

SUPERINTENDENCIA Y COMERCIO

Radicación: 02113247 / 00000000

Folios: 17

Fecha (VFO): 2004-12-04 09:27:53

Tramite : 011 PCT-PATENTE 470 FASE NUCI 444 RESPUESTA

Dependencia: DEEN DIVISION DE NUEVAS CREACIONES

Señores
DIVISIÓN DE NUEVAS CREACIONES
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Bogotá, D.C.

Re.: Código 011-379-444
Expediente No. 02-113.247
Fase Nacional de la Solicitud
de Patente PCT
SMITHKLINE BEECHAM
CORPORATION

En relación con el expediente de la referencia y dando cumplimiento a la última providencia recaída sobre este asunto por medio del presente escrito me permito manifestarles lo siguiente:

1. Acompaño una copia auténtica del documento que acredita la cesión de los inventores a la sociedad solicitante, debidamente legalizado y oficialmente traducido.
2. Adjunto también una copia del reporte y el examen preliminar internacional que, como fácilmente podrá notar, no contiene ningún anexo y por lo tanto la traducción solicitada es claramente impertinente.
3. Aclaro que esta solicitud se tramita por el Capítulo II.

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Renuncio al término faltante de traslado, y les solicito ordenar la publicación del extracto.

De Ustedes Atentamente,

GERMAN CASTILLO GRAU
T.P. No. 2.978 del C.S.J.



78 74

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

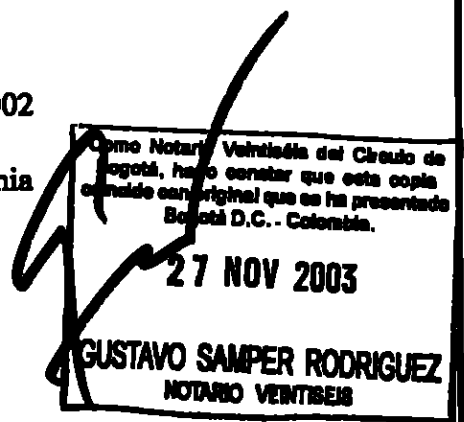
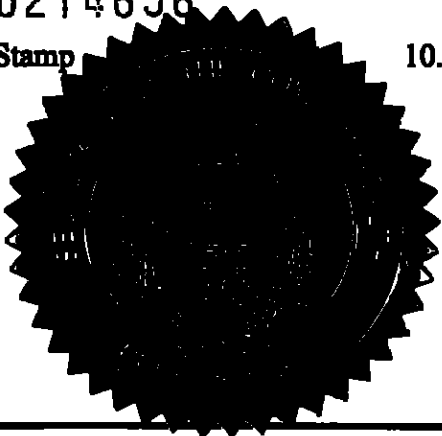
1. Country: United States of America
2. This public document has been signed by **Edward J. Richards**
3. acting in the capacity of **Notary Public, Chester County**
4. bears the seal/stamp of **Edward J. Richards, Notary Public, Commonwealth of Pennsylvania**

Certified

5. at **Harrisburg, Pennsylvania**
6. The **27th** day of **November, 2002**
7. by **C. Michael Weaver, Secretary of the Commonwealth of Pennsylvania**

8. No. **A0214656**

9. Seal/Stamp
10. Signature:



C. Michael Weaver

C. Michael Weaver

79 80

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

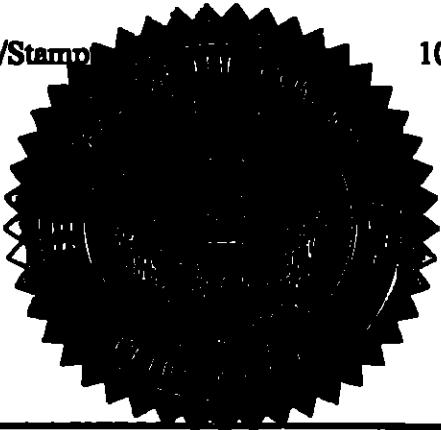
1. Country: United States of America
2. This public document has been signed by Irene M. Mulligan
3. acting in the capacity of Notary Public, Montgomery County
4. bears the seal/stamp of Irene M. Mulligan, Notary Public, Commonwealth of Pennsylvania

