

TM TAMAYO & ASOCIADOS
INTERNATIONAL PATENT AND TRADEMARK

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 08-067531 - 00003-0000

Fecha: 2008-09-05 08:59:12 Dep. 2020 NUECREACIONES
Tra. 11 PATENTE IYII Eve. 378 FASE NACIONAL I
Act. 329 C/O INFORMACION Fotos: 21

titarios
no
nacionales

Señor
JEFE DIVISIÓN DE NUEVAS CREACIONES
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
E. S. D.

REF: EXPEDIENTE : 08-067531

PATENTE PCT : "SAL DE SULFATO DE HIDROGENO NOVEDOSA"

ACTUACIÓN : COMPLEMENTO DE INFORMACIÓN
: DOCUMENTOS ANEXOS AL PCT

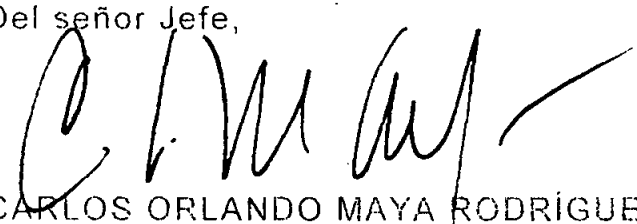
Estimados señores:

Damos alcance a la solicitud de patente PCT Fase nacional, presentada ante su Despacho y radicada el día 02 de Julio de 2008 bajo expediente citado en la referencia, con el fin de presentar copias de documentos expedidos según el Tratado de Cooperación en Materia de Patentes, así:

1. Copia del formulario de notificación sobre transmisión de copia de informe preliminar Internacional de patentabilidad, con su traducción al español, regla 44 bis. 1 (c). Formulario PCT/IB/326.

Ruego a usted tener en cuenta el anterior documento y una vez finiquitada esta diligencia, ordenar lo pertinente para que el expediente siga su curso normal.

Del señor Jefe,


CARLOS ORLANDO MAYA RODRÍGUEZ

No. 17.117.818 expedida en Bogotá,

T.P. No. 17.402 del C.S.J.

Patentes
Registros Sanitarios
Derechos de Autor
Software

From the INTERNATIONAL BUREAU

HOGAN & HARTSON, LLP

PCT

NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)
(PCT Rule 44bis.1(c))

To:

BURTON, Carol, W.
HOGAN & HARTSON, LLP
1200 17th Street, Suite 1500
Denver, CO 80202
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)
03 July 2008 (03.07.2008)

Applicant's or agent's file reference
ARR-100-17-PCT

IMPORTANT NOTICE

International application No.
PCT/US2006/061895

International filing date (day/month/year)
12 December 2006 (12.12.2006)

Priority date (day/month/year)
21 December 2005 (21.12.2005)

Applicant

ARRAY BIOPHARMA INC. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

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

Authorized officer

Philippe Becamel

Facsimile No. +41 22 338 82 70

e-mail: pt12.pct@wipo.int

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference ARR-100-17-PCT	FOR FURTHER ACTION See item 4 below	
International application No. PCT/US2006/061895	International filing date (<i>day/month/year</i>) 12 December 2006 (12.12.2006)	Priority date (<i>day/month/year</i>) 21 December 2005 (21.12.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ARRAY BIOPHARMA INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a). 2. This REPORT consists of a total of 5 sheets, including this cover sheet. In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																
3. This report contains indications relating to the following items: <table border="0"> <tr> <td>☒ Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td>☐ Box No. II</td> <td>Priority</td> </tr> <tr> <td>☐ Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td>☐ Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td>☒ Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement</td> </tr> <tr> <td>☐ Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td>☐ Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td>☒ Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> 4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).	☒ Box No. I	Basis of the report	☐ Box No. II	Priority	☐ Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	☐ Box No. IV	Lack of unity of invention	☒ Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement	☐ Box No. VI	Certain documents cited	☐ Box No. VII	Certain defects in the international application	☒ Box No. VIII	Certain observations on the international application
☒ Box No. I	Basis of the report															
☐ Box No. II	Priority															
☐ Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability															
☐ Box No. IV	Lack of unity of invention															
☒ Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement															
☐ Box No. VI	Certain documents cited															
☐ Box No. VII	Certain defects in the international application															
☒ Box No. VIII	Certain observations on the international application															

