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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Rad: 06-008541-00002-0000
Fes: 2006-12-11 10:02:34 Dep. 2020 NUECREACIONES
TG. 11 PATENTEYH
Nº: 579 FASE NACIONAL
Nº 444 DEPARTAMENTO

Señores

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES

E. _____ S. _____ D. _____

Ref.: Expediente N°. 06-098.541

Solicitud de Patente de Invención titulada: "DERIVADOS DE SULFONAMIDA-TIAZOLPIRIDINA COMO ACTIVADORES DE GLUCOCINASA UTILES EN EL TRATAMIENTO DE DIABETES DE TIPO 2".

Solicitante: NOVARTIS A.G.

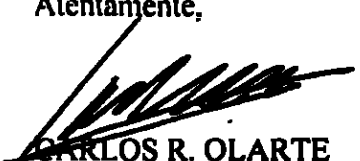
RESPUESTA AL OFICIO N°. 13585 NOTIFICADO
POR FIJACION EN LISTA No. 416, DE FECHA 24 DE NOVIEMBRE DE 2006,
(EXAMEN DE FORMA)

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, el cual, valga la pena aclarar, no contiene anexos.
2. En respuesta a la segunda observación del Examinador, me permito aportar junto al presente memorial, dos (2) documentos de cesión debidamente legalizados (correspondiente a

cinco (5) inventores), junto con su correspondiente traducción, según lo previsto en el Art. 26- k de la Decisión 486.

Atentamente,



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

Anexos: Copia del Reporte de Examen Preliminar Internacional.
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 PC/4-33717A/USN	FOR FURTHER ACTION	See item 4 below
International application No. PCT/EP2005/003458	International filing date (day/month/year) 01 April 2005 (01.04.2005)	Priority date (day/month/year) 02 April 2004 (02.04.2004)
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 8 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 04 October 2006 (04.10.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Agnes Wittmarin-Regis e-mail: pt06@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

REC'D 20 JUL 2005

WIPO

PCT

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43b/s.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/EP2005/003458

International filing date (day/month/year)
01.04.2005

Priority date (day/month/year)
02.04.2004

International Patent Classification (IPC) or both national classification and IPC
C07D513.04, A61K31A29

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 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 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 sprmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Samsam Bakhtiary, M
Telephone No. +49 89 2399-8526



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2005/003458

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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:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

28.6

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. 33-36

because:

- ☒ the said international application, or the said claims Nos. 33-36 only with regard to industrial applicability relate to the following subject matter which does not require an international preliminary examination (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.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form

- ☐ has not been furnished
- ☐ does not comply with the standard

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

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

1. Statement

Novelty (N)	Yes: Claims	1-45
	No: Claims	
Inventive step (IS)	Yes: Claims	1-45
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-32,37-45
	No: Claims	33-36

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43b/s.1 and 70.10)

and /or

2. Non-written disclosures (Rules 43b/s.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

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 33-36 relate 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 these claims (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Prior art

- D1: WO 03/080585 A (BANYU PHARMACEUTICAL CO., LTD; NISHIMURA, TERUYUKI; IINO, TOMOHARU; NA) 2 October 2003 (2003-10-02)
D2: WO 02/46173 A (F. HOFFMANN-LA ROCHE AG) 13 June 2002 (2002-06-13)
D3: WO 2004/050645 A (NOVARTIS AG; NOVARTIS PHARMA GMBH; BEBERNITZ, GREGORY, RAYMOND) 17 June 2004 (2004-06-17)

2. Novelty

The claimed subject matter of this application is concerned with sulfonylamide-thiazolopyridine derivatives.

None of the documents part of the state of the art namely D1 and D2 disclose compounds which contains all the structural features of the claimed compounds.

The subject matter of claims 1-45 is novel.

3. Inventive step

The closest prior art may be considered as being D1, which disclose thiazolopyridine derivatives having the same activity as the compounds claimed in this application.

The problem to be solved by this application may be considered as being to provide novel derivative active as glucokinase and useful in the treatment of diabetes.

