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Señores

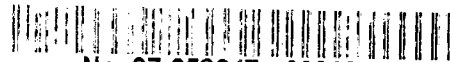
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

DIVISIÓN DE NUEVAS CREACIONES

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 07-058647- -00002-0000

Fecha 2007-08-04 16:52:17 Dep. 2020 NUECREACIONE
Tra. 11 FASENACIONALII Ever 379 FASENACIONALII
Act. 444 RESPUESTAREQUE Folios 10

Ref.: Expediente N°. 07-058.647

Solicitud de Patente de Invención titulada: "PROCESO DE FABRICACION DE SALICILAMIDAS N-SUSTITUIDAS."

Solicitante: NOVARTIS A.G.

RESPUESTA AL OFICIO N°. 8909 NOTIFICADO
POR FIJACION EN LISTA No. 269, DE FECHA 27 DE JULIO DE 2007,
(EXAMEN DE FORMA)

CARLOS R. OLARTE, mayor de edad y vecino de Bogotá, identificado tal como aparece al pie de mi firma, en mi carácter de apoderado de la sociedad en referencia, me permito dar respuesta al auto emanado de ese Despacho, dentro del término legal previsto en el artículo 39 de la Decisión 486, en los siguientes términos:

1. En respuesta a la primera observación del Examinador, me permito aclarar al despacho que la presente solicitud entra en Fase Nacional Capítulo I y no Capítulo II como inicialmente se presentó. Para tal efecto, adjunto copia del Reporte Preliminar Internacional de Patentabilidad, junto con su correspondiente traducción.

Atentamente,

CARLOS R. OLARTE
C.C. N°. 79.782.747 de Bogotá
T.P. 74.295

Anexos: Copia del Reporte de Examen Preliminar Internacional.

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REPORTE DE EXAMEN PRELIMINAR INTERNACIONAL – HOJA ANEXA
Solicitud Internacional No. PCT/EP2005/013454

Ítem III

No formulación de opinión con respecto a la novedad, nivel inventivo y aplicación industrial

La reivindicación 60 se relaciona con materia considerada por esta Autoridad cubierta por provisiones de la Regla 67.1(iv) del PCT. De manera que no se formulará ningún concepto con respecto a la aplicación industrial de la materia en estas reivindicaciones (Artículo 34(a) (i) del PCT) .

Ítem V

Declaración razonada con respecto a la novedad, nivel inventivo y aplicación industrial; citas y explicaciones sustentando dicha declaración

Se hace referencia a los siguientes documentos:

- D1: US 2003/216593 A1 (BAY WILLIAM E ET AL) 20 de noviembre de 2003
- D2: US 2002/065255 A1 (BAY WILLIAM E ET AL) 30 de mayo de 2002
- D3: WO 00/59863 A (EMISPHERE TECHNOLOGIES, INC; BAY, WILLIAM, E; AGARWAL, RAJESH, K; CHAU) 12 de octubre de 2000 citado en la solicitud

La presente solicitud no cumple con los criterios del Artículo 33(1) del PCT, puesto que la materia de la reivindicación 1 no es novedosa a la luz del Artículo 33(2) del PCT. El documento D1 divulga (párrafos 3, 4, 11-57, 65; ejemplo 2; reivindicaciones 1-48) la materia de las reivindicaciones 1, 2, 4-15, 17-35, 51, 57-62. Aunque esta cita no divulga explícitamente reaccionar un derivado de carsalam con un compuesto cloro-sustituido en presencia de una fuente de iones bromuro, si enseña el uso del compuesto bromuro IIIb. Por la misma razón D2 (párrafo 4; reivindicaciones 1-28; ejemplos 1, 6, 7, 18, 23 y 26) como también D3 (reivindicaciones 1-28; ejemplos 1, 2 y 7) desvirtúan la novedad de dichas reivindicaciones.

Las presentes reivindicaciones 1-62 no poseen nivel inventivo (Artículo 33(3) del PCT) puesto que el objeto de la presente solicitud, a saber el proporcionar un proceso para la producción de salicilamidas N-sustituidas de alta calidad, ya estaba sugerido por D1-D3.