	Date of issuance of this report 24 June 2008 (24.06.2008)
The International Bureau of WIPO 3-1, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Philippe Becamel e-mail: pt12.pct@wipo.int

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

BURTON, Carol W.
Hogan & Harston, LLP
1200 17th Street, Suite 1500
Denver, Colorado 80202
United States of America

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

23 NOV 2007

Applicant's or agent's file reference
ARR-100-17-PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US2006/061895

International filing date (day/month/year)

12 December 2006

Priority date (day/month/year)

21 December 2005

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

INT. CL. C07D 235/06 (2006.01) A61K 31/4184 (2006.01) A61P 35/00 (2006.01)

US CL. 548/304.4

Applicant

ARRAY BIOPHARMA INC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
FACSIMILE NO. 571-273-3201

Date of completion of this opinion

11 July 2007

Authorized Officer:

Blaine R. Copenhaver

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US2006/061895

156

Box No. 1	Basis of this opinion
1.	With regard to the language, this opinion has been established on the basis of: ☒ The international application in the language in which it was filed ☐ A translation of the international application into, _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3(a) and 23.1(b)).
2.	With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of: a. type of material ☐ a sequence listing ☐ table(s) related to the sequence listing b. format of material ☐ on paper ☐ in electronic form c. time of filing/furnishing ☐ contained in the international application as filed. ☐ filed together with the international application in electronic form. ☐ furnished subsequently to this Authority for the purposes of search.
3.	☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4.	Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US2006/061895

152

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-16	YES
	Claims	NO
Inventive step (IS)	Claims	YES
	Claims 1-16	NO
Industrial applicability (IA)	Claims 1-16	YES
	Claims	NO

2. Citations and explanations:

The following documents, as cited in the International Search Report, are referred to:

D1: WO 2003/077914 A1 (ARRAY BIOPHARMA, INC), 25 September 2003

D2: WO 2005/023251 A1 (ARRAY BIOPHARMA, INC), 17 March 2005

Novelty (N)

D1 discloses compounds including Compound 1 as defined in the present claims, and indicates that these compounds can be produced in the form of salts, including sulfuric salts (see page 18, lines 2-4). D2 similarly discloses compounds including Compound 1 as salts of sulfuric acid (see page 13, lines 28-30). Neither document has specifically made hydrogen sulfate salts of Compound 1, therefore Claims 1-16 are novel.

Inventive Step (IS)

Claims 1-16 are not inventive in light of each of D1 and D2 (considered separately). These documents teach the preparation of salts of the compounds disclosed, and define hydrogen sulfates as one possible counterion. The problem to be solved by the present claims is to produce Compound 1 in a form that has beneficial properties (as stated in paragraph [0013] of the description). The skilled person, faced with this problem, would be aware that there are a finite number of identified, predictable solutions, and would have good reason to pursue the known options (as outlined by the citations). Consequently, Claims 1-8 are not inventive in light of these documents. The citations also disclose the pharmaceutical uses of these drugs (see, for example, page 17 of D2), therefore Claims 14-16 are not inventive. The methods defined in present Claims 9-13 are routine methods of producing salts of known compounds. The skilled person, faced with the problem of producing the hydrogen sulfate salt of Compound 1 (as taught by either of D1 or D2), would consider it a matter of routine to react sulfuric acid with the compound in an organic solvent, and recover the salt. Therefore, Claims 9-13 are not inventive.

Industrial Applicability (IA)

The claims are directed to compounds, their pharmaceutical use and their methods of preparation. These are considered to have industrial applicability.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US2006/061895

158

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 1 is not clear as the structure of "Compound 1" is not defined in this claim.

