczy G. u. 5/b H-1042 HUNGARY	This person is: ☐ applicant only ☒ applicant and inventor ☐ inventor only (If this check-box is marked, do not fill in below.) Applicant's registration No. with the Office
State (that is, country) of nationality: HUNGARY	State (that is, country) of residence: HUNGARY
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box	
☒ Further applicants and/or (further) inventors are indicated on another continuation sheet.	

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)	
<i>If none of the following sub-boxes is used, this sheet should not be included in the request.</i>	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) VASVÁRI, Árpádné Budapest, Goldmark K. u. 33. H-1022 HUNGARY	This person is: ☐ applicant only ☒ applicant and inventor ☐ inventor only (If this check-box is marked, do not fill in below.) Applicant's registration No. with the Office
State (that is, country) of nationality: HUNGARY	State (that is, country) of residence: HUNGARY
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	This person is: ☐ applicant only ☐ applicant and inventor ☐ inventor only (If this check-box is marked, do not fill in below.) Applicant's registration No. with the Office
State (that is, country) of nationality:	State (that is, country) of residence:
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	This person is: ☐ applicant only ☐ applicant and inventor ☐ inventor only (If this check-box is marked, do not fill in below.) Applicant's registration No. with the Office
State (that is, country) of nationality:	State (that is, country) of residence:
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	This person is: ☐ applicant only ☐ applicant and inventor ☐ inventor only (If this check-box is marked, do not fill in below.) Applicant's registration No. with the Office
State (that is, country) of nationality:	State (that is, country) of residence:
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box	
☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.	

Box No.V DESIGNATION OF STATES

Mark the applicable check-boxes below; at least one must be marked.

The following designations are hereby made under Rule 4.9(a):

Regional Patent

- ☒ AP ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, MZ Mozambique, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ EA Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ EP European Patent: AT Austria, BE Belgium, CH & LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, TR Turkey, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ OA OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line)

National Patent (if other kind of protection or treatment desired, specify on dotted line):

- | | | |
|---|--|--|
| ☒ AE United Arab Emirates | ☒ GE Georgia | ☒ MW Malawi |
| ☒ AG Antigua and Barbuda | ☒ GH Ghana | ☒ MX Mexico |
| ☒ AL Albania | ☒ GM Gambia | ☒ MZ Mozambique |
| ☒ AM Armenia | ☒ HR Croatia | ☒ NO Norway |
| ☒ AT Austria | ☒ HU Hungary | ☒ NZ New Zealand |
| ☒ AU Australia | ☒ ID Indonesia | ☒ PL Poland |
| ☒ AZ Azerbaijan | ☒ IL Israel | ☒ PT Portugal |
| ☒ BA Bosnia and Herzegovina | ☒ IN India | ☒ RO Romania |
| | ☒ IS Iceland | ☒ RU Russian Federation |
| ☒ BB Barbados | ☒ JP Japan | |
| ☒ BG Bulgaria | ☒ KE Kenya | ☒ SD Sudan |
| ☒ BR Brazil | ☒ KG Kyrgyzstan | ☒ SE Sweden |
| ☒ BY Belarus | ☒ KP Democratic People's Republic of Korea | ☒ SG Singapore |
| ☒ BZ Belize | ☒ KR Republic of Korea | ☒ SI Slovenia |
| ☒ CA Canada | ☒ KZ Kazakhstan | ☒ SK Slovakia |
| ☒ CH & LI Switzerland and Liechtenstein | ☒ LC Saint Lucia | ☒ SL Sierra Leone |
| ☒ CN China | ☒ LK Sri Lanka | ☒ TJ Tajikistan |
| ☒ CO Colombia | ☒ LR Liberia | ☒ TM Turkmenistan |
| ☒ CR Costa Rica | ☒ LS Lesotho | ☒ TR Turkey |
| ☒ CU Cuba | ☒ LT Lithuania | ☒ TT Trinidad and Tobago |
| ☒ CZ Czech Republic | ☒ LU Luxembourg | |
| ☒ DE Germany | ☒ LV Latvia | ☒ TZ United Republic of Tanzania |
| ☒ DK Denmark | ☒ MA Morocco | ☒ UA Ukraine |
| ☒ DM Dominica | ☒ MD Republic of Moldova | ☒ UG Uganda |
| ☒ DZ Algeria | | ☒ US United States of America |
| ☒ EE Estonia | ☒ MG Madagascar | ☒ UZ Uzbekistan |
| ☒ ES Spain | ☒ MK The former Yugoslav Republic of Macedonia | ☒ VN Viet Nam |
| ☒ FI Finland | ☒ MN Mongolia | ☒ YU Yugoslavia |
| ☒ GB United Kingdom | | ☒ ZA South Africa |
| ☒ GD Grenada | | ☒ ZW Zimbabwe |