In view of the drastic structural differences between the compounds of D1 and those of this application, the skilled man would not obviously derive to the claimed subject matter.

Re Item VI

Certain documents cited

Document D3 cited as PX category in the international search report is very relevant. Document D3 concerns the same applicant and also the same inventors as this application.

Should this application being further proceeded in the european phase, then this document could become relevant against the patentability of this application.

The specific examples disclosed in D3 do not affect novelty of the claimed subject matter of this application.

However the subject matter of claim 6 overlaps with the subject matter of claim 1 of this application. (see claim 6, R5= -S(O)₂-R7; R7 is -(CR₈R₉)_m-W-R10; m can be zero and W can be -N-R11).

We also draw the attention of the Applicant that in view of the content of the priority document of this application and of D3, a loss of (total or part) priority rights may occur.

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

International application No.

PCT/EP2005/003456

Re Item VIII

Certain observations on the international application

1. For the assessment of the present claims 33-36 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 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.
2. The terms "lower" alkyl, alkoxy and "substituted" used in the definitions of claim 1 should be clarified (article 6 PCT).

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TRADUCCIÓN OFICIAL DE UN DOCUMENTO QUE ESTÁ ORIGINALMENTE EN INGLÉS

El documento de Cesión de Gregory Raymond y otros a Novartis AG, lleva la siguiente certificación notarial:

Mancomunidad de Massachusetts

Condado de Middlesex

Ante mí, un Notario Público, se presentó personalmente Gregory Raymond Bebernitz, a quien conozco y sé que es la persona nombrada en el documento adjunto, estando el mismo debidamente firmado y ejecutado.

Juramentado y suscrito ante mí el día 25 de octubre de 2006.

(Firmado) Patricia A. Hofstetter

Sello: "Patricia A. Hofstetter – Notario Público – Mancomunidad de Massachusetts – Mi comisión vence el 17 de mayo de 2013".

Apostille Adjunta:


Traductor Oficial
JORGE EL SIERRA REYES
Licencia 376 - 1993 Alajuela

APOSTILLA: (Convention de La Haye du 5 octobre 1961)	
1. País:	Estados Unidos de América
<u>El presente documento público</u>	
2. Ha sido firmado por:	Patricia A. Hofstetter
3. Actuando en calidad de:	Notario Público
4. Lleva el sello/estampilla de:	El Estado de Massachusetts, cuya comisión vence el 17 de mayo de 2013.
<u>Certificado</u>	
5. En:	Boston, Massachusetts.
6. El:	30 de octubre de 2006
7. Por:	Secretario de la Mancomunidad
8. Bajo el No.:	1182727
9. Sello / estampilla:	Gran Sello de la Mancomunidad
10. Firma:	William Francis Galván, Secretario de la Mancomunidad.

Certificación:

Certifico que la presente es una traducción verdadera y completa del documento adjunto:

Título: "Novartis - Cert."

Fecha: 29 de Noviembre de 2006.

Traductor: Jorge Enrique Sierra Reyes.

Licencia No. 376 de 1993, del Ministerio de Justicia.

Dirección: Carrera 15 No. 99-13 Oficina 411. Bogotá, Colombia.

Teléfono: (57-1) 2182308, (57-1) 6232925.

E-mail: treseser1@yahoo.com. 8948


Traductor Oficial
JORGE E. SIERRA REYES
Licencia 376 - 1993 Ministerio de Justicia

The Commonwealth of Massachusetts

William Francis Galvin
Secretary of the Commonwealth

293

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APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. **Country:** United States of America

This public document

2. **has been signed by:** Patricia A. Hofstetter

3. **acting in the capacity of:** Notary Public

4. **bears the seal/stamp of:** the State of Massachusetts
whose commission expires on: May 17, 2013