Para la evaluación de las reivindicaciones 60 y 61 con respecto a si son industrialmente aplicables, no existen criterios unificados entre los Estados pertenecientes al PCT. La patentabilidad también puede depender de la formulación de las reivindicaciones. La Oficina de Patentes Europea, EPO, por ejemplo, no reconoce como cumplimiento del requisito de la aplicación industrial, un contenido de reivindicaciones con respecto al uso de un compuesto en un tratamiento médico, pero si permite sin embargo, reivindicaciones con respecto a un compuesto para primer uso en un tratamiento médico y el uso de tal compuesto para la producción de un medicamento para un tratamiento médico nuevo.

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VI.

La actual evaluación se basa sobre la presunción que la presente prioridad es reivindicada de manera válida. Los documentos citados, D4 (US 2005/148497) y D5 (US 2005/054557), por lo tanto no se consideran estado de la técnica como parte de los antecedentes con relación al Artículo 33(2)(3) del PCT según la Regla 64(3) del PCT.

VIII.

Una reivindicación debería definirse por sus características técnicas y no debería basarse en referencias a la memoria descriptiva (ver la reivindicación 62).

PCT

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

(PCT Rule 44bis)

Applicant's or agent's file reference PA/4-33991A	FOR FURTHER ACTION	See item 4 below
International application No. PCT/EP2005/013454	International filing date (<i>day/month/year</i>) 14 December 2005 (14.12.2005)	Priority date (<i>day/month/year</i>) 16 December 2004 (16.12.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant NOVARTIS AG		

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 7 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:

- | | |
|--|---|
| ☒ 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 |

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).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 19 June 2007 (19.06.2007)
Facsimile No. +41 22 338 82 70	Authorized officer Agnes Wittmann-Regis e-mail: pt06.pct@wipo.int

REC'D 19 APR 2006

WIPO

PCT

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

22/6
PCT06WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing

(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference

see form PCT/ISA/220

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/EP2005/013454

International filing date (day/month/year)

14.12.2005

Priority date (day/month/year)

16.12.2004

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

INV. C07C235/60 C07C231/08 C07C233/24 A61K47/18 C07D265/26

ADD. C07C235/58

Applicant

NOVARTIS AG

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 usually 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:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Date of completion of
this opinionsee form
PCT/ISA/210

Authorized Officer

Butkowskyj-Walkiw, T

Telephone No. +49 89 2399-8594



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
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Box No. I Basis of the 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 (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 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/EP2005/013454

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

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. 60

because:

☒ the said international application, or the said claims Nos. 60 relate to the following subject matter which does not require an international search (*specify*):

see separate 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 (*specify*):

☐ no international search report has been established for the whole application or for said claims Nos.

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
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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)	Yes: Claims	3,16,36-50,52-56
	No: Claims	1,2,4-15,17-35,51,57-62
Inventive step (IS)	Yes: Claims	
	No: Claims	1-62
Industrial applicability (IA)	Yes: Claims	1-59,62
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and /or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

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:

see separate sheet

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Re Item III.

Claim 60 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(I) PCT).

Re Item V.

Reference is made to the following documents:

- D1 : US 2003/216593 A1 (BAY WILLIAM E ET AL) 20 November 2003 (2003-11-20)
- D2 : US 2002/065255 A1 (BAY WILLIAM E ET AL) 30 May 2002 (2002-05-30)
- D3 : WO 00/59863 A (EMISPHERE TECHNOLOGIES, INC; BAY, WILLIAM, E; AGARWAL, RAJESH, K; CHAU) 12 October 2000 (2000-10-12) cited in the application

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (paragraphs 3,4,11-57,65; example 2; claims 1-48) the subject-matter of claims 1,2,4-15,17-35,51,57-62. Although this citation does not disclose explicitly reacting a carsalam derivative with a chloro-substituted compound in the presence of a source of bromide ions, it teaches the use of the bromine compound IIIb. For the same reason D2 (para 4; claims 1-28; examples 1,6,7,18,23 and 26) as well as D3 (claims 1-28; examples 1,2 and 7) are novelty destroying for said claims.

The present claims 1-62 do not involve an inventive step (Art. 33(3) PCT) as the object of the present application, namely to provide a process for producing high quality N-substituted salicylamides has already been suggested by D1-D3.

For the assessment of the present claims 60 and 61 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2005/013454

example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item VI.

The current assessment is based on the assumption that the present priority is validly claimed. The cited documents D4 (US 2005/148497) and D5 (US 2005/054557) are therefore not considered art of the prior art for the purposes of Art. 33(2)(3) PCT pursuant to Rule 64(3) PCT.

Re Item VIII.

A claim should be defined by its technical features and should not rely on references to the description (see claim 62).