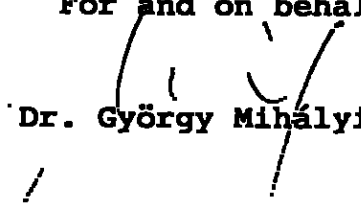
Check-boxes below reserved for designating States which have become party to the PCT after issuance of this sheet:

- | | | |
|--------------------------|--------------------------|--------------------------|
| ☐ | ☐ | ☐ |
| ☐ | ☐ | ☐ |

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)

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Box No. VI PRIORITY CLAIM				
The priority of the following earlier application(s) is hereby claimed:				
Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		national application: country	regional application: regional Office	international application: receiving Office
item (1) 7 April 2000 (07.04.2000)	POO 01417	HUNGARY		
item (2)				
item (3)				
item (4)				
item (5)				
☐ Further priority claims are indicated in the Supplemental Box.				
The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of this international application is the receiving Office) identified above as:				
☐ all items ☒ item (1) ☐ item (2) ☐ item (3) ☐ item (4) ☐ item (5) ☐ other, see Supplemental Box				
<i>* Where the earlier application is an ARIPO application, indicate at least one country party to the Paris Convention for the Protection of Industrial Property or one Member of the World Trade Organization for which that earlier application was filed (Rule 4.10(b)(II)):</i>				
Box No. VII INTERNATIONAL SEARCHING AUTHORITY				
Choice of International Searching Authority (ISA) (if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):				
ISA / European Patent Office				
Request to use results of earlier search; reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority):				
Date (day/month/year)	Number	Country (or regional Office)		
Box No. VIII DECLARATIONS				
The following declarations are contained in Boxes Nos. VIII (i) to (v) (mark the applicable check-boxes below and indicate in the right column the number of each type of declaration):				Number of declarations
☐ Box No. VIII (i)	Declaration as to the identity of the inventor			:
☐ Box No. VIII (ii)	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent			:
☐ Box No. VIII (iii)	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application			:
☐ Box No. VIII (iv)	Declaration of inventorship (only for the purposes of the designation of the United States of America)			:
☐ Box No. VIII (v)	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty			:

Box No. IX CHECK LIST: LANGUAGE OF FILING		
This international application contains: (a) the following number of sheets in paper form: request (including declaration sheets) : 8 description (excluding sequence listing part) : 4 claims : 2 abstract : 1 drawings : 1 Sub-total number of sheets : 16 sequence listing part of description (actual number of sheets if filed in paper form, whether or not also filed in computer readable form; see (b) below) : 0 Total number of sheets : 16 (b) sequence listing part of description filed in computer readable form (i) ☐ only (under Section 801(a)(i)) (ii) ☐ in addition to being filed in paper form (under Section 801(a)(ii)) Type and number of carriers (diskette, CD-ROM, CD-R or other) on which the sequence listing part is contained (additional copies to be indicated under item 9(ii), in right column):	This international application is accompanied by the following item(s) (mark the applicable check-boxes below and indicate in right column the number of each item): 1. ☒ fee calculation sheet : 2. ☐ original separate power of attorney : 3. ☐ original general power of attorney : 4. ☒ copy of general power of attorney: reference number, if any: : 5. ☐ statement explaining lack of signature : 6. ☐ priority document(s) identified in Box No. VI as item(s): : 7. ☐ translation of international application into (language): : 8. ☐ separate indications concerning deposited microorganism or other biological material : 9. ☐ sequence listing in computer readable form (indicate also type and number of carriers (diskette, CD-ROM, CD-R or other)) (i) ☐ copy submitted for the purposes of international search under Rule 13ter only (and not as part of the international application) : (ii) ☐ (only where check-box (b)(i) or (b)(ii) is marked in left column) additional copies including, where applicable, the copy for the purposes of international search under Rule 13ter : (iii) ☐ together with relevant statement as to the identity of the copy or copies with the sequence listing part mentioned in left column : 10. ☐ other (specify): :	Number of items
Figure of the drawings which should accompany the abstract:	Language of filing of the international application: English	
Box No. X SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE <i>Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).</i>		
Budapest, 30 March 2001 For and on behalf of SANOFI-SYNTHELABO  Dr. György Mihályi  Katalin Marmarosi		

For receiving Office use only	
1. Date of actual receipt of the purported international application:	2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):	
5. International Searching Authority (if two or more are competent): ISA /	6. ☐ Transmittal of search copy delayed until search fee is paid
For International Bureau use only	
Date of receipt of the record copy by the International Bureau:	

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The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line below:

IPEA/ European Patent Office

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:

The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).