Certified

5. **at:** Boston, Massachusetts

6. **the:** 30 October, 2006

7. **by:** the Secretary of the Commonwealth

8. **No.:** 1182727

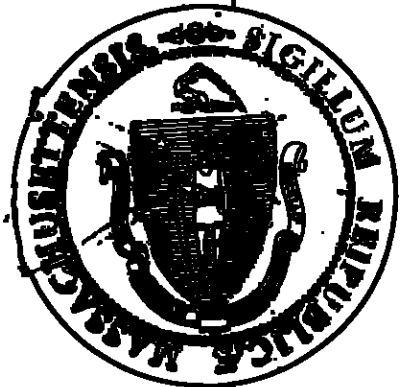
9. **Seal/stamp:**

Great Seal of the Commonwealth

10. **Signature:**

William Francis Galvin

William Francis Galvin
Secretary of the Commonwealth



DOCUMENTO DE CESIÓN
ASSIGNMENT DOCUMENT

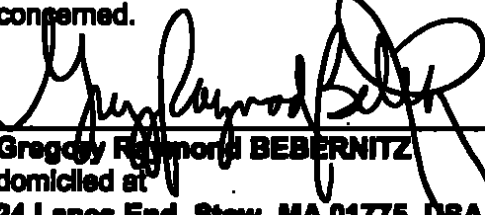
El (los) suscrito (s), en su calidad de inventor (es) de

declara (an) que cede (n) y traspasa (n) todos los derechos que les correspondan en y sobre el invento atrás mencionado a NOVARTIS AG, una compañía suiza constituida y existente bajo las leyes de Suiza, domiciliada en CH-4002 Basilea, Suiza, en cuanto se refiere a la República de Colombia.

The undersigned, as inventor (s) of

ORGANIC COMPOUNDS

hereby declare (s) that assign (s) all the rights in and to the aforementioned invention to NOVARTIS AG, a Swiss company incorporated and existing in conformity with the laws of Switzerland, domiciled at CH-4002 Basel, Switzerland, as far as the Republic of Colombia is concerned.



Gregory Raymond BEBERNITZ
domiciled at
24 Lanes End, Stow, MA 01775, USA

FIRMA DEL CEDENTE
domiciliado en

Ramesh Chandra GUPTA
domiciled at
2, Sarathi Apt., Opp Gurudwara, Kalyan
Nagar, Maninagar, Ahmedabad 380008,
India

FIRMA DEL CEDENTE
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Vikrant Vijaykumar JAGTAP
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Sector 3A, Plot No. 44/1, Gandhinagar
382007, India

FIRMA DEL CEDENTE
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Appaji Baburao MANDHARE
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Paldi Char Rasta, Ahmedabad 380007, India

FIRMA DEL CEDENTE
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Davinder TULI
domiciled at
431/2 Sector 6A, Gandhinagar 382007, India

FIRMA DEL CEDENTE
domiciliado en



295

COMMONWEALTH OF MASSACHUSETTS)

)ss:

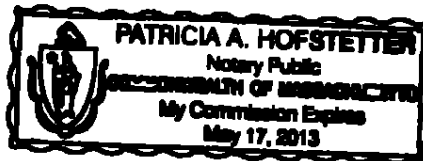
COUNTY OF *Middlesex*)

Before me, a Notary Public, personally appeared Gregory Raymond BEBERNITZ, known to me and known to be the person(s) named in the attached document, duly signed and executed the same.

Sworn and subscribed to
before me the
day of *25 October*, 2008

Patricia A. Hofstetter
Notary

Seal



LICENCIA NO. 370 DE 1993, DEL MINISTERIO DE JUSTICIA.

Dirección: Carrera 15 No. 99-13 Oficina 411. Bogotá, Colombia.

Teléfono: (57-1) 2182308, (57-1) 6232925.

E-mail: treseser1@yahoo.com. 8949

[Signature]

Traductor
JORGE E. SIERRA REYES
Licencia 376-1993 Ministerio

El documento de cesión adjunto, de Ramesh Chandra Gupta y otros a Novartis AG, lleva los siguientes sellos en inglés:

"Firmado ante mí, CU Shelat, Notario, (...) India, 17 de Noviembre de 2006"

"Gobierno de India - Notario - (ilegible)"

Certificación:

Certifico que la presente es una traducción verdadera y completa del documento adjunto:

Título: "Novartis - Cesion"

Fecha: 29 de Noviembre de 2006.