Certified

5. at Harrisburg, Pennsylvania
6. The 27th day of November, 2002
7. by C. Michael Weaver, Secretary of the Commonwealth of Pennsylvania

8. NoA0214657

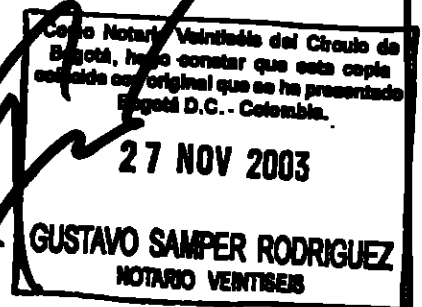
9. Seal/Stamp



10. Signature:

C. Michael Weaver

C. Michael Weaver



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P51137

Colombia

20 A1

Insert here full name and address of inventor
Leave blank

El abajo firmado

nombra por el presente al

Title of Invention

domiciliados en Bogotá República de Colombia, con dirección en la de la misma ciudad, como su representante con poder amplio y suficiente, incluyendo el de recibir notificaciones y nombrar apoderados judiciales y extra-judiciales, para solicitar y obtener de las oficinas y autoridades nacionales Patentes de Invención para

Name and address of assignee

cuyo título deberá extenderse a

Amount of consideration, if any

a quien ha cedido todos sus derechos a la invención anteriormente citada en cuanto se refiere al territorio de Colombia, sin restricción de ninguna clase, mediante el pago de que declara haber recibido. El cesionario firma también el presente en prueba de aceptación de la cesión y nombra igualmente al expresado apoderado como su representante en Bogotá con iguales facultades, y para dar ante dichas oficinas y autoridades todos los pasos necesarios al objeto indicado; elevar solicitudes, declaraciones, reclamos; formular y firmar descripciones, enmiendas y apelaciones; pagar todos los impuestos y cuotas y efectuar toda clase de pagos determinados por la ley y retirar los mismos al fuere necesario; recibir todos los documentos y valores dando el descargo respectivo; deslitar y percibir, llenar cualesquiera otros requisitos y tomar, en fin, todas las medidas que creyere conducentes al resguardo de los intereses del mandante, quien ratifica y confirma por el presente todo cuanto hiciera legalmente dicho apoderado en virtud del presente poder, con plena facultad de sustitución y renovación y de nombrar apoderados judiciales y extra-judiciales y recibir notificaciones.

Place and date of execution

King of Prussia, Pennsylvania, USA on 05 July 2001

Kyung O. Johanson
KYUNG O. JOHANSON
Robert B. Kirkpatrick
ROBERT B. KIRKPATRICK
Allan R. Shatzman
ALLAN R. SHATZMAN
Patrick McDevitt
PATRICK MCDEVITT

Berwyn, Pennsylvania, USA on
YEN SEN HO
YEN SEN HO

Notarize both inventor's and applicant's signature.

Legalize by Colombian Consular Officer

The undersigned (See Attachment I)

hereby appoints Dr. German Castillo Grau, and/or Dr. Alvaro Castillo Grau, and/or Luis Felipe Castillo Gibsons

domiciled in Carrera 13 N° 37-43 Piso 12 in Bogotá Colombia as attorney with ample and sufficient power, including that of receiving notifications and appointing judicial and extra-judicial attorneys, to apply for and obtain from the national offices and authorities Patent of invention for "METHOD FOR PREPARING A PHYSIOLOGICALLY ACTIVE IL-18 POLYPEPTIDE"

to be issued in the name of SMITHKLINE BEECHAM CORPORATION of One Franklin Plaza, Philadelphia, Pennsylvania 19103, United States of America