For International Preliminary Examining Authority use only

Identification of IPEA		Date of receipt of DEMAND	
Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION		Applicant's or agent's file reference Case 875 PCT	
International application No. PCT/HU01/00039	International filing date (day/month/year) 04 April 2001 (04.04.2001)	(Earliest) Priority date (day/month/year) 07 April 2000 (07.04.2000)	
Title of invention THERAPEUTICALLY USEFUL NEW SALTS, PROCESS FOR THE PREPARATION THEREOF AND PHARMACEUTICAL PREPARATIONS CONTAINING THEM			
Box No. II APPLICANT(S)			
Name and address: (family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) SANOFI-SYNTHELABO 174, avenue de France F-75013 Paris FRANCE		Telephone No. +33 1 41 24 12 37	
		Facsimile No. +33 1 41 24 12 66	
		Teleprinter No.	
		Applicant's registration No. with the Office	
State (that is, country) of nationality: FRANCE		State (that is, country) of residence: FRANCE	
Name and address: (family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) HERMECZ, István Budapest, Molnár u. 53. H-1056 HUNGARY			
State (that is, country) of nationality: HUNGARY		State (that is, country) of residence: HUNGARY	
Name and address: (family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) HORVÁTH, Ágnes Budapest, Budenz u. 30/a H-1021 HUNGARY			
State (that is, country) of nationality: HUNGARY		State (that is, country) of residence: HUNGARY	
☒ Further applicants are indicated on a continuation sheet.			

Continuation of Box No. 11 APPLICANT(S)

If none of the following sub-braces is used, this sheet should not be included in the demand.

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

KISS, Gyuláné
Budapest, Ajtósi Dürer sor 33/b
H-1146 HUNGARY

State (that is, country) of nationality:

HUNGARY

State (that is, country) of residence:

HUNGARY

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

MORVAI, Miklós
Mogyoród, Zsák u. 11.
H-2146 HUNGARY

State (that is, country) of nationality:

HUNGARY

State (that is, country) of residence:

HUNGARY

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

PODÁNYI, Benjámín
Dunakeszi, Kazinczy u. 29.
H-2120 HUNGARY

State (that is, country) of nationality:

HUNGARY

State (that is, country) of residence:

HUNGARY

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

SIMON, Kálmán
Budapest, Ratkóc u. 9.
H-1118 HUNGARY

State (that is, country) of nationality:

HUNGARY

State (that is, country) of residence:

HUNGARY

Further applicants are indicated on another continuation sheet.

Continuation of Box No. 11 APPLICANT(S)

If none of the following sub-boxes is used, this sheet should not be included in the demand.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

SIPOS, Judit
Budapest, Sáfrány u. 40.
H-1116 HUNGARY

State *(that is, country)* of nationality:

HUNGARY

State *(that is, country)* of residence:

HUNGARY

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

SMELKÓNÉ ESEK, Ágota
Budapest, Patakhegyi u. 9/a
H-1028 HUNGARY

State *(that is, country)* of nationality:

HUNGARY

State *(that is, country)* of residence:

HUNGARY

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

SZABÓ, Anna
Budapest, Berzeviczy G. u. 5/b
H-1042 HUNGARY

State *(that is, country)* of nationality:

HUNGARY

State *(that is, country)* of residence:

HUNGARY

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

VASVÁRI, Árpádné
Budapest, Goldmark K. u. 33.
H-1022 HUNGARY

State *(that is, country)* of nationality:

HUNGARY

State *(that is, country)* of residence:

HUNGARY

☐ Further applicants are indicated on another continuation sheet.

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The following person is ☒ agent ☐ common representativeand ☒ has been appointed earlier and represents the applicant(s) also for international preliminary examination.☐ is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.☐ is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

SANOFI-SYNTHELABO c/o

Dr. György Mihályi and Katalin Mármárosi
Budapest, Tó u. 1-5.,
H-1045 HUNGARY

Telephone No.

+36 1 369 5706

Facsimile No.

+36 1 272 0727

Teleprinter No.