Traductor: Jorge Enrique Sierra Reyes.

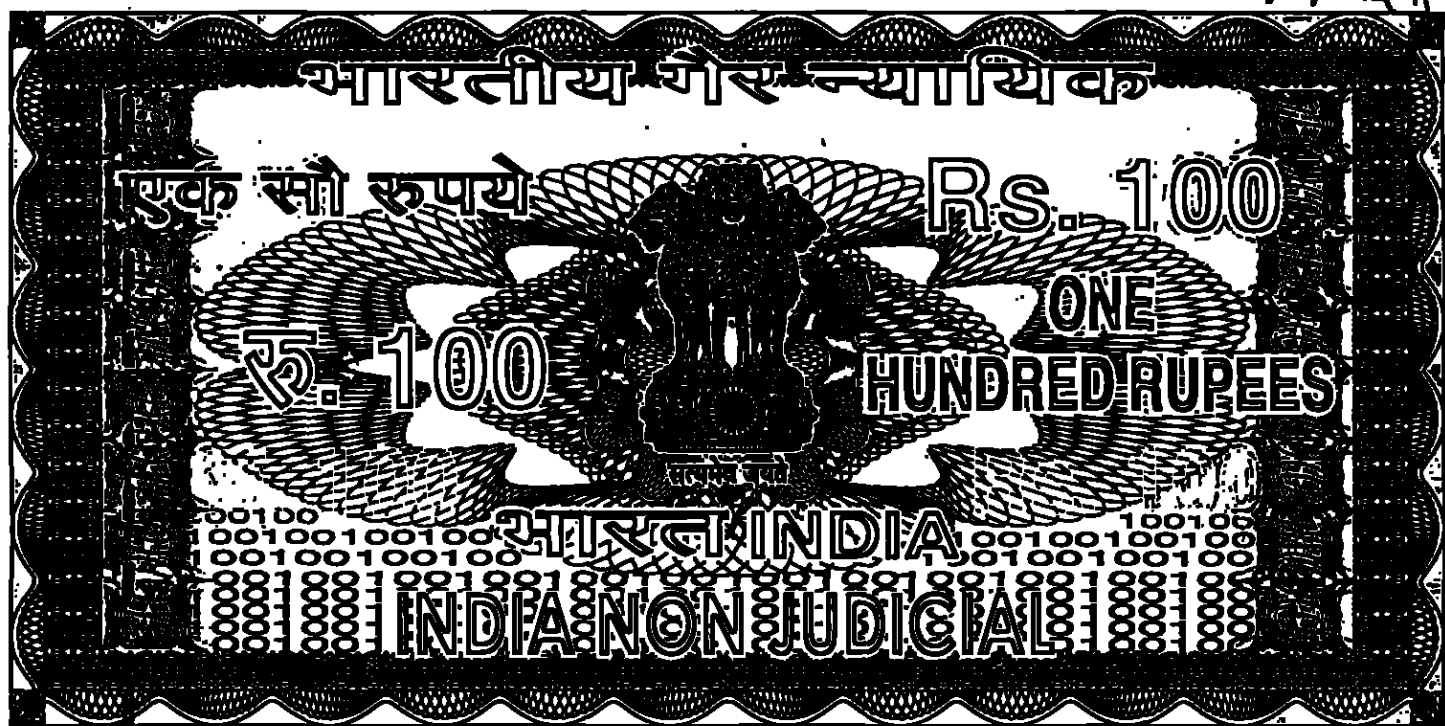
Licencia No. 376 de 1993, del Ministerio de Justicia.

Dirección: Carrera 15 No. 99-13 Oficina 411. Bogotá, Colombia.

Teléfono: (57-1) 2182308, (57-1) 6232925.

