



No. 14-062064- -00018-0000

Fecha: 2016-01-12 15:28:34 Dep. 2020 DIR NUEVASCR
Tra. 11 PATENTEIYII Eve. 379 FASENACIONALII
Act. 412 REPOSPRESRECU Folios: 9

Señor

SUPERINTENDENTE DE INDUSTRIA Y CO

E.

S.

D.

TV

REF: Expediente No. PCT/14-062064

TÍTULO SOLICITADO: "1-(3-TERC-BUTIL-1-P-TOLIL-1H-PIRAZOL-5-IL)-3-(4-(2-(FENILAMINO)PIRIMIDIN-4-IL-OXI) NAFTALEN-1-IL)-UREA INHIBIDOR P38 MAPK α , C-SRC Y SYK QUINASA"

PUBLICACIÓN: Gaceta 691 del 31/03/2014, N° de publicación 202.

SOLICITANTE: RESPIVERT LIMITED.

APODERADO: ALICIA LLOREDA RICAURTE.

TRÁMITE: Recurso de Reposición y en subsidio el de apelación en contra de la Resolución 89865 de noviembre 20 de 2015 por la cual se concede una patente de invención tramitada bajo el número de expediente PCT/14-062064.

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 89865 de noviembre 20 de 2015 por la cual se concedió a la solicitud PCT/14-062064 el privilegio de patente de invención.

I. PETICIÓN

Sírvase, Señor Superintendente, reponer íntegramente la Resolución 89865 de noviembre 20 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 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 89865 de noviembre 20 de 2015, que concede el privilegio de patente de invención solicitado para el capítulo reivindicatorio del expediente 14-062064 del título de referencia, 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.

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.

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 2013/050757

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.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference RES - P1327PCT	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/GB2012/052445	International filing date (day/month/year) 03/10/2012	(Earliest) Priority Date (day/month/year) 03/10/2011
Applicant RESPIVERT LIMITED		

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 5 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:

1 - PYRAZOLYL - 3 - (4 - ((2 - ANILINOPYRIMIDIN - 4 - YL) OXY) NAPHTHALEN - 1 - YL) UREAS AS P38
MAP KINASE INHIBITORS

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

A. CLASSIFICATION OF SUBJECT MATTER		
INV. C07D403/12	A61K31/4155	A61K31/506 C07D491/10
ADD.		
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)		
C07D A61K		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
EPO-Internal, CHEM ABS Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/072569 A1 (BOEHRINGER INGELHEIM PHARMA [US]) 4 September 2003 (2003-09-04) claims 1-13	1-16
Y	WO 2010/067130 A1 (RESPIVERT LTD; ITO KAZUHIRO [GB]; STRONG PETER [GB]; RAPEPORT WILLIAM) 17 June 2010 (2010-06-17) claims 1-19	1-16
Y	WO 2010/067131 A1 (RESPIVERT LTD.) 17 June 2010 (2010-06-17) claims 1-22	1-16
Y	WO 2010/112936 A1 (RESPIVERT LTD [GB]; ITO KAZUHIRO [GB]; STRONG PETER [GB]; RAPEPORT WIL) 7 October 2010 (2010-10-07) claims 1-9	1-16
	-/--	
☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* 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		Date of mailing of the international search report
5 November 2012		12/11/2012
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Herz, Claus

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	WO 2011/158039 A1 (RESPIVERT LTD [GB]; CASS LINDSEY [GB]; ITO KAZUHIRO [GB]; RAPEPORT WIL) 22 December 2011 (2011-12-22) claims 1-21 -----	1-16
X,P	WO 2011/158042 A2 (RESPIVERT LTD [GB]; CHARRON CATHERINE ELISABETH [GB]; ITO KAZUHIRO [GB]) 22 December 2011 (2011-12-22) claims 1-38 -----	1-16
Y	WO 2011/070368 A1 (RESPIVERT LTD [GB]; KING-UNDERWOOD JOHN [GB]; ITO KAZUHIRO [GB]; STRON) 16 June 2011 (2011-06-16) claims 1-25 -----	1-16

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 03072569	A1	04-09-2003	AT 386030 T	15-03-2008
			AU 2003213806 A1	09-09-2003
			CA 2473634 A1	04-09-2003
			DE 60319066 T2	26-02-2009
			EP 1480973 A1	01-12-2004
			ES 2299689 T3	01-06-2008
			JP 4629978 B2	09-02-2011
			JP 2005518447 A	23-06-2005
			US 2003232865 A1	18-12-2003
			WO 03072569 A1	04-09-2003