TRATADO DE COOPERACIÓN EN MATERIA DE PATENTES

De: OFICINA INTERNACIONAL

PCT

NOTIFICACIÓN REFERIDA A LA
REMISIÓN DE COPIA DE INFORME
PRELIMINAR INTERNACIONAL
SOBRE PATENTABILIDAD
(CAPÍTULO I DEL TRATADO DE
COOPERACIÓN EN MATERIA DE
PATENTES)

(Norma 44bis.1(c) del PCT)

Fecha de remisión

(día/mes/año):

3 de julio de 2008 (3-07-
2008)

Referencia de archivo del
Solicitante o agente
ARR-100-17-PCT

Para:

BURTON, Carol W.

HOGAN & HARTSON, LLP

1200 17th Street, Suite 1500

Denver, Colorado 80202

Estados Unidos de América

NOTIFICACIÓN IMPORTANTE

Solicitud de patente
internacional N°
PCT/US2006/061895

Fecha de presentación
internacional
(día/mes/año):
12 de diciembre de
2006
(12-12-2006)

Fecha de
prioridad
(día/mes/año):
21 de diciembre
de 2005 (21-12-
2005)

Solicitante

ARRAY BIOPHARMA INC. et al

La Oficina Internacional remite adjunto a la presente una copia del informe preliminar internacional sobre patentabilidad (Capítulo I del Tratado de Cooperación en Materia de Patentes)

La Oficina Internacional de la WIPO 34, chemin des Colombettes, 1211 Geneva 20, Suiza Fax 41-22-338-8270	Funcionario autorizado Philippe Becamel e-mail: ptl2.pct@wipo.int
--	---

Formulario PCT/IB/326 (enero de 2004)

161

TRATADO DE COOPERACIÓN EN MATERIA DE PATENTES

PCT

INFORME PRELIMINAR INTERNACIONAL SOBRE PATENTABILIDAD

(Capítulo I del Tratado de Cooperación en Materia de Patentes)

(Norma 44bis del PCT)

Referencia de archivo del solicitante o agente ARR-100-17-PCT	PARA OTRAS MEDIDAS. Véase el punto 4 a continuación		
Solicitud de patente internacional N° PCT/US2006/061895	Fecha de presentación internacional (día/mes/año): 12 de diciembre de 2006 (12-12-2006)	Fecha de prioridad (día/mes/año) 21 diciembre de 2005 (21-12-2005)	
Clasificación Internacional de Patente (IPC) o clasificación nacional e IPC: Véase la información relevante en Formulario PCT/IS/237			
Solicitante: ARRAY BIOPHARMA INC.			

1. Este informe preliminar internacional sobre patentabilidad (Capítulo I) es expedido por la Oficina Internacional en representación de la Autoridad de Búsqueda Internacional conforme a la Norma 44 bis.1(a).

163

4. La Oficina Internacional comunicará este informe a las Oficinas designadas de acuerdo con las Normas 44bis.3(c) y 93bis.1 pero, excepto que el solicitante haga un pedido expreso conforme a la Cláusula 23(2), no con anterioridad al vencimiento de 30 meses desde la fecha de la prioridad (Norma 44bis.2).

	Fecha de emisión de este informe 24 de junio de 2008 (24-06-2008)
La Oficina Internacional de la WIPO 34, chemin des Colombettes, 1211 Geneva 20, Suiza Fax 41-22-338-8270	Funcionario autorizado Philippe Becamel e-mail: pt12.pct@wipo.int

Formulario PCT/IB/373 (enero de 2004)

13
164

TRATADO DE COOPERACIÓN EN MATERIA DE PATENTES

De la

AUTORIDAD DE BÚSQUEDA INTERNACIONAL

Para: BURTON, Carol W. Hogan & Hartson, LLP 1200 17th Street, Suite 1500 Denver, Colorado 80202 Estados Unidos		PCT OPINIÓN ESCRITA DE LA AUTORIDAD DE BÚSQUEDA INTERNACIONAL (Norma 43bis.1 del PCT)	
		Fecha de remisión (día/mes/año) 23 de noviembre de 2007	
Referencia de archivo del Solicitante o Agente ARR-100-17-PCT		PARA OTROS TRAMITES ver párrafo 2 más abajo	
Solicitud Internacional No. PCT/US2006/061895	Fecha de Presentación internacional (día, mes, año) 12 de diciembre de 2006	Fecha de prioridad (día/mes/año) 12 de diciembre de 2005	
Clasificación Internacional de Patente (IPC) o tanto clasificación nacional como IPC INT CL.: C07D 235/06 (2006.01) A61K 31/4184 (2006.01) A61P 35/00 (2006.01) US CL: 548/304.4			
Solicitante ARRAY BIOPHARMA INC.			

