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Señores

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

DIVISIÓN DE NUEVAS CREACIONES

E. _____ S. _____ D. _____

Ref.: Expediente No. 07-058.646

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

Solicitante: NOVARTIS A.G.

RESPUESTA AL OFICIO No. 10972 NOTIFICADO
POR FIJACION EN LISTA No. 323, DE FECHA 7 DE SEPTIEMBRE 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 única 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 la correspondiente traducción de sus anexos.

Atentamente,

CARLOS R. OLARTE
CC. No. 79.782.747 de Bogotá
T.P. 74.295

Adjunto: Reporte Preliminar Internacional de Patentabilidad

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 PA/4-33978A	FOR FURTHER ACTION	See item 4 below
International application No. PCT/EP2005/013452	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 6 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 Facsimile No. +41 22 338 82 70	Date of issuance of this report 19 June 2007 (19.06.2007)
	Authorized officer Agnes Wittmann-Regis e-mail: pt06.pct@wipo.int

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

REC'D 04 JUL 2006 PCT
WIPO PCT

WRITTEN 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/EP2005/013452	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. C07C231/02 C07C235/52 C07C231/12 A61K31/197		
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 opinion see form PCT/ISA/210	Authorized Officer Bedel, C Telephone No. +49 89 2399-2506
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/EP2005/013452

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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/EP2005/013452

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	3-7,14,15
	No: Claims	1,2,8-13,16-26
Inventive step (IS)	Yes: Claims	
	No: Claims	1-26
Industrial applicability (IA)	Yes: Claims	1-26
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

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

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

International application No.

PCT/EP2005/013452

- D1: LEONE-BAY A ET AL: "SYNTHESIS AND EVALUATION OF COMPOUNDS THAT FACILITATE THE GASTROINTESTINAL ABSORPTION OF HEPARIN" JOURNAL OF MEDICINAL CHEMISTRY, AMERICAN CHEMICAL SOCIETY, US, vol. 41, no. 7, 26 March 1998 (1998-03-26), pages 1163-1171, XP001018961 ISSN: 0022-2623
- D2: US-A-5 773 647 (LEONE-BAY ET AL) 30 June 1998 (1998-06-30)
- D3: WO 00/59863 A (EMISPHERE TECHNOLOGIES, INC; BAY, WILLIAM, E; AGARWAL, RAJESH, K; CHAU) 12 October 2000 (2000-10-12)
- D4: US 2004/242478 A1 (AZRIA MOISE ET AL) 2 December 2004 (2004-12-02)
- D5: EP-A-0 576 941 (NISSHIN FLOUR MILLING CO., LTD) 5 January 1994 (1994-01-05)
- D6: WO 03/015822 A (NOVARTIS AG; NOVARTIS PHARMA GMBH; AZRIA, MOISE; BATEMAN, SIMON, DAVID) 27 February 2003 (2003-02-27)

D1 and D2 disclose a process for making N-substituted salicylamide from a salicylic acid or derivative which is reacted with an amine under basic conditions and an aprotic solvent. Since triethylamine is the base used in D1-D2 as well as in the present application (see p.10), it is assumed that triethylamine is likely to deprotonate the phenolic hydroxide like in the present application (see cited passages in the ISR).

The subject-matter of claims 1,2,8-13, 16, 17, 19 is not novel.

The method for making the disodium salt (claims 3-7 and 18) is known from D3, its combination with D1-D2 is obvious for the skilled person, since the technical fields are the same in all documents (obtention of delivery agents).

The subject-matter of claims 14 and 15 encompasses that R1 is a carboxy activating group. These features are however known from the prior art dealing with formation of amide from acid and amine or peptide coupling. It is therefore obvious for a skilled person to use said features in order to obtain N-substituted salicylamides.

Furthermore, since these features are not illustrated by examples in the application, the technical problem cannot be considered as solved, leading to lack of inventive step for the subject-matter of claims 14 and 15.

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

International application No.

PCT/EP2005/013452

Documents D1-D4 and D6 disclose the use of N-substituted salicylamides as described in claims 20-26 as delivery agents for pharmaceutical compounds. Since most of the compounds described are made in reaction mixture containing aprotic solvent, the final products necessarily contains traces amount of aprotic solvent, thus destroying the novelty and inventive step of these claims.

Also in D5 is described the preparation 8-{N-(2,5-dihydroxybenzoyl)amino}octanoic acid in the presence of cyclohexene.

Furthermore, the present authority does not see what technical problem is solved by the presence of traces amount of aprotic solvent. For a composition of two compounds to be inventive over one of its component taken individually, there must be an unexpected effect caused by the added component. Such is apparently not the case in the present application.

Further remarks :

Claim 1 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim, with the expression "conditions in which at least...deprotonated", attempts to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

In claim 15, it is unclear which group is a peptide coupling reagent. The search examiner assumed however that it is R1 but this mistakes should be corrected.

The closest prior art D1 and D2 should be mentioned and briefly discussed.