to whom assignment has been made of all rights and titles on said invention for the territory of Colombia, without any restriction whatsoever, the consideration for said assignment being the sum of receipt whereof is hereby acknowledged. The assignee also signs this document in acknowledgement of acceptance of said assignment and hereby appoints the above mentioned attorney as his representative in Bogotá with the same faculties; and to take all necessary steps before said offices and authorities for the purpose stated above, to file applications, declarations and claims; to draw and sign specifications, amendments and appeals; to pay all fees and installments and to make all payments required by law and withdraw the same if necessary; to receive all documents and securities issuing receipts therefor, to desist and to receive; to fulfill all other requirements and finally, to use all means which said attorney shall deem proper for the safe guard of the interests of the constituent, who hereby ratifies and confirms all and whatsoever the said attorney shall lawfully do by virtue of these present with full powers of substitution and to receive notifications and to appoint extra-judicial or judicial attorneys.
Given and signed at King of Prussia, PA, USA on 09 July 2001

SMITHKLINE BEECHAM CORPORATION
BY: Stephen Venetianer
Vice President, Pharmaceuticals
Corporate Intellectual Property

Notaría Veintiseis del Circuito de Bogotá, hago constar que esta copia coincide con original que me ha presentado Bogotá D.C. - Colombia.
27 NOV 2003
GUSTAVO SAMPER RODRIGUEZ
NOTARIO VEINTISEIS

La declaración Notarial a la Vista

Notarial acknowledgment on other side

5

DECLARACION NOTARIAL
(Individuals)

A los días del mes de 2001 comparecí
personalmente ante mi Notario Público

a quien(es) doy fe de conocer y me consta que es (son)
la(s) persona(s) descrita(s) y firmante(s) del documento
que precede, declarando ante mí que otorga(n) el mismo
para los fines que en él se expresan.

El Notario Público,

NOTARIAL CERTIFICATE
(Individual)

On this 5th day of July, 2001
personally appeared before me, a Notary Public,
KYUNG O. JOHANSON, ROBERT B.
KIRKPATRICK, ALLAN R. SHATZMAN, and
PATRICK McDEVITT

to me known, and known to me to be the person(s)
described in and who executed the foregoing
document, and he (they) duly acknowledged to me
that he (they) executed same for the uses and
purposes therein expressed.


Notary Public
Irene M. Mulligan, Notary Public
Upper Merion Twp., Montgomery County
My Commission Expires Oct. 20, 2001
Member, Pennsylvania Association of Notaries

On this 25th day of July, 2001
personally appeared before me, a Notary Public,
YEN SEN HO,

to me known, and known to me to be the person(s)
described in and who executed the foregoing
document, and he (they) duly acknowledged to me
that he (they) executed same for the uses and
purposes therein expressed.


Notary Public
Notarial Seal
Edward J. Richards, Notary Public
Thedyffrin Twp., Chester County
My Commission Expires August 30, 2004

(Sociedades)

El infrascrito Notario certifica: que la(s) firma(s) que
antecede(n) y dice(n).....

es (son) auténtica(s); que el (los) signatario(s) es (son)

de

que tiene(n) facultad para otorgar este poder; y que dicha
compañía exists y está domiciliada en

conforme a las leyes de

Todos los hechos anteriores le constan por haber
examinado los documentos respectivos y de todo ello da
fe.

Dado y firmado en


Como Notario Veintiseis del Estado de
Bogotá, hago constar que esta copia
coincide con original que se ha presentado
Bogotá D.C. - Colombia.

El Notario Público

27 NOV 2003

GUSTAVO SAMPER RODRIGUEZ
NOTARIO VEINTISEIS

(Corporations)

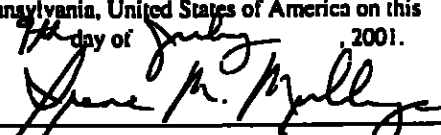
The undersigned Notary Public certifies: that the
preceding signature(s) reading Stephen Venetianer
is (are) authentic(s); that the signer(s) is (are)
Vice President, Pharmaceuticals of
SMITHKLINE BEECHAM CORPORATION

and that he (they) is (are) empowered to grant
this power; and that said company exists and is
domiciled at One Franklin Plaza, Philadelphia,
Pennsylvania 19103, United States of America
in accordance with the laws of the Commonwealth
of Pennsylvania.

