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Señor

SUPERINTENDENTE DE INDUSTRIA Y COMERCIO

E. S. D.

REF: Expediente No. PCT/14-085830

TÍTULO SOLICITADO: "COMPOSICIONES FARMACÉUTICAS QUE
COMPRENDEN DOLUTEGRAVIR Y RILVIPIRINA
CON ACTIVIDAD ANTIVIRAL PARA VIH"

PUBLICACIÓN: Gaceta 660 del 18/01/2013, N° de publicación 2152.

SOLICITANTE: VIIV HEALTHCARE COMPANY /
GLAXOSMITHKLINE LLC.

TRÁMITE: Recurso de Reposición y en subsidio el de apelación en
contra de la Resolución 8099 de febrero 27 de 2015 por la
cual se concede una patente de invención tramitada bajo
el número de expediente PCT/14-085830.

TITO NOÉ PARRA MURILLO, mayor de edad, identificado como aparece al pie de mi
firma, reconocido apoderado de la sociedad LAFRANCOL S.A.S. en el asunto de la
referencia, de manera respetuosa, y dentro de los términos de ley, presento Recurso de
Reposición y en subsidio de apelación contra la Resolución 8099 de febrero 27 de 2015
por la cual se concedió a la solicitud PCT/14-085830 el privilegio de patente de invención.

I. PETICIÓN

Sírvase, Señor Superintendente, reponer íntegramente la Resolución 8099 de febrero 27 de
2015, por la cual se declaró infundada la oposición presentada y se otorgó el privilegio de
patente solicitado en el expediente de la referencia, y en su remplazo emitir otra que, con

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fundamento en los argumentos expuestos en el escrito de observación y en el presente escrito, declare fundada dicha oposición y niegue el privilegio de patente mencionado, procediendo luego al definitivo archivo del expediente en cuestión.

II. ARGUMENTOS SOBRE LOS FUNDAMENTOS DE LA CONCESIÓN Y MOTIVOS DE INCONFORMIDAD

La Resolución 8099 de febrero 27 de 2015, que concede el privilegio de patente de invención solicitado para el capítulo reivindicatorio del expediente 14-085830 del titulado referenciado, viola flagrantemente la Decisión 486 si se tiene en cuenta que existían motivos suficientes para afectar los requisitos de novedad y nivel inventivo de la solicitud en mención. Es evidente que el solicitante y la Resolución cometen un error cuando afirman que la oposición presentada por mi representada no muestra ningún tipo de argumento soportado técnicamente, ni desvirtúa la patentabilidad del objeto de estudio, declarándola infundada por cuanto, al momento de presentación del escrito de oposición se dejó en claro que para el presente caso nos encontramos frente a una combinación de compuestos, lo cual indudablemente afecta el requisito de nivel inventivo, éste mismo indispensable para acceder a cualquier beneficio patentario.

Así las cosas, me permito reiterar que la concesión de patente objeto del presente escrito se ve afectada por los documentos del estado del arte que fueron presentados inicialmente en el escrito de observación, por lo cual, basado en lo siguiente, solicito respetuosamente a ese Despacho dar análisis completo y a cabalidad sobre los siguientes documentos, los cuales sin lugar a dudas objetan la concesión en mención, toda vez que develan de manera expresa y sucinta lo que se pretende proteger en la presente solicitud.

Dicho así, me permito manifestar que agentes tales como Abacavir, Lopinavir, Efavirenz, Lamivudina han sido ampliamente divulgados en el sector químico-farmacéutico, y concretamente se han develado materias muy similares, las cuales ruego a ese Despacho analizar, en los siguientes documentos:

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- 3
- EP 349242
 - US 5034394
 - WO 9721685
 - US 5914332
 - EP 582455
 - US 5519021
 - WO 9117159

Así como resulta imprescindible manifestar que los anteriores documentos deben ser analizados a profundidad y cabalidad para así determinar finalmente si afectan o no la novedad y nivel inventivo de la presente solicitud, toda vez que en nuestra opinión se revelan materias muy similares, también es necesario reiterar que la solicitud de la referencia pretende proteger mediante el derecho patentario objetos que no son considerados invenciones. Es claro que una invención es toda creación humana que permita transformar la materia o energía que existe en la naturaleza, para su aprovechamiento por los seres humanos y satisfacer sus necesidades concretas. De igual modo, como ya se mencionó, según los parámetros de la Decisión 486 y normas concordantes, serán patentables las invenciones que cumplan con los requisitos de novedad, nivel inventivo y aplicación industrial. No obstante, puede observarse que la solicitud en comento pretende reivindicar combinaciones, las cuales no se consideran invenciones. En este sentido, la mezcla (Combinaciones) de productos (Moléculas) conocidos y su variación, bien sea en uso, forma, dimensión o de materia, NO se consideran invenciones por cuanto no son susceptibles de aplicación industrial, nivel inventivo y novedad, luego NO pueden acceder a beneficios patentarios. Por lo tanto, se suma una circunstancia más que imposibilita definitivamente la concesión de la solicitud en mención.

