

134 1/10

PARRA, RODRIGUEZ & CAVELIER

Bogotá, D.C., 26 de Enero de 2005

SUPERINDUSTRIA Y COMERCIO
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Dependencia: 2920 DIVISION DE NUEVAS CREACIONES

Señora Jefe
División de Nuevas Creaciones
Superintendencia de Industria y Comercio
E. S. D.

Patente: USO DE DERIVADO DE INDOLOPIRROLOCARBAZOL
Y OTRO AGENTE ANTICANCEROSO EN
COMBINACION

Solicitante: BANYU PHARMACEUTICAL CO. LTD.

Expediente: 04.095.472

Solicitud Internacional: PCT/JP02/10186

Anexo al presente:

1. Copia del formato PCT/IB/306, correspondiente a la notificación del cambio de dirección del solicitante de la patente.
2. Copia del formato PCT/IB/306, correspondiente a la notificación del cambio de dirección del segundo inventor.
3. Copia del Reporte de Examen Preliminar Internacional.

De la Señora Jefe,



Ernesto Cavellier Franco
C.C. 19.081.620
T.P. 11519

PATENT COOPERATION TREATY

PGT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 32bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

BANYU PHARMACEUTICAL CO., LTD.
2-3, Nihombashi Honcho 2-chome
Chou-ku, Tokyo 103-8416
Japan

Date of mailing (day/month/year) 21 August 2004 (21.08.2004)		
Applicant's or agent's file reference PCT-0210	IMPORTANT NOTIFICATION	
International publication No. PCT/JP2002/010186	International filing date (day/month/year) 30 September 2002 (30.09.2002)	
1. The following indications appeared on record concerning: ☐ the applicant ☐ the inventor ☐ the agent ☒ the common representative		
Name and Address BANYU PHARMACEUTICAL CO., LTD. 2-3, Nihombashi Honcho 2-chome Chou-ku, Tokyo 103-8416 Japan	State of Nationality	State of Residence
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning: ☐ the person ☐ the name ☒ the address ☐ the nationality ☐ the residence		
Name and Address BANYU PHARMACEUTICAL CO., LTD. 2-3, Nihombashi Honcho 2-chome Chou-ku, Tokyo 103-8416 Japan	State of Nationality	State of Residence
	Telephone No. 03(5841)6570	
	Facsimile No. 03(5841)6953	
	Teleprinter No.	
3. Further observations, if necessary:		
4. A copy of this notification has been sent to: ☒ the receiving Office ☐ the designated Offices concerned ☐ the International Searching Authority ☒ the elected Offices concerned ☐ the International Preliminary Examining Authority ☐ other:		
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 23, Switzerland		Authorized officer Virendra SINGH GAUTAM
Facsimile No. (41-22) 338.79.10		Telephone No. (41-22) 338 8038

Form PCT/IB/306 (March 1994)

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PATENT COOPERATION TREATY

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PCT

From the INTERNATIONAL BUREAU

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

BANYU PHARMACEUTICAL CO., LTD.
2-3, Nihombashi Honcho 2-chome
Chuo-ku, Tokyo 103-8418
Japan

Date of mailing (day/month/year) 20 August 2004 (20.08.2004)	
Applicant's or agent's file reference PCT-0210	IMPORTANT NOTIFICATION
International application No. PCT/JP2002/010186	International filing date (day/month/year) 30 September 2002 (30.09.2002)

1. The following indications appeared on record concerning:

☒ the applicant ☒ the inventor ☐ the agent ☐ the common representative

Name and Address

MONDEN, Yoshiaki
c/o BANYU PHARMACEUTICAL CO., LTD.
Licensing
5-1, Nihombashi-Kabutocho
Chuo-ku, Tokyo 103-0028
Japan

State of Nationality

JP

State of Residence

JP

Telephone No.

Facsimile No.

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☐ the name ☒ the address ☐ the nationality ☐ the residence

Name and Address

MONDEN, Yoshiaki
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Japan

State of Nationality

JP

State of Residence

JP

Telephone No.

Facsimile No.

Teleprinter No.

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office ☐ the designated Offices concerned
☐ the International Searching Authority ☒ the elected Offices concerned
☐ the International Preliminary Examining Authority ☐ other:

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

Authorized officer

Virendra SINGH GAUTAM

Facsimile No. (41-22) 338.70.10

Telephone No. (41-22) 338 8038

Form PCT/IB/008 (March 1994)

018/018



PATENT COOPERATION TREATY

PCT/JP2002/0

From the INTERNATIONAL BUREAU

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PCT

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

To:

BANYU PHARMACEUTICAL CO., LTD.
2-3, Nishimbashi Honcho 2-chome
Chou-ku, Tokyo 103-8416
JAPAN

