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SUPERINDUSTRIA Y COMERCIO
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Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

Señor

Jefe de la División de Nuevas Creaciones

Superintendencia de Industria y Comercio

Ministerio de Comercio, Desarrollo, Industria y Turismo

E. S. D

Ref Expediente No. 03 112.806

Solicitud de Patente PCT entrada fase nacional para "NUEV S
COMPUESTOS HETEROCICLICOS QUE COMPRENDEN UN ANILL DE
TETRAHIDROISOQUINOLINA Y USO FARMACEUTICO DE LOS MISM S".

Solicitante: KYOTO PHARMACEUTICAL INDUSTRIES, LTD.

PRESENTACION DEL EXAMEN PRELIMINAR INTERNACIONAL

MARGARITA CASTELLANOS ABONDANO, mayor de edad, identificada
y domiciliada como aparece al pie de mi firma, atentamente me permito
presentar copia en inglés del examen preliminar internacional junto con su
traducción simple al español

En consecuencia, atentamente solicito a Ud se anexe dicho documento al
expediente correspondiente a esta solicitud de Patente de Invención.

Del Señor Jefe,


Margarita Castellanos Abondano
C.C. No. 39.779.654 de Usaquén
T.P.A. No.70819 del C. Sup de la Judicatura.
Carrera 9 No 93 - 09 - Bogotá
Teléfonos 610 74 80 y 610 74 60

Bogotá, **03 MAYO 2004**
xgt/4906FNPCT

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 09477	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP02/05097	International filing date (day/month/year) 27 May 2002 (27 05 02)	Priority date (day/month/year) 29 May 2001 (29 05 01)
International Patent Classification (IPC) or national classification and IPC C07D 217/26, 413/12, 417/12, A61K 31/472, 31/4725, A61P 3/04, 3/06, 3/10, 9/10, 29/00, 43/00		
Applicant KYOTO PHARMACEUTICAL INDUSTRIES, LTD		

- 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 6 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 _____ 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 02 December 2002 (02 12 02)	Date of completion of this report 03 April 2003 (03 04.2003)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP02/05097

I. Basis of the report

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

- ☒ the international application as originally filed
- ☐ the description.
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the claims.
 pages _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description.
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, 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 Rule 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 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.

4 ☐ The amendments have resulted in the cancellation of

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

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 (Rule 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/JP02/05097

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

1 The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

- ☐ the entire international application.
- ☒ claims Nos. 26

because:

- ☒ the said international application, or the said claims Nos. 26 relate to the following subject matter which does not require an international preliminary examination (*specify*)

See supplemental sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*)

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 26

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
- ☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP 02/05097

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

Continuation of III. 1.

Claim 26 pertains to methods for treatment of the human body by therapy, and thus relates to subject matter which does not require international preliminary examination by this International Preliminary Examining Authority.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP 02/05097

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

1 Statement

Novelty (N)	Claims	1-25, 27	YES
	Claims		NO
Inventive step (IS)	Claims	1-25, 27	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-25, 27	YES
	Claims		NO

2. Citations and explanations

Document 1. WO, 98/00403, A1

Document 2: Margaret M. Faul et al., "Synthesis of 2-phenyloxazole derivatives containing amino acids as insulin sensitivity enhancers for treatment of type II diabetes", Heterocycles, 1 April 2004, Vol. 55, No. 4, pp. 689-704

Document 3: WO, 93/23378, A1

Claims 1-25 and 27 are not disclosed or suggested in any of the documents cited in the international search report and are thus novel and involve an inventive step. In particular, the documents do not disclose or suggest compounds having a basic structure represented by general formula (I) in which Y is a substituent group described in the present application.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP02/05097

VI. Certain documents cited

1 Certain published documents (Rule 70 10)

<u>Application No Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
WO 01/40192 A1	07 June 2001 (07.06.2001)	29 November 2000 (29 11 2000)	03 December 1999 (03 12.1999)
[EX]			

2 Non-written disclosures (Rule 70 9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>
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TRATADO DE COOPERACION DE PATENTES

PCT

INFORME DEL EXAMEN PRELIMINAR INTERNACIONAL

(Artículo 36 y Regla 70 del PCT)