All the foregoing facts are known to the Notary
who examined the respective documents, to which
he, the Notary attests.

Granted and signed in King of Prussia,

Pennsylvania, United States of America on this
5th day of July, 2001.

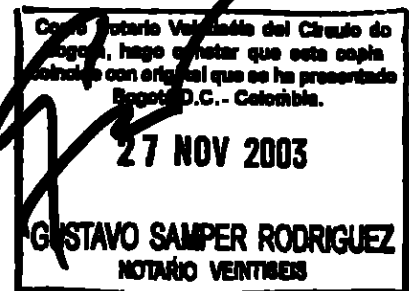

Notary Public

Notarial Seal
Irene M. Mulligan, Notary Public
Upper Merion Twp., Montgomery County
My Commission Expires Oct. 20, 2001
Member, Pennsylvania Association of Notaries

81 42

Attachment I

We, **KYUNG O. JOHANSON** of 709 Swedeland Road, King of Prussia, Pennsylvania 19406-0939, United States of America, a citizen of the United States of America; **ROBERT B. KIRKPATRICK** of 709 Swedeland Road, King of Prussia, Pennsylvania 19406-0939, United States of America, a citizen of the United States of America; **ALLAN R. SHATZMAN** of 709 Swedeland Road, King of Prussia, Pennsylvania 19406-0939, United States of America, a citizen of the United States of America; **YEN SEN HO** of 362 Old State Road, Berwyn, Pennsylvania 19312, United States of America, a citizen of the United States of America; and **PATRICK McDEVITT** of 709 Swedeland Road, King of Prussia, Pennsylvania 19406-0939, United States of America, a citizen of the United States of America;



EN BLANCO
NOTARIA VEINTISEIS

EN BLANCO
NOTARIA VEINTISEIS

TRADUCCIÓN OFICIAL NO. 9184 DE UN DOCUMENTO ESCRITO EN INGLES, realizada por María Mercedes Uricoechea T., Traductora/Intérprete Oficial según Res. 10607 del 31 de diciembre de 1981 del Ministerio de Justicia. Bogotá, 25 de noviembre de 2003.

LEGALIZACIONES DE UN PODER/CESION CON TRADUCCIÓN AL ESPAÑOL, CONFERIDO A LOS DRS. GERMAN CASTILLO GRAU Y/O ALVARO CASTILLO GRAU Y/O LUIS FELIPE CASTILLO GIBSON PARA LA OBTENCIÓN DE LA PATENTE "MÉTODO PARA ELABORAR UN POLIPÉPTIDO I-18 FISIOLÓGICAMENTE ACTIVO"

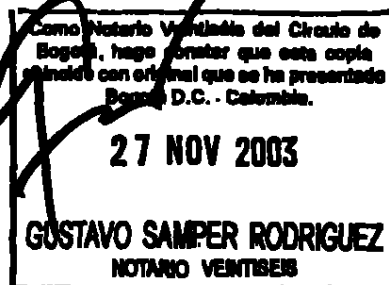
PODER/CESIÓN FIRMADO por los señores KYUNG O. JOHANSSON, ROBERT V. KIRKPATRICK, ALLAN R. SHATZMAN, PATRICK MCDEVITT en King of Prussia, Pennsylvania, EUA, el 5 de julio de 2001, y por YEN SEN HO, en Berwyn, Pennsylvania, EUA en Pittsburg, Pennsylvania, EUA, el 25 de julio de 2001. (Cedentes)

PODER/CESION FIRMADO en King of Prussia, PA. EUA, el 9 de julio de 2001 por Stephen Venetianer, VP de Patentes Farmacéuticas – Propiedad Intelectual Corporativa - de SMITHKLINE BEECHAM CORPORATION (Cesionaria).