1. Esta opinión escrita contiene indicaciones relacionadas con los siguientes puntos:

☒ Casillero N° I. Fundamento del informe

☐ Casillero N° II. Prioridad

☐ Casillero N° III. No establecimiento de opinión sobre la novedad, paso inventivo y aplicabilidad industrial

☐ Casillero N° IV. Falta de unidad de invención

☒ Casillero N° V. Declaración fundamentada conforme a la Cláusula 35(2) sobre la novedad, paso inventivo o aplicabilidad industrial; citas y explicaciones que fundamentan dicha declaración.

☐ Casillero N° VI. Ciertos documentos citados

☐ Casillero N° VII. Ciertos defectos en la solicitud internacional

☒ Casillero N° VIII. Ciertas Observaciones sobre la solicitud de patente internacional

2. OTRAS MEDIDAS

Si se presenta un pedido de informe preliminar internacional, esta opinión se considerará como la opinión escrita de la Autoridad de Examen de Búsqueda Internacional ("IPEA") excepto que ésta no corresponda cuando el solicitante elige una Autoridad diferente de ésta para que sea la IPEA y la IPEA elegida ha notificado a la Oficina Internacional conforme a la Norma 66.1bis(b) que la opinión escrita de esta Autoridad de Búsqueda Internacional no se considerará así.

Si esta opinión, proporcionada anteriormente, se considera la

166

opinión escrita de la IPEA, se invita al solicitante a presentar ante la IPEA una contestación escrita junto con, cuando corresponda, enmiendas, con anterioridad al vencimiento de tres meses desde la fecha de la remisión del Formulario PCT/ISA/220 o con anterioridad al vencimiento de 22 meses desde la fecha de la prioridad, la que sea posterior.

Para más opciones, véase el Formulario PCT/ISA/220.

3. Para más detalles, véase las notas al Formulario PCT/ISA/220

Nombre y domicilio para correspondencia de la ISA/US Casillero de PCT, Atención: ISA/US, Comisario de Patentes, Casilla de Correo 1450, Alexandria, Virginia 22313-1450 Fax: (571) 273-3201	Fecha de finalización de esta opinión 11 de julio de 2007	Funcionario Autorizado: [firma] Blaine R. Copenheaver Escritorio de Ayuda del PCT: 571-272-4300 OSP de PCT: 571- 272-7774
--	--	---

Formulario (PCT/ISA/237) (Carátula) (abril de 2005)

168

c. fecha de presentación/provisión

☐ contenida en la solicitud de patente internacional presentada

☐ presentada junto con la solicitud de patente internacional en forma legible por computadora

☐ presentada con posterioridad ante esta Autoridad con propósitos de búsqueda.

3. ☐ Además, en caso de que se haya presentado o provisto más de una versión o copia de un listado de secuencias y/o una tabla relacionada con él, se presentaron las declaraciones requeridas de que la información de las copias posteriores o adicionales es idéntica a aquella de la solicitud presentada o no va más allá de la solicitud presentada, según corresponda.

4. Observaciones adicionales

OPINIÓN ESCRITA DE LA Solicitud de Patente Internacional N°
AUTORIDAD DE BÚSQUEDA PCT/US2006/061895
INTERNACIONAL

**Casillero N° VIII. Ciertas observaciones sobre la solicitud de
patente internacional**

Se hacen las siguientes observaciones sobre la claridad de las
reivindicaciones, la memoria descriptiva y los dibujos o sobre
la cuestión de si las reivindicaciones están completamente
respaldadas por la memoria descriptiva:

La Reivindicación 1 no es clara ya que la estructura del
"Compuesto 1" no se define en esta reivindicación.

Formulario PCT/ISA/237 (Casillero N° VIII) (abril de 2005)