También es necesario reiterar que la solicitud de la referencia pretende proteger mediante el derecho patentario objetos que no son considerados invenciones. Es claro que una invención es toda creación humana que permita transformar la materia o energía que existe en la naturaleza, para su aprovechamiento por los seres humanos y satisfacer sus necesidades concretas. De igual modo, como ya se mencionó, según los parámetros de la

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Decisión 486 y normas concordantes, serán patentables las invenciones que cumplan con los requisitos de novedad, nivel inventivo y aplicación industrial. No obstante, puede observarse que la solicitud en comento pretende reivindicar combinaciones, las cuales no se consideran invenciones. En este sentido, la mezcla (Combinaciones) de productos (Moléculas) conocidos y su variación, bien sea en uso, forma, dimensión o de materia, NO se consideran invenciones por cuanto no son susceptibles de aplicación industrial, nivel inventivo y novedad, luego NO pueden acceder a beneficios patentarios. Por lo tanto, se suma una circunstancia más que imposibilita definitivamente la concesión de la solicitud en mención.

Y sobre el particular, es imprescindible señalar que un efecto sinérgico nuevo no se considera inventivo como tal, dado que puede ser obvio para una persona versada en la materia, cosa que sucede en el presente caso. En palabras del Doctor Carlos Correa, *"El efecto sinérgico entre dos o más drogas se puede considerar un "descubrimiento" y no una "invención", dado que la sinergia ocurre en el cuerpo y se descubre a través de ensayos clínicos. Asimismo, cabe destacar que, en algunos casos, las reivindicaciones de combinaciones pueden equivaler, en términos prácticos, a reivindicaciones sobre tratamientos médicos (cuya patentabilidad está excluida en la mayoría de los países), cuando sólo brindan un método para administrar una combinación de drogas conocidas. Asimismo, la combinación de drogas para evitar la resistencia particular a una de ellas es una práctica normal en el desarrollo farmacéutico y, por lo general, es evidente para el hombre del oficio de nivel medio"* (Pautas para el examen de patentes farmacéuticas, CEIDIE, Pág. 8). En estos términos, está claro que nos encontramos frente a un tema totalmente sensible que merece toda la evaluación por cuanto las combinaciones deben considerarse excluidas de beneficios de patente.

Y en caso que ese Despacho decidiera insistir en el cabal cumplimiento de los requisitos exigidos para acceder al beneficio de patente, me permito allegar copia del International Search Report y el respectivo Written Opinion Of The International Searching Authority, documentos en los cuales se resalta que la presente invención no cumple con los requisitos de novedad y nivel inventivo por cuanto existen documentos citados del estado del arte que

afectan de manera definitiva tales exigencias. Lo anterior deja entrever, sin lugar a equívocos, que la presente solicitud no debió ser concedida, por lo cual es procedente la revocatoria de la Resolución objeto de este escrito.

En este sentido, reitero con el debido respeto la necesidad de analizar a profundidad los requisitos de novedad y nivel inventivo para así determinar si la presente solicitud es merecedora de concesión de privilegio de patente.

ANEXOS

International Search Report y el Written Opinion Of The International Searching Authority de la equivalente internacional WO 2011/094150

En subsidio apelo.

Señor Superintendente,



TITO NOÉ PARRA MURILLO

C.C. 79.579.680 de Bogotá

✓ T.P. 71168 del C. S de la J.



PCT/US2011/022219 28.03.2011

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference PR64101WO	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 11/22219	International filing date (day/month/year) 24 January 2011 (24.01.2011)	(Earliest) Priority Date (day/month/year) 27 January 2010 (27.01.2010)
Applicant GLAXOSMITHKLINE LLC		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out 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)).

b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☒ Certain claims were found unsearchable (see Box No. II).

3. ☐ Unity of invention is lacking (see Box No. III).