RECONOCIMIENTO NOTARIAL (Cedentes) (1)

En la fecha, 5 de julio de 2001, comparecieron ante mi, una Notaria Pública, los señores KYUNG O. JOHANSSON, ROBERT V. KIRKPATRICK, ALLAN R. SHATZMAN, PATRICK MCDEVITT quienes se que fueron las personas descritas y quienes firmaron el documento adjunto y reconocieron ante mi que firmaron el mismo para los usos y propósitos que allí se expresan.

(FIRMA Y SELLO SECO) Irene M. Mulligan, Notaria Pública. Upper Merion, Condado de Montgomery. Mi comisión vence el 20 de octubre de 2001.



María Mercedes Uricoechea T.
Traductora/Intérprete Oficial
Bogotá, D.C. - Colombia

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RECONOCIMIENTO NOTARIAL (Cedente) (2)

En la fecha, 25 de julio de 2001, compareció ante mí, un Notario Público, el señor YEN SE HO quien se que fue la persona descrita y quien firmó el documento adjunto y reconoció ante mí que firmó el mismo para los usos y propósitos que allí se expresan.

(FIRMA Y SELLO SECO) Edward J. Richards, Notario Público. Upper Merion, Condado de Chester. Mi comisión vence el 20 de octubre de 2001.

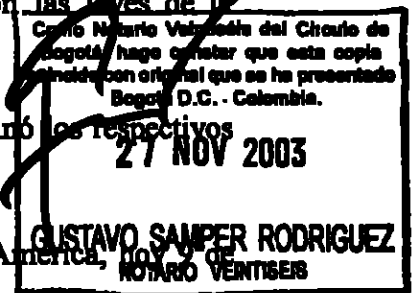
RECONOCIMIENTO NOTARIAL (Cesionaria)

La suscrita Notaria Pública certifica que la firma anterior que lee Stephen Venetianer es auténtica; que el firmante es el Vicepresidente de Productos Farmacéuticos de SMITHKLINE BEECHAM CORPORATION y que está facultado para otorgar este poder; y que dicha compañía existe y está domiciliada en One Franklin Plaza, Philadelphia, Pennsylvania 19103, Estados Unidos de América, de conformidad con las leyes de la Mancomunidad de Pennsylvania.

Todo los hechos anteriores fueron conocidos por la Notaria quien examinó los respectivos documentos, de lo cual, la Notaria da fé.

Dado y firmado en King of Prusia. Pennsylvania, Estados Unidos de América, el 25 de julio de 2001.

Firma y sello de Irene M. Mulligan, Notaria Pública, Municip. Upper Merion, Condado de Montgomery. Mi comisión vence el 30 de agosto de 2004. (SELLO SECO)



ANEXO 1

Nosotros **KYUNG O. JOHANSON** residente en 709 Swedeland Road, King of Prusia, Pennsylvania 19406-0939, Estados Unidos de América, estadounidense; **ROBERT B. KIRKPATRICK** residente en 709 Swedeland Road, King of Prusia, Pennsylvania 19406-0939, Estados Unidos de América, estadounidense; **ALLAN R. SHATZMAN** residente en 709 Swedeland Road, King of Prusia, Pennsylvania 19406-0939, Estados Unidos de América, estadounidense; **YEN SEN HO** residente en 362 Old State Road, Berwyn, Pennsylvania 19312, Estados Unidos de América, estadounidense; y **PATRICK**

2

Traducción Oficial No. 9184

McDEVITT residente en 709 Swedeland Road, King of Prusia, Pennsylvania 19406-0939, Estados Unidos de América, estadounidense.

LEGALIZACIONES

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. País: Estados Unidos de América

Este documento público

2. fue suscrito por EDWARD J. RICHARDS

3. quien actúa en capacidad de Notario Público, Condado de Chester

4. lleva el sello de: Edward J. Richards, Notario Público, Mancomunidad de Pennsylvania

