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EL SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
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Act 444 RESPUESTA REQUE Folio 7

Señores

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

DIVISIÓN DE NUEVAS CREACIONES

E. _____ S. _____ D. _____

Expediente No. 06-074.304

Solicitud de Patente de Invención titulada: "COMPOSICIONES FARMACÉUTICAS QUE CONTIENEN UNA COMBINACIÓN DE (4R)-N-ALIL-3-[(2S-3S)-2-HIDROXI-3-[(3-HIDROXI-2-METILBENZOIL)AMINO]-4-FENILBUTANOIL]-5,5-DIMETIL-1,3-TIAZOLIDINA-4-CARBOXAMIDA, PARA EL TRATAMIENTO DE INFECCIONES POR VIH EN MAMÍFEROS Y UN AGENTE TERAPEUTICO ADICIONAL".

Solicitante: PFIZER INC.

RESPUESTA AL OFICIO No. 10481 NOTIFICADO
POR FIJACION EN LISTA No. 321, DE FECHA 15 DE SEPTIEMBRE 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 solicitante, me permito manifestar lo siguiente ante el auto emanado de ese Despacho, dentro del plazo de prórroga solicitado en mi memorial de fecha 09 de noviembre de 2006, en los siguientes términos:

1. En respuesta a la primera observación del Examinador me permito aportar junto al presente memorial, copia del Examen Preliminar Internacional de la presente solicitud. Dicho Examen no tiene anexos para traducir.
2. En respuesta a la segunda observación del Examinador me permito informar a ese Despacho que por demoras en la legalización consular, el documento de Cesión no ha podido ser

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remitido a nuestra oficina para ser aportado a la fecha de la presente contestación, dicho documento será allegado inmediatamente sea recibido.

3. En respuesta a la tercera observación del Examinador, me permito presentar un nuevo título: "COMPOSICIONES FARMACÉUTICAS QUE CONTIENEN UNA COMBINACIÓN DE (4R)-N-ALIL-3-[(2S-3S)-2-HIDROXI-3-[(3-HIDROXI-2-METILBENZOIL)AMINO]-4-FENILBUTANOIL]-5,5-DIMETIL-1,3-TIAZOLIDINA-4-CARBOXAMIDA, PARA EL TRATAMIENTO DE INFECCIONES POR VIH EN MAMÍFEROS Y UN AGENTE TERAPEUTICO ADICIONAL", el cual permite identificar claramente el objeto de la solicitud de patente según lo previsto en la Regla 4.3 PCT, Artículos 26 y 27 de la Decisión 486 y Circular Única de la SIC numeral 5.2.9.

Atentamente,



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

Adjunto: Copia del Examen Preliminar Internacional

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference PC32141A	FOR FURTHER ACTION See Form PCT/PEAA/16	
International application No. PCT/IB2005/000101	International filing date (day/month/year) 17.01.2005	Priority date (day/month/year) 30.01.2004
International Patent Classification (IPC) or national classification and IPC INV. A61K31/40 A61K31/41 A61P31/18		
Applicant PFIZER INC. et al.		
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 38. 2. This REPORT consists of a total of 5 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 of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 807 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		
Date of submission of the demand 17.02.2005	Date of completion of this report 01.09.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80299 Munich Tel. +49 89 2399 - 0 Tx: 523858 epmu d Fax +49 89 2399 - 4485	Authorized officer Cattell, James Telephone No. +49 89 2399-	



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No. **PCT/B2005/000101**

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Box No. I 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, unless otherwise indicated under this item.
 - ☐ This report is based on translations 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))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
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)*:

Description, Pages

1-43 as originally filed

Claims, Numbers

1-10 as originally filed

☐ 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 these sheets may be marked "superseded."

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos. .

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)	Yes: Claims	1,3,5,7,8,10
	No: Claims	2,4,6,9
Inventive step (IS)	Yes: Claims	
	No: Claims	1-10
Industrial applicability (IA)	Yes: Claims	1-10
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

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Re Item IV.

The separate inventions/groups of inventions are:

1, 4(part), 5, 8

The use of compound of claim 1

2, 4(part), 6, 9

the use of the compound of claim 2

3, 4(part), 7, 10

The use of the compound of claim 3

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

The cited document discloses the claimed use of the compound of claim 2 together with other anti HIV agents. The compounds of claims 1 and 3 are selections from this prior art. Once the skilled man knows that selections can be made and combined with other agents, each of the features of claims 1 to 3 would appear to relate to separate "inventions". There is no novel link between these claims.

Re Item V.

1). Reference is made to the following document:

D1 : WO 02/100844 A (AGOURON PHARMACEUTICALS, INC) 19 December 2002
(2002-12-19)

2). D1 discloses the use of the compound of claim 2 with other anti HIV agents falling within the scope of claims 2, 4(part), 6 and 9 under Article 33(2) PCT.

3). The remaining claims appear to be selections from the formula given in D1. There appear to be no data in the description showing how such selections have resulted in a technical effect which could not have been predicted from D1. No inventive step

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No. ~~2~~ 1

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can therefore be recognised under Article 33(3) PCT.