Agent's registration No. with the Office

☐ Address for correspondence: Mark this check-box where no agent or common representative has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION

Statement concerning amendments: *

1. The applicant wishes the international preliminary examination to start on the basis of:

☒ the international application as originally filedthe description ☐ as originally filed☐ as amended under Article 34the claims ☐ as originally filed☐ as amended under Article 19 (together with any accompanying statement)☐ as amended under Article 34the drawings ☐ as originally filed☐ as amended under Article 342. ☐ The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.3. ☐ The applicant wishes the start of the international preliminary examination to be postponed until the expiration of 20 months from the priority date unless the International Preliminary Examining Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). *(This check-box may be marked only where the time limit under Article 19 has not yet expired.)*

* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: English☒ which is the language in which the international application was filed.☐ which is the language of a translation furnished for the purposes of international search.☐ which is the language of publication of the international application.☐ which is the language of the translation (to be) furnished for the purposes of international preliminary examination.

Box No. V ELECTION OF STATES

The applicant hereby elects all eligible States *(that is, all States which have been designated and which are bound by Chapter II of the PCT)*

excluding the following States which the applicant wishes not to elect:

Box No. VI CHECK LIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

- | | | |
|--|---|--------|
| 1. translation of international application | : | sheets |
| 2. amendments under Article 34 | : | sheets |
| 3. copy (or, where required, translation) of amendments under Article 19 | : | sheets |
| 4. copy (or, where required, translation) of statement under Article 19 | : | sheets |
| 5. letter | : | sheets |
| 6. other (specify) | : | sheets |

For International Preliminary Examining Authority use only

- | | |
|--------------------------|--------------------------|
| received | not received |
| ☐ | ☐ |
| ☐ | ☐ |
| ☐ | ☐ |
| ☐ | ☐ |
| ☐ | ☐ |
| ☐ | ☐ |

The demand is also accompanied by the item(s) marked below:

- | | |
|---|--|
| 1. ☒ fee calculation sheet | 5. ☐ statement explaining lack of signature |
| 2. ☐ original separate power of attorney | 6. ☐ sequence listing in computer readable form |
| 3. ☐ original general power of attorney | 7. ☒ other (specify): Transmittal Letter |
| 4. ☒ copy of general power of attorney: reference number, if any: | |

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).

Budapest, 15 October 2001

For and on behalf of SANOFI-SYNTHELABO

Dr. György Mihályi

Katalin Mármárosi

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:

2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):

3. ☐ The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5. below. does not apply.

☐ The applicant has been informed accordingly.

4. ☐ The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.

5. ☐ Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.

For International Bureau use only

Demand received from IPEA on:

VJ

CHAPTER II

PCT.

FEE CALCULATION SHEET

Annex to the Demand

International application No. PCT/HU01/00039		For International Preliminary Examining Authority use only	
Applicant's or agent's file reference Case 875 PCT		Date stamp of the IPEA	
Applicant SANOFI-SYNTHELABO, Paris, France; István Hermecz, Budapest, Hungary et al.			
CALCULATION OF PRESCRIBED FEES			
1. Preliminary examination fee		EUR 1 533	P
2. Handling fee (Applicants from certain States are entitled to a reduction of 75% of the handling fee. Where the applicant is (or all applicants are) so entitled, the amount to be entered at II is 25% of the handling fee.)		EUR 147	H
3. Total of prescribed fees Add the amounts entered at P and H and enter total in the TOTAL box		EUR 1 680	
		TOTAL	
MODE OF PAYMENT			
☐ authorization to charge deposit account with the IPEA (see below)	☐ cash		
☐ cheque	☐ revenue stamps		
☐ postal money order	☐ coupons		
☒ bank draft	☐ other (specify):		
AUTHORIZATION TO CHARGE (OR CREDIT) DEPOSIT ACCOUNT (This mode of payment may not be available at all IPEAs)			
☐ Authorization to charge the total fees indicated above.		IPEA: _____	
☐ (This check-box may be marked only if the conditions for deposit accounts of the IPEA so permit) Authorization to charge any deficiency or credit any overpayment in the total fees indicated above.		Deposit Account No.: _____	
		Date: _____	
		Name: _____	
		Signature: _____	

**NUEVAS SALES TERAPEÚTICAMENTE ÚTILES DE INHIBIDORES CCK,
PROCESO PARA LA PREPARACIÓN DE ESTOS Y PREPARACIONES
FARMACEÚTICAS QUE LOS CONTIENEN.**

La invención se relaciona con nuevas sales terapéuticamente útiles de la formula general (I) (figura 1). Sus solvatos, polimorfos y pseudopolimorfos, con el proceso para la preparación de estos y con las preparaciones farmacéuticas que las contienen, en donde en la formula

X significa etanolamina, dietanolamina, o dietilamina.

El compuesto de formula (II) (figura 2) es un agonista de colecistoquinina A(CCK-A), el cual puede ser utilizado para el tratamiento de desordenes del sistema gastrointestinal y el sistema nervioso central.

