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Señor

SUPERINTENDENTE DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES

E S D

SUPERINDUSTRIA Y COMERCIO

Radicacion 84022925 00000003 Folios 8
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Tramite 011 PCT-PATENT 379 FASE NACI 329 COMPLETEN
Dependencia 2020 DIVISION DE NUEVAS CREACIONES

REF Expediente No 04-044 545
Patente de Invencion "CRISTALES DE DERIVADO DE
HIDROXINOREFEDRINA"
Titular KISSEI PHARMACEUTICAL
CO , LTD

DESTINO 09

HUMBERTO RUBIO CAMACHO, mayor de edad, domiciliado en Bogota, D C , identificado con la cedula de ciudadanía numero 17 192 062 de Bogota, abogado Titulado con Tarjeta Profesional No 50 007 del Consejo Superior de la Judicatura, actuando en caracter de APODERADO de la Sociedad KISSEI PHARMACEUTICAL CO , LTD , domiciliada en 19-48, Yoshino, Matsumoto-shi, Nagano, Japon, debidamente reconocido por su Despacho, me permito anexar

- 1 - Copia del Examen Preliminar correspondiente a la solicitud PCT/JP2002/08596 de 27 de agosto de 2 002
- 2 - Teniendo en cuenta lo anterior solicito se continúe con el trámite correspondiente

Del Señor Superintendente,



HUMBERTO RUBIO CAMACHO
C C 17 192 062 de Bogota
T P 50 007 Consejo Superior
de la Judicatura
COD 4134

04/844-09/PI/cpfm -

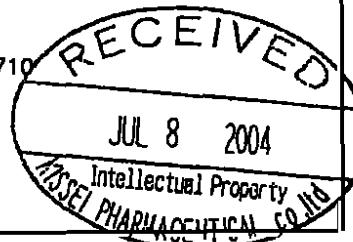
608

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 72.2)

To

KISSEI PHARMACEUTICAL CO. LTD
Intellectual Property
19-48 Yoshino
Matsumoto-shi Nagano 399-8710
JAPANDate of mailing (day/month/year)
01 July 2004 (01/07/2004)Applicant's or agent's file reference
PCT A0232

IMPORTANT NOTIFICATION

International application No
PCT/JP2002/008596International filing date (day/month/year)
27 August 2002 (27/08/2002)

Applicant

KISSEI PHARMACEUTICAL CO. LTD et al

1 Transmittal of the translation to the applicant

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority

2 Transmittal of the copy of the translation to the elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation

AZ CA CH CN CO EP GH KG KR MK MZ RO RU TM

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request

AE AG AL AM AP AT AU BA BB BG BR BY BZ CR CU CZ DE DK DM DZ EA EC EE ES FI GB GD GE
GM HR HU ID IL IN IS JP KE KZ LC LK LR LS LT LU LV MA MD MG MN MW MX NO NZ OA OM PH
PL PT SD SE SG SI SK SL TJ TN TR TT TZ UA UG US UZ VN YU ZA ZM ZW

3 Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that 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 (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details

The International Bureau of WIPO
34 chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

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Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

PCT Application
PCT/JP2002/008596



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Applicant's or agent's file reference PCT-A0232	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No PCT/JP02/08596	International filing date (day/month/year) 27 August 2002 (27 08 02)	Priority date (day/month/year) 13 September 2001 (13 09 01)
International Patent Classification (IPC) or national classification and IPC C07C 217/60 A61K 31/216, A61P 13/10		
Applicant KISSEI PHARMACEUTICAL CO., 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 04 March 2003 (04 03 03)	Date of completion of this report 01 December 2003 (01 12 2003)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No	Telephone No

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP02/08596

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

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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. 9

because

☒ the said international application or the said claims Nos. 9 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. 9

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 02/08596

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

Continuation of III 1

Claim 9 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, under the provisions of PCT Article 34(4)(a)(i) and PCT Rule 67 1(iv)

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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	3-4	YES
	Claims	1-2, 5-8	NO
Inventive step (IS)	Claims	3-4	YES
	Claims	1-2, 5-8	NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO

2 Citations and explanations

- Document 1 / WO 00/02846 A1 (Kissei Pharmaceutical Co),
20 January 2000
- Document 2 JP 2000-212137 A (Kissei Pharmaceutical Co),
2 August 2000
- Document 3 JP 2000-212138 A (Kissei Pharmaceutical Co),
2 August 2000
- Document 4 JP 2000-212139 A (Kissei Pharmaceutical Co),
2 August 2000

Claims 1-2 and 5-8 are not novel and do not involve an inventive step in the light of document 1 cited in the international search report

Document 1 discloses the usefulness of hydrochloride salts of phenoxyacetic acid derivatives as therapeutic agents for urinary frequency and incontinence

Claims 2 and 5-8 do not involve an inventive step in the light of documents 1-4 cited in the international search report

Documents 2-4 disclose the outstanding storage properties of crystals of phenoxyacetic acid, therefore, a person skilled in the art could easily conceive of crystals of the hydrochloride disclosed in document 1, which has the same chemical structure

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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PCT/JP 02/08596

Claims 3-4 are novel and involve an inventive step relative to documents 1-4 cited in the international search report

Claims 3-4 claim crystals of a compound which are represented by formula (I) and have a specified X-ray diffraction pattern, and documents 1-4 do not mention such crystals, nor could they be deduced easily from documents 1-4

2020
Bogota D C

Doctor(a)
HUMBERTO RUBIO CAMACHO
Apoderado(a)

REFERENCIA	Radicacion N°	04-22925
	Solicitud internacional	PCT/JP02/08596
	Fecha limite fase nacional	13/04/2004
	Tramite	011
	Evento	379
	Actuación	416
	Oficio N°	583
	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

Cumplase

Dado en Bogota D C

12 JUL 2005


ALIX CARMENZA CESPEDES DE VERGEL
Jefe División de Nuevas Creaciones

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