Archivo de referencia del solicitante o del agente 09477	PARA ACCION POSTERIOR	Ver Notificación de Transmisión del Informe del Examen Preliminar Internacional (Formato PCT/1PEA/416)
Solicitud Internacional No PCT/JP02/05097	Fecha de presentación internacional (día/mes/año) 27 de Mayo de 2002 (27 05 2002)	Fecha de prioridad (día/mes/año) 29 de Mayo de 2001 (29 05.2001)
Clasificación Internacional de Patente (CIP) o Clasificación Nacional y CIP C07D 217/26, 413/12, 417/12, A61K 31/472, 31/4725, A61P 3/04, 3/06, 3/10, 9/10, 29/00, 43/00		
Solicitante KYOTO PHARMACEUTICAL INDUSTRIES, LTD.		
1 Este informe de examen preliminar internacional ha sido preparado por esta Autoridad Examinadora Preliminar Internacional y se transmite al solicitante de acuerdo con el Artículo 36 2 Este INFORME consiste en un total de <u>6</u> hojas, incluyendo esta carátula ☐ Este Informe también se acompaña de los ANEXOS, esto es, hojas de descripción, reivindicaciones y/o dibujos que han sido modificados y son la base de este Informe y/o hojas que contienen rectificaciones hechas ante esta Autoridad (ver Regla 70 16 y Sección 807 de las Instrucciones Administrativas según el PCT Estos anexos consisten en un total de <u> </u> hojas		
3 Este Informe contiene Indicaciones relacionadas con los siguientes ítems I ☒ Base del informe II ☐ Prioridad III ☒ No establecimiento de opinión con respecto a la novedad, nivel inventivo y aplicación industrial IV ☐ Carencia de unidad de la invención V ☒ Declaración razonada según artículo 35(2) con relación a la novedad, nivel inventivo o aplicación industrial, citas y explicaciones que apoyan tal declaración VI ☒ Ciertos documentos citados VII ☐ Ciertos defectos en la solicitud internacional VIII ☐ Ciertas observaciones sobre la solicitud internacional		
Fecha de presentación de la solicitud de examen 2 de Diciembre de 2002 (02 12 02)	Fecha de completamiento de este informe 3 de Abril de 2003 (03 04.2003)	
Nombre y dirección de correo de la autoridad de Examen Preliminar Internacional	Funcionario autorizado	
Fax	Teléfono No	

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**INFORME DEL EXAMEN PRELIMINAR
INTERNACIONAL**

**No. de Solicitud
Internacional PCT/JP02/05097**

**III. No se establece ninguna opinión en cuanto a la novedad, nivel
inventivo y aplicación Industrial.**

1 No se efectuó examen con respecto a que si la invención reivindicada sea
novedosa, tenga nivel inventivo (que no sea obvia), o que tenga aplicación
industrial para

La reivindicación No 26

debido a que dicha reivindicación se relaciona con un tema que no requiere un
examen preliminar internacional

*La reivindicación 26 pertenece a métodos para el tratamiento del cuerpo
humano mediante terapia, y por lo tanto se relaciona con un tema que no se le
realiza examen preliminar internacional por ésta oficina*

No se ha efectuado el informe de búsqueda internacional para dicha
reivindicación 26

**V. Declaración razonada bajo el artículo 35(2) con relación a la novedad,
altura inventiva o aplicación Industrial: citas y explicaciones que apoyan
tal declaración.**

1 Declaración

Novedad (N)	Reivindicaciones	1-25, 27	SI
	Reivindicaciones		NO
Altura inventiva (IS)	Reivindicaciones	1-25, 27	SI
	Reivindicaciones		NO

Aplicación Industrial (IA)	Reivindicaciones	1-25, 27	SI
	Reivindicaciones		NO

2 Citaciones y explicaciones

Documento 1 WO, 98/00403, A1

Documento 2 Margaret M Faul et al , "Síntesis de derivados de 2-feniloxazol que contienen aminoácidos como la insulina de secuencia sensible para el tratamiento de la diabetes tipo II",
Heterocíclicos, 1 de Abril de 2004, Vol 55, No 4, pp 689-704

Documento 3 WO, 93/23378, A1

Las reivindicaciones 1 a 25 y 27 no se revelan ni se sugieren en ninguno de los documentos citados en el informe de búsqueda internacional y son por lo tanto novedosas e involucran nivel inventivo. En particular, los documentos no revelan los compuestos sugeridos que tienen una estructura básica representada por la fórmula general (I) en donde Y es un grupo sustituyente descrito en la presente solicitud.

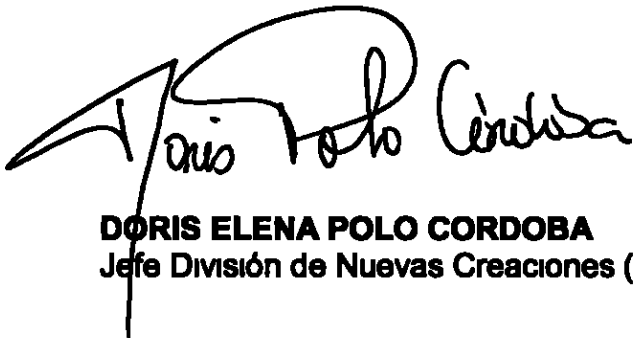
2020
Bogotá D C

Doctor(a)
MARGARITA CASTELLANOS ABONDANO
Apoderado(a)

REFERENCIA:	Radicación N°	03-112806
	Solicitud internacional	PCT/JP02/05097
	Fecha limite fase nacional	29/12/2003
	Trámite	011
	Evento	379
	Actuación	416
	Oficio N°	267
	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 los artículos 26 y 27 de la Decisión 486, de la Comisión de la Comunidad Andina, y en las demás disposiciones vigentes sobre la materia, se envía el extracto de la solicitud a la oficina de comunicaciones para efecto de su publicación en la Gaceta de Propiedad Industrial, conforme lo establece el artículo 40 de la Decisión 486

Cúmplase
Dado en Bogotá D C, **25 MAYO 2005**


DORIS ELENA POLO CORDOBA
Jefe División de Nuevas Creaciones (E)

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