Las siguientes sales de los compuestos de formula (II) y los procesos para su preparación se describen en la publicación WO 99/15525: sal con ácido trifluoroacético, sal con ácido clorhídrico, sales mono y sodio, sales mono y dipotasio. La sal con ácido

trifluoroacético y su hidrato, en razón de la fuerte toxicidad del ácido trifluoroacético, no son adecuados para uso terapéutico. La composición de la sal con ácido clorhídrico no es estequiométrica, no es reproducible.

Las sales de mono-y diosodio, así como también las sales de mono-y dipotasio y sus hidratos son altamente hidroscópicos y compuestos químicamente no estables, a saber los compuestos de la fórmula (II) descomponen el enlace amida dando origen a productos de descomposición de la fórmula (IV) (figura 6) y (V) (figura 7).

Los sujetos de la presente invención, las nuevas sales terapéuticamente aplicables de la fórmula general (I) y sus solvatos, polimorfos y pseudopolimorfos, en donde en la fórmula X tienen el significado como se dio anteriormente, con especial relación a la sal de etanolamina y sus solvatos,, son químicamente estables, no hidroscópicos y su preparación es bien reproducible.

La preparación de los sujetos de la presente invención, las nuevas sales terapéuticamente aplicables de la fórmula general (I) y sus solvatos, polimorfos y pseudopolimorfos se lleva a cabo al hacer reaccionar el

ácido 2-[[[4-(-cloro-2,5-dimetoxifenil)-5-(2-ciclohexiletil)-2-tiazolil]amino]carbonil]-5,7-dimetil-1H-indol-1-acético de la formula (II) con la etanolamina de la formula (IIIa) (figura 3) o la dietanolamina de la formula (IIIb) (figura 4) o la dietilamina de la formula (IIIc) (figura 5).

Los compuestos (IIIa), (IIIb) o (IIIc) se aplican preferiblemente en un exceso de equivalentes 1, 2-1, 5. La reacción se lleva a cabo preferiblemente en solventes próticos, a una temperatura entre 40-100°C, preferiblemente al punto de ebullición del solvente. Como solventes próticos se pueden aplicar preferiblemente etanol, acetonitrilo, o una mezcla de etanol-agua.

Las nuevas sales terapéuticamente aceptables de la formula general (I) y sus solvatos, polimorfos y pseudopolimorfos de la presente invención son agonistas de colecistoquinina A (ACCK-A), que se pueden utilizar para el tratamiento de desordenes del sistema gastrointestinal, y del sistema nervioso central.

El efecto agonista de los compuestos de acuerdo con la presente invención se investigó como se describió en

la publicación WO/99/15525 al investigar su efecto al desocupar el estomago en ratas, p. o. Hemos encontrado que el valor ED₅₀, 34 µg/kg p. o, es del mismo orden que el valor ED₅₀ de la sal de ácido trifluroacético y la sal de potasio.

El sujeto adicional de la presente invención son las preparaciones farmacéuticas que contienen la sal de la formula (I), sus solvatos, polimorfos y pseudopolimorfos, como ingredientes activos.

Las preparaciones farmacéuticas de acuerdo con la presente invención, además de los ingredientes activos, pueden contener los excipientes farmacéuticos usuales y se pueden formular como productos de drogas orales, sublinguales, subcutáneas, intramusculares, intravenosos, tópicos, intratraqueales, intravasales, transdérmicos, rectales, intraoculares, etc.

La dosis diaria puede ser 0,01-50 mg por kilogramo de peso del cuerpo/día dependiendo de la severidad de la enfermedad, del sexo y del peso del paciente.

Detalles adicionales de la invención se demuestran por medio de los siguientes ejemplos sin limitar la invención a los ejemplos.

EJEMPLOS

1. Preparación de sal de etanolamina de ácido 2-[[[4-(4-cloro-2,5-dimetoxifenil)-5-(2-ciclohexiletil)-2-tiazolil]amino]carbonil]-5,7-dimetil-1H-indol-1-acético.

647,4 g (1.060 mol) de ácido 2-[[[4-(4-cloro-2,5-dimetoxifenil)-5-(2-ciclohexiletil)-2-tiazolil]amino]carbonil]-5,7-dimetil-1H-indol-1-acético y 7 cm³ de etanol se mezclan y la suspensión resultante se calienta a 72°C. Luego se agregan 95,3 cm³ (97,2 g = 1.592 mol) de 2-aminoetanol a la suspensión. La mezcla de reacción se calienta a temperatura de reflujo y se refluje durante 30 minutos. La suspensión resultante amarillo pálido se le permite enfriarse hasta temperatura ambiente, bajo agitación. Los cristales son filtrados, lavados con etanol, secados en una campana de secado al vacío a 60-65°C.

