



No. 09-126923-A-00004-0000

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 Tra 11 PATENTEIYII Eve: 378 FASENACIONALI
 Act. 412 REPOSPRESRECU Folios: 11

1488

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Señor

SUPERINTENDENTE DE INDUSTRIA Y COMERCIO

E. S. D.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 09-126923-00022-0000

Fecha: 2015-02-06 15:15:46 Dep. 2003 G TRAB. VIA. GUI
 Tra 11 PATENTEIYII Eve: 378 FASENACIONALI
 Act. 422 APELARECUR Folios: 11

REF: Expediente No. PCT/09-126923A

TÍTULO SOLICITADO: "COMPOSICIONES FARMACÉUTICAS DE N-(3-{[3-
 {2-CLORO-5-(METOXI)FENIL}AMINO}
 QUINOXALIN-2-IL)AMINO}SULFONIL}-4-
 METILFENIL)-2-METILALANINAMIDA CON
 CARBOPLATINO O RAPAMICINA O ERLOTINIB"

PUBLICACIÓN: Gaceta 614 del 19/03/2010, N° 2157 de publicación 24.

SOLICITANTE: EXELIXIS INC.

APODERADO: CARLOS ORLANDO MAYA RODRÍGUEZ.

TRÁMITE: Recurso de Reposición y en subsidio el de apelación en
 contra de la Resolución 78612 de diciembre 19 de 2014 por
 la cual se concede una patente de invención tramitada
 bajo el número de expediente PCT/09-126923A.

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 78612 de diciembre 19 de
 2014 por la cual se concedió a la solicitud PCT/09-126923A el privilegio de patente de
 invención.

I. PETICIÓN

Sírvase, Señor Superintendente, reponer íntegramente la Resolución 78612 de diciembre 19

TOTAL 7
 11
 2

de 2014, 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 78612 de diciembre 19 de 2014, que concede el privilegio de patente de invención solicitado para el capítulo reivindicatorio del expediente 09-126923A 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 Docetaxel, Rapamicina, Carboplatino, Cetuximab y Trastuzumab, 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:

- EP 253738
- US 4814470
- DE 2347682

- US 3929992
- NL 7307863
- US 4140707
- WO 9640210
- WO 9216553
- US 5677171

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.

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 2008/127594

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.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
23 October 2008 (23.10.2008)

PCT

(10) International Publication Number
WO 2008/127594 A3

(51) International Patent Classification:

A61K 31/337 (2006.01) A61K 31/517 (2006.01)
A61K 31/436 (2006.01) A61K 31/555 (2006.01)
A61K 31/497 (2006.01) A61K 45/06 (2006.01)
A61K 31/498 (2006.01) A61P 35/00 (2006.01)
A61K 31/4985 (2006.01)

(21) International Application Number:

PCT/US2008/00470

(22) International Filing Date: 8 April 2008 (08.04.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/923,164 11 April 2007 (11.04.2007) US

(71) Applicant (for all designated States except US): EX-ELIXIS, INC. [US/US]; 210 East Grand Avenue, P.O. Box 511, South San Francisco, California 94083-0511 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): LAMB, Peter [US/US]; 814 Mandana Blvd, Oakland, California 94610 (US). MATTHEWS, David [GB/US]; 2 Balceta Avenue, San Francisco, California 94127 (US).

(74) Agents: WADE, Janice V. et al.; 210 East Grand Avenue, P.O. Box 511, South San Francisco, California 94083-0511 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available):

AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available):

ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SI, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

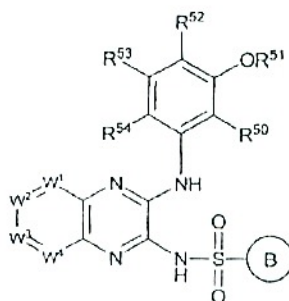
Published:

— with international search report
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:

30 April 2009

(54) Title: COMBINATION THERAPIES COMPRISING QUINOXALINE INHIBITORS OF PI3K-ALPHA FOR USE IN THE TREATMENT OF CANCER



(I)

(57) Abstract: The present invention provides methods of treating cancer by administering a compound of Formula I, optionally as a pharmaceutically acceptable salt, solvate and/or hydrate thereof, in combination with other cancer treatments.

