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Act. 444 RESPUESTAREQUE Folios: 16

Señores

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

DIVISIÓN DE NUEVAS CREACIONES

E. _____ S. _____ D. _____

Ref.: Expediente No. 07-058.649

Solicitud de Patente de Invención titulada: "IMPLANTE FORMADO IN SITU PARA ANIMALES"

Solicitante: NOVARTIS A.G.

RESPUESTA AL OFICIO No. 10370 NOTIFICADO
POR FIJACION EN LISTA No. 314, DE FECHA 31 DE AGOSTO DE 2007
(EXAMEN DE FORMA)

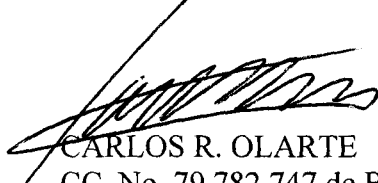
CARLOS R. OLARTE, mayor de edad y vecino de Bogotá, identificado tal como aparece al pie de mi firma, en mi carácter de apoderado de la sociedad en referencia, me permito dar respuesta al auto emanado de ese Despacho, dentro del término legal previsto en el Artículo 39 de la Decisión 486, en los siguientes 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 la correspondiente traducción de sus anexos.
2. En respuesta a la segunda observación del Examinador, me permito informar al Despacho que se cometió un error en el número de la publicación internacional en el petitorio, el cual debe leer de la siguiente manera: **WO2006/063794**.

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3. Finalmente, y aunque el Despacho no lo solicitó, me permito adjuntar a la solicitud el documento de cesión del inventor Caroline Sautter, debidamente legalizado, junto con su correspondiente traducción, según lo previsto en el Art. 26- k de la Decisión 486.

Atentamente,



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

Adjunto: Reporte Preliminar Internacional de Patentabilidad
 Documento de Cesión

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 H-33901	FOR FURTHER ACTION		See item 4 below
International application No. PCT/EP2005/013377	International filing date (day/month/year) 13 December 2005 (13.12.2005)	Priority date (day/month/year) 14 December 2004 (14.12.2004)	
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.

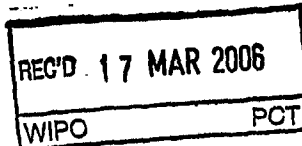
3. This report contains indications relating to the following items:

- | | |
|---|---|
| ☒ 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).

Date of issuance of this report 19 June 2007 (19.06.2007)	
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Yolaine Cussac
Facsimile No. +41 22 338 82 70	e-mail: pt11.pct@wipo.int

PATENT COOPERATION TREATY



From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

15/11
14/16

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/EP2005/013377

International filing date (day/month/year)
13.12.2005

Priority date (day/month/year)
14.12.2004

International Patent Classification (IPC) or both national classification and IPC
A61K9/08

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"). However, 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 65.1b/s(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 three 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

Authorized Officer

Sindel, U

Telephone No. +49 89 2399-7064



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2005/013377

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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, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 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:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable 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/EP2005/013377

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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	1-20
	No: Claims	
Inventive step (IS)	Yes: Claims	1-20
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-20
	No: Claims	

2. Citations and explanations

see separate sheet

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Item V

- 1 The following documents are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: EP-A-0 539 751 (ATRIX LABORATORIES, INC) 5 May 1993
D2: EP-A-0 950 403 (ATRIX LABORATORIES, INC) 20 October 1999
D3: US-A-4 938 763 (DUNN ET AL) 3 July 1990
D4: PACKHAEUSER C B ET AL: "In situ forming parenteral drug delivery systems: an overview" EUROPEAN JOURNAL OF PHARMACEUTICS AND BIOPHARMACEUTICS, ELSEVIER SCIENCE PUBLISHERS B.V., AMSTERDAM, NL, vol. 58, no. 2, September 2004, pages 445-455

D1 discloses a composition for forming a solid implant in-situ comprising an active compound, 27,5% of polylactic acid and 67,5% of the solvent N-methyl-2-pyrrolidone (see claim 1 and example 6). The composition for animal use may comprise an antiparasitic agent as active (see claims 1, 10). Polyvinylpyrrolidone or sugar are added as adjuvants, e.g. as pore forming agents (see column 11, lines 1-17).