Certificado

5. Harrisburg, Pennsylvania,

6. hoy 27 de noviembre de 2002

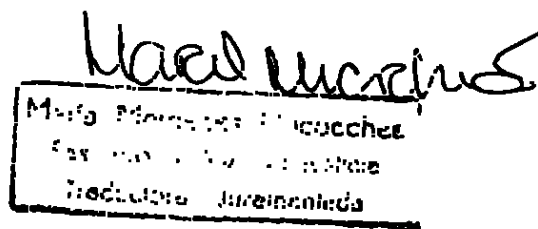
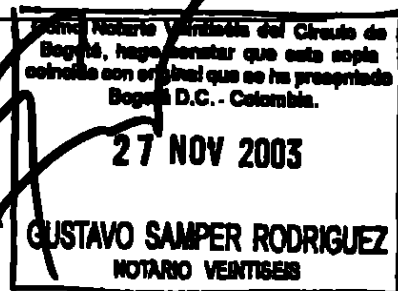
7. por C. Michael Weaver, Secretario de la Mancomunidad de Pennsylvania

8. No. A 0214656

9. Sello Dorado en relieve

10. Firma

C. Michael Weaver



JS
AB

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. País: Estados Unidos de América

Este documento público

2. fue suscrito por IRENE M. MULLIGAN

3. quien actúa en capacidad de Notaria Pública, Condado de Montgomery

4. lleva el sello de: IRENE M. MULLIGAN, NOTARIA PÚBLICA, CONDADO DE MONTGOMERY, MANCOMUNIDAD DE PENNSYLVANIA

Certificado

5. en Harrisburg, Pennsylvania

6. hoy 27 de noviembre de 2002

7. por C. Michael Weaver, Secretario de la Mancomunidad de Pennsylvania

8. No. A 0214657

9. Sello Dorado en relieve

10. Firma
C. Michael Weaver

LA ANTERIOR ES UNA TRADUCCIÓN FIEL Y COMPLETA DE LA CUAL SE DEJA COPIA EN LOS ARCHIVOS DE LA CALLE 84 NO. 18-38 (OF. 201) PARA SU CONFRONTACIÓN. TEL. 218 1007 - 623 3301

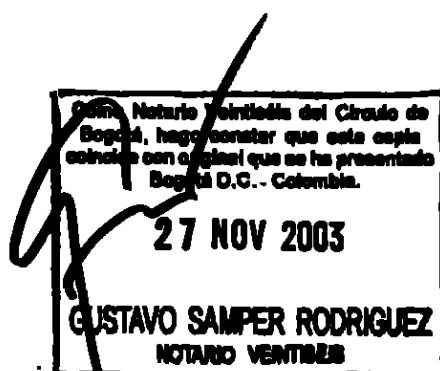
MARIA MERCEDES URICOECHEA T.

C.C. 41.319.274 BOGOTÁ

TRADUCTORA/INTÉRPRETE OFICIAL

RES. 10607 DEL 31 DE DICIEMBRE/81, MINJUSTICIA

FIN DE LA TRADUCCION OFICIAL NO. 9184



Handwritten signature of Maria Mercedes Uricoechea T.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
ZOLTAN KEREKES
GLAXOSMITHKLINE
CORPORATE INTELLECTUAL PROPERTY, UW2220
709 SWEDELAND ROAD, P.O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

PCT 2b NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day/month/year)

19 NOV 2003

Applicant's or agent's file reference

P51137

IMPORTANT NOTIFICATION

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US01/18804

11 June 2001 (11.06.2001)

15 June 2000 (15.06.2000)

Applicant

SMITHLINE BEECHAM CORPORATION

1. 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.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. 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.
4. **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/US

Mail Stop PCT, Attn: IPEA/US
Commissioner for Patents
P.O. Box 1490
Alexandria, Virginia 22313-1490

Facsimile No. (703)305-3230

Form PCT/IPEA/416 (July 1992)