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. _____
☐ as suggested by the applicant.
☐ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.
b. ☒ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 11/22219

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 11, 13-16
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

PCT/US2011/022219 28.03.2011

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 11/22219

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A01N 43/00 (2011.01) USPC - 514/211.1 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) USPC: 514/211.1 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched USPC: 514/263.24, 254.11 (see search terms below) Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Electronic Database Searched: PUBWEST (PGPUB, EPAB, JPAB, USPT), Google. Search Terms Used oxazine-9-carboxamide, oxazine near5 pyrazino, HIV, oxazine pyrazino, lamivudine, abacavir, tenofovir, efavirenz, combination therapy		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2006/0084627 A1 (Mardh) 20 April 2006 (20.04.2006) entire document especially abstract; para [0001], [0005]-[0006]	1-10, 12 and 17
Y	US 2009/0318421 A1 (Johns et al.) 24 December 2009 (24.12.2009) especially abstract; para [0008], [0604], [0762]	1-10, 12 and 17
Y	US 6,544,961 B1 (St. Clair et al.) 08 April 2003 (08.04.2003) especially col 1, ln 8-26	4, 8, 12 and 17
A	US 2008/0076738 A1 (Cai et al.) 27 March 2008 (27.03.2008) entire document	1-10, 12 and 17
☐ Further documents are listed in the continuation of Box C. ☐		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 06 March 2011 (06.03.2011)		Date of mailing of the international search report 28 MAR 2011
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201		Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

PCT/US2011/022219 28.03.2011

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: KAREN L. PRUS
C/O GLAXOSMITHKLINE
GLOBAL PATENTS DEPT.
FIVE MOORE DRIVE, P. O. BOX 13398
RESEARCH TRIANGLE PARK, NC 27709

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) 28 MAR 2011

Applicant's or agent's file reference
PR64101WO

FOR FURTHER ACTION

See paragraph 2 below

International application No. PCT/US 11/22219	International filing date (day/month/year) 24 January 2011 (24.01.2011)	Priority date (day/month/year) 27 January 2010 (27.01.2010)
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International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A01N 43/00 (2011.01)
USPC - 514/211.1

Applicant GLAXOSMITHKLINE LLC

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 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/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Date of completion of this opinion
06 March 2011 (06.03.2011)

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (July 2009)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 11/22219

Box No. 1	Basis of this 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. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a)). 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished: a. (means) ☐ on paper ☐ in electronic form b. (time) ☐ in the international application as filed ☐ together with the international application in electronic form ☐ subsequently to this Authority for the purposes of search 4. ☐ In addition, in the case that more than one version or copy of a sequence listing 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. 5. Additional comments:	

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 11/22219

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. 11, 13-16

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international search (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 11, 13-16 are so unclear that no meaningful opinion could be formed (*specify*):

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 11, 13-16

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).

☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US 11/22219

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)	Claims	1-10, 12 and 17		YES
	Claims	NONE		NO
Inventive step (IS)	Claims	NONE		YES
	Claims	1-10, 12 and 17		NO
Industrial applicability (IA)	Claims	1-10, 12 and 17		YES
	Claims	NONE		NO
2. Citations and explanations:				
Claims 1-3, 5-7 and 9-10 lack an inventive step under PCT Article 33(3) as being obvious over US 2006/0084627 A1 to Mardh in view of US 2009/0318421 A1 to Johns et al. (hereafter 'Johns'). Regarding claims 1 and 5, Mardh teaches a combination comprising therapeutic agent selected from abacavir and alovudine for the treatment of HIV (abstract; para [0005]-[0006]), but does not teach the combination involving compound of formula I. However, Johns teaches HIV treatment comprising compound of formula I (abstract; para [0008]; [0762]). It would have been obvious to one of skill in the art to combine these references and modify the combination therapy as taught by Mardh by introducing the compound of formula I taught by Johns for more efficient treatment because both Mardh and Johns teach the method of treating HIV. Regarding claims 2 and 6, Mardh teaches a combination wherein the therapeutic agent is abacavir (para [0001]). Regarding claims 3 and 7, Johns teaches a combination wherein the pharmaceutically acceptable salt of a compound of formula (I) is the sodium salt (para [0604]). Regarding claim 9, see the discussion set forth above as to claims 1-2. In addition, Mardh teaches a pharmaceutical composition, together with a pharmaceutically acceptable carrier therefor ((para [0009]; [0018])). Regarding claim 10, Mardh teaches pharmaceutical composition wherein the therapeutic agent is abacavir (para [0001]). Claims 4, 8, 12 and 17 lack an inventive step under PCT Article 33(3) as being obvious over Mardh in view of Johns and further in view of US 6,544,961 B1 to St. Clair et al. (hereafter 'St. Clair'). Regarding claims 4, 8 and 12, Mardh in view of Johns teaches a combination according to claims 2, 6 and 10, but does not teach the combination additionally containing lamivudine. However, St. Clair teaches therapeutic combination for the treatment of HIV comprising lamivudine (col 1, in 8-26). It would have been obvious to one of skill in the art to combine these references and include additional therapeutic agent such as lamivudine taught by St. Clair into the combination treatment as taught by Mardh and Johns because Mardh, Johns and St. Clair all teach the methods of treating HIV. Regarding claim 17, see the discussion set forth above as to claim 1. In addition, St. Clair teaches patient pack comprising a compound one or more therapeutic agents (col 6, in 10-20). Claims 1-10, 12 and 17 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.				