Producto: 694,6 g de cristales blancos del compuesto del título, MP: 208-210°C.

2. Preparación de sal de dietanolamina de ácido 2-[[[4-(4-cloro-2,5-dimetoxifenil)-5-(2-ciclohexiletil)-2-tiazolil]amino]carbonil]-5,7-dimetil-1H-indol-1-acético.

1,22 g (2 mmol) de ácido 2-[[[4-(4-cloro-2,5-dimetoxifenil)-5-(2-ciclohexiletil)-2-tiazolil]amino]carbonil]-5,7-dimetil-1H-indol-1-acético y 18 cm³ de etanol se mezclan y la suspensión resultante se calienta a 70-75°C y 0,4 cm³ (4 mmol) de dietanol amina se agregan a la suspensión. La mezcla se refluje durante 20 minutos. La suspensión resultante amarillo pálida se le permite enfriarse hasta temperatura ambiente, bajo agitación. Después de enfriar los cristales se filtran, se lavan con etanol, y luego con diisopropil eter.

Producto: 1,29 g de cristales blancos del compuesto del título, mp: 215,5-216,5°.

3. Preparación de sal de dietilamina de ácido 2-[[[4-(4-cloro-2,5-dimetoxifenil)-5-(2-ciclohexiletil)-2-tiazolil]amino]carbonil]-5,7-dimetil-1H-indol-1-acético.

1,22 g (2 mmol) de ácido 2-[[[4-(4-cloro-2,5-dimetoxifenil)-5-(2-ciclohexiletil)-2-tiazolil]amino]carbonil]-5,7-dimetil-1H-indol-1-acético y 12 cm³ de acetonitrilo se mezclan, la suspensión resultante se calienta a 50°C y se agregan a este 0,62 cm³, (4 mmol) de dietilamina. La mezcla se agita a 50°C durante 20 minutos. La suspensión amarillo pálida se le permite enfriarse a temperatura ambiente, bajo agitación. Después de enfriar los cristales se filtran, se lavan con acetonitrilo, y luego con diisopropil éter.

Producto: 1,28 g de cristales blancos del compuesto del título, mp: 209,4-210,7°C.

4. Preparación de sal de monohidrato de etanolamina de ácido 2-[[[4-(4-cloro-2,5-dimetoxifenil)-5-(2-ciclohexiletil)-2-tiazolil]amino]carbonil]-5,7-dimetil-1H-indol-1-acético.

5 g (8,2 mmol) de ácido 2-[[[4-(4-cloro-2,5-dimetoxifenil)-5-(2-ciclohexiletil)-2-tiazolil]amino]carbonil]-5,7-dimetil-1H-indol-1-acético se agregan a la mezcla de 45 cm³ de etanol al 96% y 30 cm³

de agua. La suspensión resultante se calienta a 82°C, luego 0,74 cm³ (13,2 mmol) de etanolamina se agregan a esta. La mezcla se refluje durante 15 minutos. A la suspensión amarilla pálido se le permite enfriarse hasta temperatura ambiente, bajo agitación. Los cristales se filtran, se lavan con 96% de etanol.

Productos: 5 g de cristales blancos del título del compuesto, mp: 166-167/198-201°C.

REIVINDICACIONES

1. Nuevas sales de formula general (I), sus solvatos, polimorfos y pseudopolimorfos.

- en donde X representa etanolamina, dietanolamina o dietilamina-

2. Sal de etanolamina de ácido 2-[[[4-(4-cloro-2,5-dimetoxi-fenil)-5-(2-ciclohexiletíl-etil)-2-tiazolil]amino]carbonil]-5,7-dietil-1H-indol-1-acético, sus sulfatos, polimorfos y pseudopolimorfos.

3. Proceso para la preparación de nuevas sales de la formula general (I), sus solvatos, polimorfos y pseudopolimorfos en donde X representa etanolamina, dietanolamina o dietilamina, caracterizados por que se hace reaccionar ácido 2-[[[4-(4-cloro-2,5-dimetoxi-fenil)-5-(2-ciclohexil-etil)-2-tiazolil]amino]carbonil]-5,7-dietil-1H-indol-1-acético de la formula (II) con etanolamina de la formula(IIIa), y dietanolamina de la formula (IIIb) o dietilamina de la formula (IIIc).

J-J-

4. Proceso de acuerdo a la reivindicación 3 caracterizado por utilizar los compuestos de las formulas (IIIa), (IIIb) o (IIIc) en un exceso de 1,2-1,5.