Date of mailing (day/month/year) 02 December 2004 (02.12.2004)	
Applicant's or agent's file reference PCT-0210	IMPORTANT NOTIFICATION
International application No. PCT/JP2002/010186	International filing date (day/month/year) 30 September 2002 (30.09.2002)
Applicant BANYU 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, KP, KR, MK, MZ, RO, RU, TM

The following elected Offices, having advised the requirements 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, MO, 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 sentences in 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 Masashi Honda
Facsimile No. +41 22 740 14 35	Facsimile No. +41 22 338 70 10

Translation

PATENT COOPERATION TREATY

PCT/JP2002/010186



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCT-0210	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA416)	
International application No. PCT/JP2002/010186	International filing date (day/month/year) 30 September 2002 (30.09.2002)	Priority date (day/month/year) 26 March 2002 (26.03.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/7056, 31/4745, 31/282, 31/24, 31/704, 31/7048, 31/519, 45/00, A61P 35/00, 43/00		
Applicant BANYU 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 26.
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 33(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 01 September 2003 (01.09.2003)	Date of completion of this report 08 March 2004 (08.03.2004)
Name and mailing address of the IPER/JP	Authorized officer
Facsimile No.	Telephone No.

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

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP2002/010186

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 35.2 and/or 35.3).

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(a)).**

* 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.

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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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. 14-23

because:

☒ the said international application, or the said claims Nos. 14-23
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. 14-23.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the multistage and/or unique said 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.

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International application No.

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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.

The inventions set forth in claims 14-23 pertain to methods for treatment of the human body by therapy.

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V. Reasoned statement under Article 33(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	5-13, 28-33	YES
	Claims	1-4, 24-27, 34, 35	NO
Inventive step (IS)	Claims		YES
	Claims	1-13, 24-35	NO
Industrial applicability (IA)	Claims	1-13, 24-35	YES
	Claims		NO

2. Citations and explanations

Document 1: Cancer Research (1996), 56 (4), pp. 789-93

Document 2: WO 01/87307 A2

Document 3: EP 545195 A1

Document 4: JP 10-245390 A

Document 5: WO 97/9339 A1

Explanations

Document 1 above, cited in the international search report, discloses compositions having an anticancer action, in which a compound of formula [I] presented in claim 1 is used together with cisplatin. The inventions set forth in claims 1-4, 24-27, 34 and 35 are same as this; therefore, these inventions are not novel and do not involve an inventive step.

Neither documents 1-3 above, cited in the international search report, nor documents 4 and 5 above, cited for the first time in the written opinion, disclose the inventions set forth in claims 5-13 and 28-33; therefore, these inventions are novel. However, as disclosed in documents 1 and 2, concomitant use of anti-cancer drugs in order to heighten the anticancer effect is known art, and the compounds described in claims 5-9 are either compounds disclosed in documents 4 and 5 or could be derived easily by suitable alteration of the

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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substituent groups in compounds disclosed in documents 1-5. Therefore, a person skilled in the art could easily use these compounds in combination with an anticancer agent such as cisplatin. The dosage form is also such as could be selected at the discretion of a person skilled in the art. Therefore, the inventions set forth in claims 5-13 and 28-33 do not involve an inventive step.

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Bogotá D C

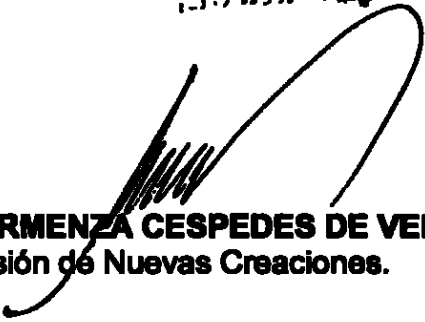
Doctor(a)
ERNESTO CAVELIER FRANCO.
Apoderado(a)

REFERENCIA:	Radicación N°	04-95472
	Solicitud Internacional	PCT/JP02/10186
	Fecha limite de inicio en fase nacional	26/10/2004
	Trámite	011
	Evento	379
	Actuación	416
	Oficio N°	1382
	Folios	001

Teniendo en cuenta que la solicitud de privilegio de patente que se tramita bajo el expediente indicado en el asunto, reúne los requisitos de forma establecidos en los artículos 26 y 27 de la Decisión 486, de la Comisión de la Comunidad Andina, el Tratado de Cooperación en Materia de Patentes (PCT), el Reglamento y la Circular Única 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, conforme lo dispone el artículo 40 de la referida Decisión 486.

Cúmplase

Dado en Bogotá D C, 23 NOV. 2005


ALIX CARMENZA CESPEDES DE VERGEL
Jefe División de Nuevas Creaciones.

202028

Al contestar favor indique el número de radicación consignado en el sticker

Sede Centro: Carrera 13 No. 27-00 Pisos 2, 5, 7 y 10
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