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CASTELLANOS & Co.

ABOGADOS
Calle 94 A No. 7 A - 09
Bogotá, D.C., COLOMBIA

Señor

Jefe de la División de Nuevas Creaciones

Superintendencia de Industria y Comercio

Ministerio de Comercio, Desarrollo, Industria y Turismo

E. S. D.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 08-033859-00003-0000

Fecha: 2008-08-12 14:34:54 Dep. 2020 NUECREACION
Tra. 11 PATENTEIYII Eve: 379 FASENACIONALI
Act. 329 CTOINFORMACION Folios: 5

Ref.: Expediente No. **08.033.859**

Solicitud de Patente de Invención Fase Nacional para: **FORMULACION RETARDADA
PARA PRALNACASAN**

Solicitante: **SANOFI-AVENTIS DEUTSCHLAND GMBH**

PRESENTACION DE DOCUMENTOS

LUIS PATIÑO LEIVA, mayor de edad, identificado y domiciliado como aparece al pie de mi firma, me permito presentar el siguiente documento:

- Copia del Reporte de Examen Preliminar Internacional capítulo II el cual no contiene anexos.

En consecuencia, atentamente solicito a Ud. se anexe dicho documento al expediente correspondiente a esta solicitud de Patente de Invención Fase Nacional.

Del Señor Jefe,

Luis Patiño Leyva

C.C. No. 2.930.616 de Bogotá

T.P.A. No. 2698 del C. Sup. de la Judicatura

Calle 94 A No. 7 A - 09 - Bogotá

Teléfonos: 6107420

Bogotá,

12 AGO. 2008

TRANSLATION

PATENT COOPERATION TREATY

PCT

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

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference DE2005/048	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2006/009466	International filing date (day/month/year) 29.09.2006	Priority date (day/month/year) 08.10.2005
International Patent Classification (IPC) or national classification and IPC A61K9/20		
Applicant SANOFI-AVENTIS DEUTSCHLAND GMBH		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows: ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). 4. 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
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Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

Form PCT/IPEA/409 (cover sheet) (April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2006/009466

Box No. 1

Basis of the report

1.

With regard to the language, this report is based on:

☒

the international application in the language in which it was filed

☐

the translation of the international application into _____, which is the language of a translation furnished for the purposes of:

☐

international search (Rule 12.3(a) and 23.1(b))

☐

publication of the international application (Rule 12.4(a))

☐

international preliminary examination (Rule 55.2(a) and/or 55.3(a))

2.

With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

☐

the international application as originally filed/furnished

☒

the description:

pages

1-7

as originally filed/furnished

pages*

received by this Authority on

pages*

received by this Authority on

☒

the claims:

nos.

1-8

as originally filed/furnished

nos.*

as amended (together with any statement) under Article 19

nos.*

received by this Authority on

nos.*

received by this Authority on

☒

the drawings:

sheets

1/2, 2/2

as originally filed/furnished

sheets*

received by this Authority on

sheets*

received by this Authority on

☐

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3.

☐

The amendments have resulted in the cancellation of:

☐

the description, pages

☐

the claims, nos.

☐

the drawings, sheets/figs

☐

the sequence listing (specify):

☐

any table(s) related to sequence listing (specify):

4.

☐

This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐

the description, pages

☐

the claims, nos.

☐

the drawings, sheets/figs

☐

the sequence listing (specify):

☐

any table(s) related to sequence listing (specify):

* If item 4 applies, some or all of those sheets may be marked "superseded."

Form PCT/ISPEA/409 (Box No. 1) (April 2005)

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY		International application No. PCT/EP2006/009466
Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	
1. Statement		
Novelty (N)	Claims <u>1-8</u>	YES
	Claims _____	NO
Inventive step (IS)	Claims <u>1-8</u>	YES
	Claims _____	NO
Industrial applicability (IA)	Claims <u>1-8</u>	YES
	Claims _____	NO
2. Citations and explanations (Rule 70.7)		
Reference is made to the following documents:		
D1: GB-A-2 230 185 (WARNER LAMBERT CO [US]), 17 October 1990 (1990-10-17)		
D2: US 2005/013863 A1 (LIM JONG [US] ET AL), 20 January 2005 (2005-01-20)		
D3: WO 95/01781 A (APPLIED PHARMA RES [CH]; CONTE UBALDO [IT]; MAGGI LAURETTA [IT]; GIUNC), 19 January 1995 (1995-01-19)		
D4: US 2005/053653 A1 (KIDANE ARGAW [US] ET AL), 10 March 2005 (2005-03-10)		
 <u>Claims 1 to 8</u>		
 <u>Novelty:</u>		
A retard tablet consisting of at least two layers, both containing the pharmaceutical pralnacasan (as defined in claim 1), with one of the layers releasing the active principle quickly and the other layer releasing it after a delay, is not known from the prior art.		
 <u>Inventive step:</u>		
The problem addressed by the present invention is that of		

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2006/009466

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

providing a retard tablet containing pralnacasan that only has to be administered twice a day and yet ensures a steady release of pralnacasan, with a total dose which is less than that provided by standard tablets.

The problem is solved by a two-layer tablet as claimed in claim 1 (see Figures 1 and 2).

This is not apparent from the cited prior art (documents D1 to D4); that is, it is not apparent from the prior art that a combination tablet would be suitable for the particular type of active principle claimed as a solution to the aforementioned problem (i.e. that, among other things, the retard portion would not be negatively influenced by the initial portion).

Industrial applicability:

There are no doubts regarding industrial applicability.

REPUBLICA DE COLOMBIA
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

Folio 59

020
Bogotá D.C.,

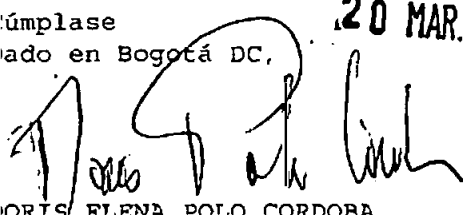
Autor(a)
MATIÑO LEYVA LUIS
poderado(a) y/o Representante de
ANOFI-AVENTIS DEUTSCHLAND GMBH

REFERENCIA	Radicación No.	8 33859
	Solicitud internacional	PCT/EP2006/009466
	Fecha inicio fase nacional	08/05/2008
	Trámite	11
	Evento	379
	Actuación	416
	Oficio No.	7866
	Folios	1

Entendiéndose 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
Bogotá DC,

20 MAR. 2009


MORIS ELENA POLO CORDOBA
Jefe de la división de Nuevas Creaciones (E)

dpall