Authorized officer -

Patricia D. Roberts
Vivian Eyster

Telephone No. 703-308-0196

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P51137	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US01/18804	International filing date (day/month/year) 11 June 2001 (11.06.2001)	Priority date (day/month/year) 15 June 2000 (15.06.2000)
International Patent Classification (IPC) or national classification and IPC IPC(7): C12P 21/00; C12N 15/00 and US Cl.: 435/68.1, 69.1, 69.5, 70.1; 530/412		
Applicant SMITHLINE BEECHAM CORPORATION		
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 <u>12</u> 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 consist of a total of <u>0</u> sheets. 3. This report contains indications relating to the following items: I ☒ Basis of the report II ☐ Priority III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability IV ☒ Lack of unity of invention V ☒ Reasoned statements 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 20 December 2001 (20.12.2001)	Date of completion of this report 04 November 2003 (04.11.2003)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1430 Alexandria, Virginia 22313-1430 Facsimile No. (703)305-3230	Administrative officer <i>Alicia D. Roberts for</i> Yvonne Byler Telephone No. 703-308-0196	

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US01/18804

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
 pages 1-18 as originally filed
 pages NONE filed with the demand
 pages NONE filed with the letter of _____.
- ☒ the claims:
 pages 19-22 as originally filed
 pages NONE as amended (together with any statement) under Article 19
 pages NONE filed with the demand
 pages NONE filed with the letter of _____.
- ☒ the drawings:
 pages 1-31 as originally filed
 pages NONE filed with the demand
 pages NONE filed with the letter of _____.
- ☒ the sequence listing part of the description:
 pages 1-10 as originally filed
 pages NONE filed with the demand
 pages NONE filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

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

- ☒ contained in the international application in printed 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.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US01/18804

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☒ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is

- ☒ complied with.
- ☒ not complied with for the following reasons:

Please See Continuation Sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US01/18804

V. Reasoned statement under Rule 66.2(a)(II) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1</u>	NO
Industrial Applicability (IA)	Claims <u>1</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claim 1 lacks novelty under PCT Article 33(2) as being anticipated by Fassy et al. (Eur. J. Biochem., April 1998, 253(1): 76-83). Fassy discloses a method for producing an active polypeptide of IL-1 β from its precursor polypeptide by contacting caspase 4 (TX), wherein one of the cleavage sites of the IL-1 β precursor comprises FEAD (the abstract, page 80, the last paragraph of the right column). Further, Fassy teaches purified active IL-1 β polypeptide by SDS-PAGE (Fig. 6, and the first paragraph of the right column). Thus, the reference anticipates claim 1.

Applicants responses to the Written Opinion filed on 16 May 2003 is acknowledged. Applicants do not agree with the Examiner's observation concerning the lack of novelty for claim 1, but prefer to deal with these issues during the national phase of the examination. As such, no response would be needed in the present report.

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az**Supplemental Box**
(To be used when the space in any of the preceding boxes is not sufficient)

IV. 3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1, drawn to a method for producing an active polypeptide from a precursor polypeptide using caspase 4.

Group II, claim(s) 2, drawn to a method for producing an active polypeptide from a precursor polypeptide using caspase 5.

Group III, claim(s) 3, drawn to a method for producing an active IL-18 from a precursor IL-18 other than the human precursor IL-18 using caspase 4.

Group IV, claim(s) 4, drawn to a method for producing an active IL-18 from a precursor IL-18 other than the human precursor IL-18 using caspase 5.

Group V, claim(s) 3, 5, 7, and 9, drawn to a method for producing an active human IL-18 from a human precursor IL-18 using caspase 4.

Group VI, claim(s) 4, 6, 8, and 10, drawn to a method for producing an active human IL-18 from a human precursor IL-18 using caspase 5.

Group VII, claim(s) 11, drawn to a method for producing an active polypeptide from a precursor polypeptide by co-expressing caspase 4 with the precursor polypeptide.

Group VIII, claim(s) 12, drawn to a method for producing an active polypeptide from a precursor polypeptide by co-expressing caspase 5 with the precursor polypeptide.

Group IX, claim(s) 14, 17, 20, and 23, drawn to a method for producing an active IL-18 from a precursor polypeptide by co-expressing caspase 4 with the precursor IL-18.

Group X, claim(s) 15, 18, 21, and 24, drawn to a method for producing an active IL-18 from a precursor polypeptide by co-expressing caspase 5 with the precursor IL-18.