D2 describes a composition for in-situ delivery systems comprising 37% polylactic acid in N-methyl-2-pyrrolidone emulsified with oil like sesame oil (see example 5). Glyceryl triacetate can be used as solvent (see paragraph [0041]).

2 Novelty and Inventive Step

The subject-matter of claims 1-20 seems to be new in the sense of Article 33(2) PCT and involves an inventive step in the sense of Article 33(3) PCT in view of the present prior art.

The problem to be solved is the provision of an improved in-situ forming polymeric implant showing a decreased initial peak of the blood level of the active agent directly after application of the composition.

The solution provided is the substitution of up to 10% of the solvent by an organic, water-soluble adjuvant like e.g. glycerol, and the reduction of the polymer concentration to 10-25%.

Closest prior art is D2 describing the reduction of the initial burst of an in-situ forming implant by adding a protective carrier like vegetable oils (see paragraphs, [0021]-[0023]). There is no hint given that adjuvants like glycerol or ethanol can be used to decrease the initial burst of the active agent.

Moreover, the teaching of D4 leads away from the addition of adjuvants like propylene glycol or 2-pyrrolidone for the decrease of the initial drug burst since no such effect was found for these substances (see page 448, last paragraph to page 449, first paragraph).

Hence, the subject-matter of present claims 1-20 seems to involve an inventive step.

3 Industrial applicability

The subject matter of claims 1-20 is industrially applicable in the sense of Article 33(4) PCT.

(joint)

Patent Case H-33901

ASSIGNMENT

For good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, we

(1) Caroline SAUTTER and (2) Ute ISELE,

respectively residing at

(1) Missionsstr. 16, 4055 Basel, Switzerland and

(2) Staufenerstrasse 11, 79115 Freiburg, Germany,

do hereby sell, assign and transfer to Novartis AG, a company organized under the laws of the Swiss Confederation, of Lichtstrasse 35, 4056 Basel, Switzerland, and its successors, assigns and legal representatives, all our right, title and interest for all countries of the world except Austria and to Novartis Pharma GmbH, a company organized under the laws of Austria, of Brunner Strasse 59, 1230 Vienna, Austria, and its successors, assigns and legal representatives, all our right, title and interest for Austria (Novartis AG and Novartis Pharma GmbH hereinafter referred to collectively as the "**ASSIGNEES**") in and to (1) all of our inventions and discoveries described in the patent application(s) entitled

ORGANIC COMPOUNDS

filed* in the RO/ _____ on _____, 20____, and accorded International Patent Application Number PCT _____, (2) said patent application(s), (3) (3) all national stages of said international patent application, (4) all other patent applications in all countries and regions claiming the priority of the European, patent application filed on December 14, 2004 and accorded Application Number 04029498.5, (5) all continuations and divisions of all of said patent applications (including further continuations and divisions such as, but not limited to, continuations of continuations and continuations of divisions), ((2)-(5) hereinafter referred to collectively as "patent applications"), (6) all patents that are granted on any of said patent applications, (7) all registrations and confirmations of, and importation certificates based on, one or more of said patents and (8) all reissues, renewals and extensions of said patents, reexamination certificates issued for said patents and supplementary protection certificates based on said patents (including the right to file patent applications on said inventions and discoveries in the names of **ASSIGNEES**, their designees or in any or all of our names, at their election and in accordance with applicable law in all countries and regions and all rights of priority in all countries and regions for all of said patent applications under the International Convention for the Protection of Industrial Property, and all other applicable similar international agreements), the same to be held and enjoyed by said **ASSIGNEES**, their successors, assigns and legal representatives, to the full ends of the terms for which all patents therefor may be granted, as fully and entirely as the same would have been held and enjoyed by us if this sale, assignment and transfer had not been made.