5. Proceso de acuerdo a las reivindicaciones 3 y 4 caracterizado por llevar a cabo la reacción en un solvente prótico.

6. Proceso de acuerdo a la reivindicación 5 caracterizado por utilizar como solvente prótico etanol acetonitrilo o una mezcla de etanol-agua.

7. Proceso de acuerdo a la reivindicación 3 a 6 caracterizado por llevar a cabo la reacción al punto de fusión del solvente.

8. Composición farmacéutica que contiene como ingrediente activo una nueva sal de la fórmula general (I), sus solvatos, polimorfos o pseudopolimorfos en donde X representa etanolamina, dietanolamina o dietilamina.

9. Composición farmacéutica de acuerdo a la reivindicación 8 que contiene como ingrediente activo sal de etanolamina de ácido 2-2-[[[4-(4-cloro-2,5-dimetoxi-

fenil)-5-(2-ciclohexil-etil)-2-tiazolil]amino]carbonil]-
5,7-dietil-1H-indol-1-acético, sus solvatos, polimorfos o
seudopolimorfos.

10. Uso de nuevas sales farmacéutica mente aceptables de
la formula general (I), sus solvatos, polimorfos o
seudopolimorfos en donde X representa etanolamina,
dietanolamina o dietilamina para la preparación de
composiciones farmacéuticas adecuadas para el tratamiento
de los desordenes del sistema gastrointestinal o nervioso
central.

11. Método de tratamiento de desordenes del sistema
gastrointestinal o nervioso central utilizando una
cantidad efectiva de una nueva sal de la formula general
(I), sus solvatos, polimorfos o seudopolimorfos en donde
X representa etanolamina, dietanolamina o dietilamina.

1/1

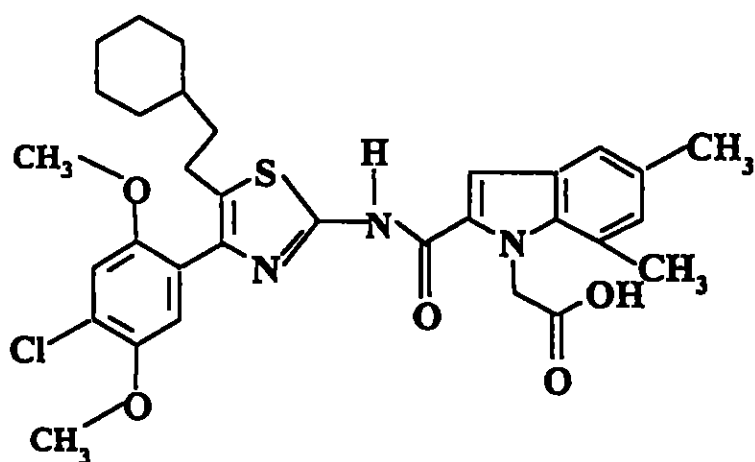
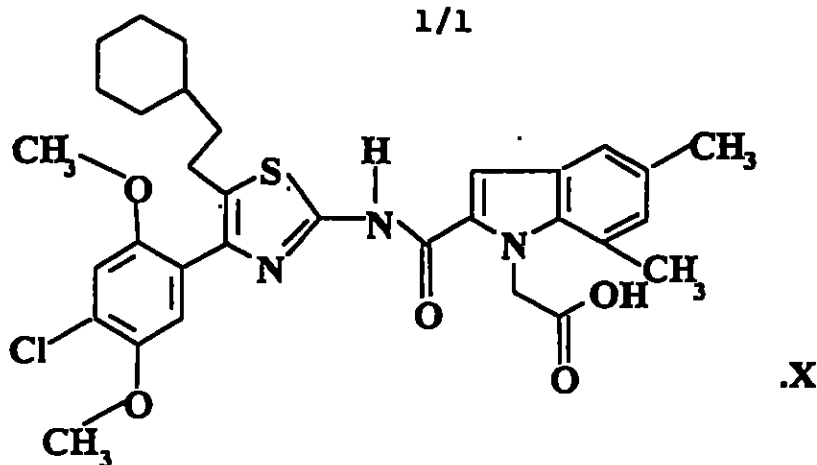
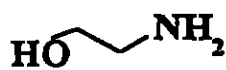
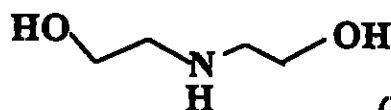