Group XI, claim(s) 13, 16, 19, and 22, drawn to a method for producing an active IL-18 from a precursor polypeptide by co-expressing ubiquitinase with a ubiquitin/IL-18 fusion.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I is directed to a method for producing an active polypeptide from a precursor polypeptide of any kind using caspase 4. It is apparent that Fassy et al. (Eur. J. Biochem., 253(1): 76-83, 1998) discloses a method for producing IFN- β from pro-interleukin-1 β using caspase 4 or caspase 5, which renders claims 1 and 2, among the other, not novel. Thus the technical feature of the claimed method is not special and the groups are not so linked under PCT Rule 13.1. Further, the methods of other groups do not correspond to the main invention, as they use different caspases (caspase 4 Vs. caspase 5), or different substrates (any protein vs. IL-18, or human IL-18), or involve different method approaches/ steps (using enzyme directly vs. co-expression), which are not coextensive, and do not share the same technical feature within the meaning of PCT Rule 13.2 and thus do not relate to a single invention concept within the meaning of PCT Rule 13.1.



**2do. EXAMEN DE FORMA PATENTE DE INVENCION
PCT**

Folio 88

Radicación no 02-113247

Concepto Técnico no 87

Clasificación Internacional de Patentes: C12N15/10

Practicado el examen de acuerdo a lo establecido en el Art. 38 de la Decisión 486 se determinó que esta solicitud de Patente de Invención:

- SI ☒ NO ☐ Contiene un resumen de la invención (Art.26-e).
- SI ☒ NO ☐ Contiene el título o nombre de la invención (Art.27-d).
- SI ☒ NO ☐ Contiene la descripción de la invención (Art.26-b).
- SI ☐ NO ☐ NO ES APLICABLE ☒ Contiene los dibujos necesarios para comprender la invención (Art.26-d)
- SI ☒ NO ☐ Contiene una o más reivindicaciones. (Art.26-c).
- SI ☐ NO ☐ NO ES APLICABLE ☒ Han sido desarrollados los productos y/o procedimientos a partir de recursos genéticos o de sus productos derivados de los que cualquiera de los Países Miembros es país de origen. (Art. 26- h).
- SI ☐ NO ☐ NO ES APLICABLE ☒ Los productos y/o procedimientos han sido obtenidos o desarrollados a partir de los conocimientos tradicionales de las comunidades indígenas, afro americanas, o locales de los países miembros, de acuerdo a lo establecido en la Decisión 391 y sus modificaciones y reglamentaciones vigentes.(Art.26-l).
- SI ☐ NO ☒ La invención se refiere a un producto relativo a un material biológico. (Art.26-j).
- SI ☒ NO ☐ NO ES APLICABLE ☐ La prioridad coincide con la materia reivindicada.
- SI ☒ NO ☐ CUMPLE LOS REQUISITOS TÉCNICOS

EXAMINADOR TÉCNICO
202057

Bogotá D. C., Enero 29 de 2004.



AS

Folio 94

2020
Bogotá DC

Doctor(a)
GERMAN CASTILLO GRAU
Apoderado(a)
SMITHKLINE BEECHAM CORPORATION

REFERENCIA:	Radicación No.	02- 113247
	Solicitud Internacional	PCT/US2001/018804
	Fecha Inicio fase nacional	15/01/2003
	Trámite	011
	Evento	379
	Actuación	416
	Oficio No.	76
	Folios	001

Teniendo en cuenta que la solicitud de privilegio de patente que se tramita bajo el expediente indicado en la referencia, reúne los requisitos de forma establecidos en la Decisión 486 de la Comisión de la Comunidad Andina, el Tratado de Cooperación en Materia de Patentes (PCT), el Reglamento y la Circular Unica de la Superintendencia de Industria y Comercio, se envía el extracto de la solicitud a la Oficina de Comunicaciones para efecto de su publicación en la Gaceta de Propiedad Industrial.

Cúmplase
Dado en Bogotá DC,

30 ENE 2004


ALIX CARMENZA CESPEDES DE VERGEL
Jefe de la División de Nuevas Creaciones

202057