WO 2010067130	A1	17-06-2010	AU 2009326148 A1	17-06-2010
			AU 2009326149 A1	17-06-2010
			CA 2746354 A1	17-06-2010
			CA 2746357 A1	17-06-2010
			CN 102333770 A	25-01-2012
			CN 102341384 A	01-02-2012
			EP 2370428 A1	05-10-2011
			EP 2370429 A1	05-10-2011
			JP 2012511563 A	24-05-2012
			JP 2012511564 A	24-05-2012
			KR 20110094127 A	19-08-2011
			KR 20110094130 A	19-08-2011
			US 2011294812 A1	01-12-2011
			US 2011312963 A1	22-12-2011
			WO 2010067130 A1	17-06-2010
			WO 2010067131 A1	17-06-2010

WO 2010067131	A1	17-06-2010	AU 2009326148 A1	17-06-2010
			AU 2009326149 A1	17-06-2010
			CA 2746354 A1	17-06-2010
			CA 2746357 A1	17-06-2010
			CN 102333770 A	25-01-2012
			CN 102341384 A	01-02-2012
			EP 2370428 A1	05-10-2011
			EP 2370429 A1	05-10-2011
			JP 2012511563 A	24-05-2012
			JP 2012511564 A	24-05-2012
			KR 20110094127 A	19-08-2011
			KR 20110094130 A	19-08-2011
			US 2011294812 A1	01-12-2011
			US 2011312963 A1	22-12-2011
			WO 2010067130 A1	17-06-2010
			WO 2010067131 A1	17-06-2010

WO 2010112936	A1	07-10-2010	AU 2010231120 A1	08-09-2011
			CA 2754609 A1	07-10-2010
			CN 102395575 A	28-03-2012
			CO 6501168 A2	15-08-2012
			EA 201171213 A1	30-03-2012
			EP 2414347 A1	08-02-2012
			JP 2012522760 A	27-09-2012
			KR 20120006033 A	17-01-2012
			PE 05162012 A1	09-05-2012
			SG 174139 A1	28-10-2011
			US 2012136031 A1	31-05-2012
			WO 2010112936 A1	07-10-2010

Information on patent family members

PCT/GB2012/052445

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2011158039	A1	22-12-2011	NONE	
WO 2011158042	A2	22-12-2011	NONE	
WO 2011070368	A1	16-06-2011	UY 33097 A	30-06-2011
			WO 2011070368 A1	16-06-2011

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

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/GB2012/052445

International filing date (day/month/year)
03.10.2012

Priority date (day/month/year)
03.10.2011

International Patent Classification (IPC) or both national classification and IPC
INV. C07D403/12 A61K31/4155 A61K31/506 C07D491/10

Applicant
RESPIVERT LIMITED

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 and 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") 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.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0
Fax: +49 89 2399 - 4465

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Herz, Claus
Telephone No. +49 89 2399-8275



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2012/052445

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
 - ☐ 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:

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:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2012/052445

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	
	No: Claims	<u>1-16</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-16</u>
Industrial applicability (IA)	Yes: Claims	<u>1-16</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

V. Regarding Claim 13 patentability thereof can be dependent upon the formulation of the claims. The EPO, for example, does not recognise as patentable claims to the use of a compound in medical treatment, but may allow claims to a product, in particular substances or compositions for use in a first or further medical treatment.

Although the group of compounds claimed in the present application overlaps with the broad group defined in WO03/072569 (D1), it embraces no specifically disclosed compounds from D1. Provided also that the overlapping area represents a proper selection, which means that it is more than an arbitrarily chosen example from D1 having merely the same kind of properties and capabilities as the prior art, novelty of the common area could be recognised. However, this is presently not the case for the following reasons.

Substituted amines as substituent in position 2 of the pyrimidine ring are already known from the documents cited in the Search Report. Due to the fact that the choice of the anilino substituent at position 2 of the pyrimidine ring is within the scope already envisaged in D1 there must be an expectation of the qualitative retention of the kinase inhibitory activity at least to the same degree when arbitrarily choosing the substituents on the pyrimidine ring. Thus representing only predictable effects the compounds claimed are considered to be obvious.

Consequently, at present, Claims 1 to 16 are lacking inventive step under Article 33 (3) PCT.

Accordingly it is to be demonstrated wherein the inventive step lies in the compounds claimed, e.g. by showing a significant improvement in the property relevant to the solution of the stated problem. If it is chosen to give evidence using comparative tests, these must be carried out in respect of the closest state of the art. This is necessary to show convincingly that any unexpected effect indeed originates from the distinguishing feature, in the present case the specific substituent at position 2 of the pyrimidine ring.

In addition in this case, in view of the closeness of the prior art and the scarcity of the evidence presently on file, it should be credible that the effect occurs over the whole claimed range.

VI. The priority documents pertaining to the present application were not available at the time of establishing the first written opinion. Hence, it is based on the assumption that all claims enjoy priority rights from the filing date of the priority document. If it later turns out that this is not correct documents WO2011/158038 and WO2011/158042 cited in the International Search Report could become relevant in order to assess whether the claims satisfy the criteria set forth in Article 33 (1) PCT.