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(joint)

Patent Case H-33901

*We hereby authorize **ASSIGNEES** and their representatives to insert in this instrument the Application Number and the filing date of said patent application when notified thereof.

And we hereby covenant and agree that we will, at any time, upon the request and at the expense of **ASSIGNEES**, execute and deliver all documents that may be necessary or desirable to perfect the title to the foregoing inventions and discoveries, patent applications, patents, registrations, confirmations, importation certificates, reissues, renewals, extensions, reexamination certificates and supplementary protection certificates in **ASSIGNEES**, their successors, assigns or other legal representatives, including the execution and procurement of all further documents evidencing this sale, assignment and transfer as may be necessary or desirable for recording the same in the patent office or other intellectual property office, agency or the like of any country or region, that we will, at any time, upon the request and at the expense of **ASSIGNEES**, execute all additional patent applications, applications for registration and/or confirmation of one or more of said patents, applications for certificates of importation based on one or more of said patents, applications for reissues, renewals and extensions of one or more of said patents and supplemental protection certificates based upon one or more of said patents, and that we will make all rightful oaths and declarations and do all lawful acts requisite for procuring the same or for aiding therein, without further compensation, but at the expense of **ASSIGNEES**, the successors, assigns or other legal representatives.

Executed this 23 day of june, 2007.

Caroline Sautter L.S.

Caroline SAUTTER

ACKNOWLEDGEMENT

State of _____)

) s.s.:

County of _____)

On this _____ day of _____, 20____, personally appeared before me _____ to me known, and known by me to be the same person described in and who executed the foregoing instrument, and acknowledged that he (she) executed the same, of his (her) own free will for the purpose set forth.

(Seal)

Notary Public

FOR TRUE COPY

BASEL, Switzerland, this 13th (thirteenth) day of July 2007 (twothousandandseven).

M. Stecher, Notar

Leg. Prot. Nr. 1178/2007

APOSTILLE

(Hague Convention of October 5th, 1961)

1. Country: Switzerland (Schweiz/Suisse)

This official document

2. is signed by *Dr. iur.*

M. Stecher

3. in his/her function as *Off. Notar*

4. and certified by the seal of the *Gen. Anst.*

Certified

30. Juli 2007

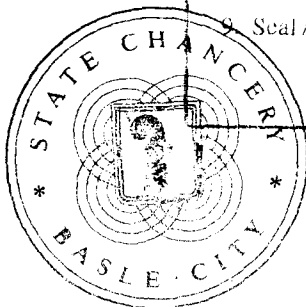
5. in Basel (Bâle) 6. on

7. by the State Chancery of the Canton of Basel-Stadt

8. no. *8245/12875*

9. Seal/stamp 10. Signature:

Heide Schaffner



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Traducción oficial de Inglés a Español
Por Gladys Adriana Pérez
Resolución No 0037, de 2002
Otorgada por El Ministerio De Justicia

Página 1

Caso de Patente: H-33901

CESIÓN

Por buena y onerosa consideración, del cual se acusa recibo suficiente, nosotros

1. Carolina SAUTER, y 2. Ute ISELE,

Domiciliados respectivamente en

(1) Missionsstr. 16, 4055 Basilea, Suiza

Y

(2) Staufferstrasse 11, 79115 Freiburg, Alemania

Por medio de la presente vendemos y transferimos a NOVARTIS AG, una compañía constituida bajo las leyes de la confederación Suiza, de Lichstrasse 35, 4056 Basilea, Suiza y sus sucesores, cesionarios y representantes legales todos nuestros derechos titulo e interés para todos los países del mundo, excepto Austria, y Novartis Pharma GmbH, una compañía constituida bajo las Leyes de Austria de Bruner Strasse 59, 1230 Vienna, Austria y sus sucesores, cesionarios y representantes legales todos nuestros derechos titulo e interés para Austria (Novartis AG y Novartis Pharma GmbH, llamados de ahora en adelante colectivamente los CESIONARIOS) en y para (1) todos nuestros inventos y descubrimientos descritos en la solicitud de patente titulada:

COMPUESTOS ORGANICOS

Presentada* en el RO el _____, 20____, y de acuerdo con la solicitud de Patente Internacional PCT_____, (2) dicha(s) solicitud(es) de patente(s), (3) (3) todas las fases nacionales de dicha solicitud de patente internacional, (4) todas las demás solicitudes de patentes en todas las regiones y países que reivindiquen prioridad de la solicitud de patente Europea presentada el 14 de diciembre de 2004 y de acuerdo con la solicitud numero 04029498.5, (5) todas las continuaciones y divisiones de todas las solicitudes de patentes mencionadas (Incluyendo además continuaciones y divisiones como tal, sin limites de continuaciones de continuaciones de divisiones),


GLADYS ADRIANA PEREZ J.
TRADUCTOR E INTERPRETE OFICIAL
RESOLUCION No. 0037 16-01-2002
MINISTERIO DE JUSTICIA

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Traducción oficial de Inglés a Español
Por Gladys Adriana Pérez
Resolución No 0037, de 2002
Otorgada por El Ministerio De Justicia

Caso de Patente: H-33901

Página 2

((2)-(5) llamados de ahora en adelante colectivamente "solicitudes de patentes"), (6) todas las patentes que sean concedidas de cualquiera de las solicitudes de patentes mencionadas, (7) todos los registros y confirmaciones y certificados de importación basados en una o mas de las patentes mencionadas y (8) todos los re-otorgamientos, renovaciones, y extensiones de dichas patentes y certificados de protección adicional basados en dichas patentes (incluyendo el derecho a presentar las solicitudes de patentes de dichos inventos y descubrimientos en nombre de los CESIONARIOS, sus designados en cualquier o en todos nuestros nombres, en todas las regiones y países para todas las solicitudes de patentes mencionadas bajo el convenio internacional para la Protección de la Propiedad Industrial, y todos los demás acuerdos internacionales similares que sean aplicables) así mismo para ser conservada y disfrutada por dichos CESIONARIOS y representantes legales, proporcionar todos los términos para que todas las patentes puedan ser concedidas, para conservar y disfrutar plenamente y totalmente por nosotros, así mismo como lo harían si esta cesión no hubiera sido vendida y transferida.


GLADYS ADRIANA PEREZ J.
TRADUCTORA INTERPRETE OFICIAL
RESOLUCION No. 0037 16-01-2002
MINISTERIO DE JUSTICIA

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Traducción oficial de Inglés a Español
Por Gladys Adriana Pérez
Resolución No 0037, de 2002
Otorgada por El Ministerio De Justicia

Caso de Patente: H-33901

Página 3

*Nosotros por medio del presente autorizamos a los CESIONARIOS y sus representantes para incorporar en este instrumento el Número de la solicitud y la fecha de presentación de dicha solicitud cuando esta sea notificada.

Y por medio de la presente nosotros convenimos y acordamos que en cualquier momento, al requerirse y a expensas de los CESIONARIOS, ejecutaremos y entregaremos cualquier y todos los documentos necesarios y deseables para perfeccionar el título de los anteriores inventos o descubrimientos, solicitudes de patente, registros confirmaciones, certificados de importación, re-otorgamientos, renovaciones, extensiones certificados de reexaminación, certificados de protección adicional a nombre de los CESIONARIOS, sus cesionarios, sucesores, u otros representantes legales, incluyendo la ejecución y consecución de cualquier y todo documento adicional que evidencie esta cesión y venta según sea necesario o deseable para el registro del mismo ante la Oficina de Patentes u otra oficina de propiedad industrial, agencia o de cualquier región o país en cuestión, y que nosotros, en cualquier momento, al requerirse y a expensas de los CESIONARIOS, ejecutaremos cualquier solicitud de patente adicional, solicitudes para registros y/o confirmaciones de una o mas de las patentes mencionadas, solicitudes de certificados de importación basada en una o mas de las patentes mencionadas, solicitudes de re-otorgamientos renovaciones y extensiones de una o mas de las patentes mencionadas y certificados de protección adicional basados en una o mas de las patentes mencionadas y realizaremos las declaraciones necesarias juramentadas y realizaremos todos los actos jurídicos necesarios para ello, sin compensación adicional, pero a expensas de los CESIONARIOS, sus sucesores, cesionarios, u otros representantes legales.