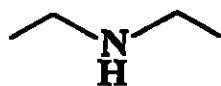
Figure 3



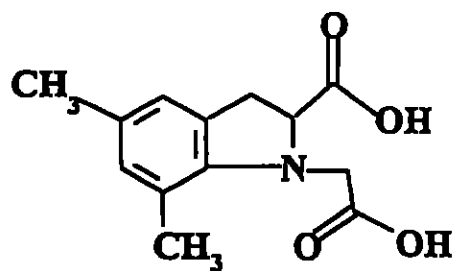
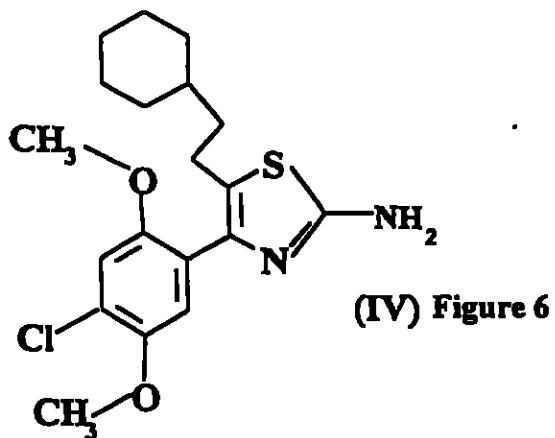
(IIIa)



(IIIb) Figure 4



(IIIc) Figure 5



Expediente No		02090225	No de Folio
Item		No de unidades	
1	CD		
2	DVD		
3	REVISTA		
4	LIBRO		
5	PERIODICO		
6	DISQUETES		
7	SOBRE DE MANILA	1	
8	SOBRE BLANCO TAMAÑO CARTA		
9	SOBRE BLANCO TAMAÑO OFICIO		
10	OTROS:		

Observaciones: are find

Figuras 12 x 12 para
Ex tracto de publicación
y Tarjetas.
ely Mayo 5/03.



59

Industria y Comercio

SUPERINTENDENCIA

SUPERINDUSTRIA Y COMERCIO
Radicación : 02090225 00000000 Folios: 59
Fecha (Nº): 2002-10-07 16:28:37
Trámite : 011 PCT-PATENT 379 FASE NACI 411 PRESENTAC
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 02 - 65,104
FECHA : SEPTIEMBRE 30 DE 2002

***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PAGO	Vr. PAGO
CAVELIER ABOGADOS	CONSIGNACION	BANCO POPULAR	050-00110-6	7030336	30/09/2002	23,260,000.00

***** CONCEPTO *****

CANT. REMITIVO	CONCEPTO	TOTAL CONCEPTO
1 50003-01-01 SOLICITUDES	1 TRAMITES DE SOL. DE PATENTE DE IN	378,000.00
	TOTAL :	\$ 378,000.00

SON: TRESCIENTOS SETENTA Y OCHO MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

Cdo 12555-841-001-0.

Carrera 13 No. 27-00 Pisos 5, 7 y 10
Conmutador 382 0840
Fax 350 5220
E-mail: info@sic.gov.co
www.sic.gov.co
Bogotá, D.C., Colombia

REQUISITOS NECESARIOS PARA PRESENTACION Y AGILIZACION DEL TRAMITE

	USUARIO	RADICADOR
PATENTE DE INVENCION	()	(/)
MODELO DE UTILIDAD	()	(/)
- Indicación de que se solicita la concesión de una patente.	()	(/)
- Datos de identificación del solicitante o de la persona que se presenta la solicitud.	()	(/)
- Descripción de la invención.	()	(/)
- Dibujos de ser estos pertinentes.	()	(/)
- Comprobante de Pago de las tasas establecidas.	()	(/)

COMPLETA (/) INCOMPLETA () ()

DISEÑO INDUSTRIAL ()

- Indicación de que se solicita el registro de Diseño Industrial	()	()
- Datos de identificación del solicitante o de la persona que presenta la solicitud.	()	()
- Representación gráfica y fotográfica del Diseño Industrial o muestra del Material que incorpora el diseño.	()	()
- Comprobante de pago de las tasas establecidas	()	()

COMPLETA () INCOMPLETA () ()

ESQUEMA DE TRAZADO ()

- Indicación de que solicita el registro de un Esquema de trazado.	()	()
- Datos de identificación del solicitante o de la persona que presenta La solicitud.	()	()
- Representación gráfica del esquema de trazado	()	()
- Comprobante de pago de las tasas establecidas.	()	()

COMPLETA () INCOMPLETA () ()

Firma Responsable:



Fecha:

Carrera 13 No. 27-00 Pisos 5 y 10
Conmutador: 334 12 21
Fax: 281 31 25
Santa Fe de Bogotá, D.C., Colombia