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Licencia 376 - 1993 Ministerio de Justicia



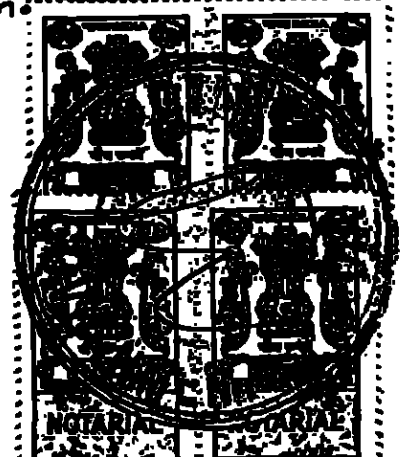
गुजरात GUJARAT

B 536379

SERIAL NO. 1111
 2005
 C. U. GUJARAT
 NOTARY
 GOVT. OF INDIA

7 NOV 2006

नं. १०१०२ १००/-
 तारीख ११/११/२००६
 वेबसाइट नं. २०१०२
 संचालक :
 गौडीनगर वि. हो. वि. कोर्टना
 स्टेशन वेस्ट ला. नं. २/२००७
 भावनादेन के. सोलंकी
 वेबसाइट सही



CO Case. 33717-CO-PCT

DOCUMENTO DE CESIÓN
 ASSIGNMENT DOCUMENT

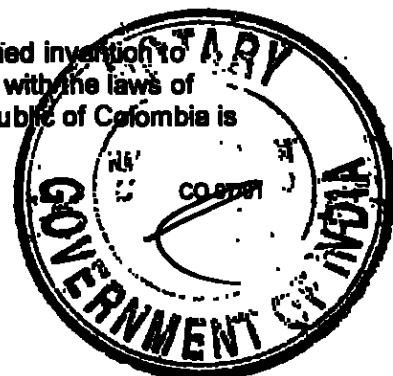
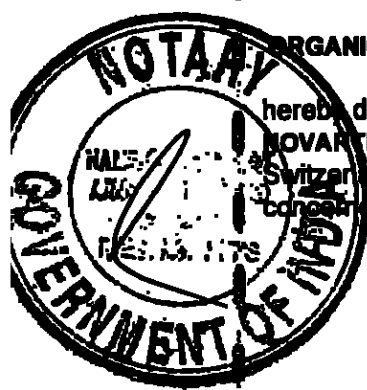
El (los) suscrito (s), en su calidad de inventor (es) de

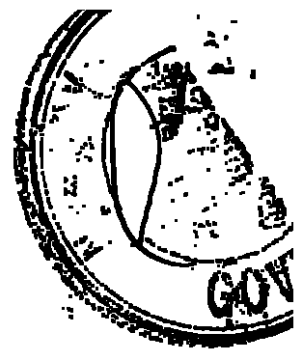
declara (an) que cede (n) y traspasa (n) todos los derechos que les correspondan en y sobre el invento atrás mencionado a NOVARTIS AG, una compañía suiza constituida y existente bajo las leyes de Suiza, domiciliada en CH-4002 Basilea, Suiza, en cuanto se refiere a la República de Colombia.

The undersigned, as inventor (s) of

ORGANIC COMPOUNDS

hereby declare (s) that assign (s) all the rights in and to the aforementioned invention to NOVARTIS AG, a Swiss company incorporated and existing in conformity with the laws of Switzerland, domiciled at CH-4002 Basel, Switzerland, as far as the Republic of Colombia is concerned.





298

60

Gregory Raymond BEBERNITZ
domiciled at
24 Lanes End, Stow, MA 01776, USA

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380007, India

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domiciliado en

Appaji Baburao MANDHARE
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26, Ambika Bhavan, Behind Uma Traders,
Paldi Char Rasta, Ahmedabad 380007, India

FIRMA DEL CEDENTE
domiciliado en

Davinder TULI
domiciled at
431/2 Sector 6A, Gandhinagar 382007, India

FIRMA DEL CEDENTE
domiciliado en

IDENTIFIED BY ME
TO HAVE
ADVOCATE

SIGNED BEFORE ME
hishelal
G. U. GABLAT
NOTARY
GOVT. OF INDIA
7 NOV 2006