Ejecutado el 23 de junio de 2007.

Caroline SAUTTER, (firma ilegible) L.S.

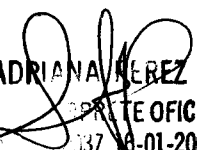
RECONOCIMIENTO

Estado de _____)

Condado de _____)

En este día ____ de _____ de 20____, se presentaron personalmente ante mi sabiendo, y sabiéndolo yo ser la misma persona descrita en este documento y quien ejecutó el anterior instrumento, y reconoce que el (ella) ejecutó el mismo, por su propia voluntad con los propósitos expuestos.

Notario Público


GLADYS ADRIANA PÉREZ J.
TRADUCTOR
RESOLUCIÓN 0037 18-01-2002
MINISTERIO DE JUSTICIA

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**Traducción oficial de Inglés a Español
Por Gladys Adriana Pérez
Resolución No 0037, de 2002
Otorgada por El Ministerio De Justicia**

Caso de Patente: H-33901

Página 4

COPIA FIEL Y VERDADERA

Basilea, Suiza, a los 13 días del mes de julio de 2007

(Firma) Dr. M. Stachelin
Notario de Basilea
Leg. Port. Nr.: 1178/2007

**APOSTILLA
(CONVENCION DE LA HAYA DEL 5 DE OCTUBRE DE 1961)**

1. PAIS: SUIZA
2. ESTE DOCUMENTO PÚBLICO HA SIDO FIRMADO POR: M. Stachelin
3. EN CALIDAD DE: NOTARIO PÚBLICO OFICIAL
4. CERTIFICADO CON EL SELLO DE: NOTARIO PÚBLICO

CERTIFICO

5. EN BASILEA
6. EL 30 DE JULIO DEL 2007
7. POR: LA CANCELLERÍA DEL ESTADO DEL CANTON DE BASILEA-STADT.
8. No. 8245/12875
9. SELLO: DE LA CANCELLERÍA DE ESTADO CIUDAD DE BASILEA
10. FIRMA: (ILEGIBLE)

Helena Schaffner


**GLADYS ADRIANA PEREZ J.
TRADUCTOR E INTERPRETE OFICIAL
RESOLUCION No. 0037 16-01-2002
MINISTERIO DE JUSTICIA**

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REPUBLICA DE COLOMBIA
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

Folio 90

2020
Bogotá D.C.,

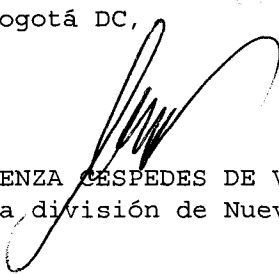
Doctor(a)
OLARTE GARCIA CARLOS REINALDO
Apoderado(a) y/o Representante de
NOVARTIS AG

REFERENCIA	Radicación No.	07 58649
	Solicitud internacional	PCT/EP2005/013377
	Fecha inicio fase nacional	14/07/2007
	Trámite	11
	Evento	379
	Actuación	416
	Oficio No.	6483
	Folios	1

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 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.

Cúmplase
Dado en Bogotá DC,

27 JUL 2008


ALIX CARMENZA CESPEDES DE VERGEL
Jefe de la división de Nuevas Creaciones

adpa10