WO 2008/127594 A3

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

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/US2008/004570	International filing date (day/month/year) 08.04.2008	Priority date (day/month/year) 11.04.2007	
International Patent Classification (IPC) or both national classification and IPC INV. A61K31/337 A61K31/436 A61K31/497 A61K31/498 A61K31/4985 A61K31/517 A61K31/555 A61K45/06 A61P35/00			
Applicant EXELIXIS, INC.			

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") 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:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Date of completion of this opinion see form PCT/ISA/210	Authorized Officer Renard, Delphine Telephone No. +49 89 2399-4744
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2008/004570

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 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:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished 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 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.
5. Additional comments:

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2008/004570

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 43*bis*.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 43*bis*.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:

see separate sheet

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

- 1. Statement

Novelty (N)	Yes: Claims	<u>1-28</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-28</u>
Industrial applicability (IA)	Yes: Claims	<u>1-28</u>
	No: Claims	
- 2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

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

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

see form 210

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

International application No.

PCT/US2008/004570

- 1) The present application relates to combination therapies comprising quinoxaline derivatives for use in the treatment of cancer.

Re Item V.

- 2) Claims 1-28 relate subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv)/67.1(iv) PCT. The patentability 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.

- 3) Reference is made to the following documents: unless otherwise indicated reference is hereafter made to the passages cited in the search report

D1: WO 2007/023186 A (APPLIED RESEARCH SYSTEMS [NL]; GAILLARD PASCALE [FR]; QUATTROPANI ANNA) 1 March 2007 (2007-03-01)

D2: WO 2007/044729 A (EXELIXIS INC [US]; BAJJALIEH WILLIAM [US]; BANNEN LYNNE CANNE [US]; BR) 19 April 2007 (2007-04-19)

D3: WO 2008/021389 A (EXELIXIS INC [US]; AFTAB DANA T [US]; LAIRD DOUGLAS A [US]; LAMB PETER) 21 February 2008 (2008-02-21)

D4: WO 2008/101979 A (SERONO LAB [CH]; GAILLARD PASCALE [FR]; POMEL VINCENT [FR]; JEANCLAUDE) 28 August 2008 (2008-08-28)

- 4) Priority

The priority document US60,923,164 filed on 11 April 2007 partially supports the present application.

Documents D2 and D3 are relevant in assessing novelty for claims 1, 2, 17 and 18. However, these claims are supported by the priority document (cf. claims 1, 2, 45 and page 39 wherein formula Ia is disclosed).

Therefore, documents D2-D3 will not be further used.

- 5) Novelty

The generic disclosure of D1 overlaps the general formula 1 of the present application. The document contains specific examples of compounds falling within the scope of the present claim 1 for use in the treatment of cancer. However no combination of these compounds with a second agent or radiation or surgery is mentioned.

Therefore, the subject-matter of the present application is considered novel.

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

International application No.

PCT/US2008/004570

6) Inventive step

In the light of D1 as closest prior art, the problem underlying the present application may be seen as a treatment of cancer.

The main difference between the prior art and the present application resides in the second agent.

The combination of a known anti-cancer agent with a further agent known to be useful in the treatment of cancer is not considered to support an inventive step as combination is a known measure of treatment of cancer.

Data are provided for compound A in combination with taxol, rapamycin, carboplatin, compound B and erlotinib (cf. figures 1-5). However, at present, it is not clear which compound is really compound A. Therefore, no inventive step can be acknowledged. In case compound A is only one specific compound, it is inherently unlikely that all combinations of claim 1, or at least substantially all of them, possess the alleged technical effect.

Accordingly, the subject-matter of the present application does not involve an inventive step.

Re Item VI. Cited documents

Document D2 discloses the same compounds as the one of the present application to be combined with surgery, radiation and chemotherapeutics for use in the treatment of cancer.

Document D3 discloses the combination of PI3k and MEK for use in the treatment of cancer.

Document D4 discloses compounds of the present application for use in the treatment of cancer. No combination is disclosed.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/004570

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	WO 2008/101979 A (SERONO LAB [CH]; GAILLARD PASCALE [FR]; POMEL VINCENT [FR]; JEANCLAUDE) 28 August 2008 (2008-08-28) abstract claims 1-24 -----	1-28

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2008/004570

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2007023186 A	01-03-2007	AU 2006283846 A1 CA 2618479 A1 KR 20080049767 A	01-03-2007 01-03-2007 04-06-2008
WO 2007044729 A	19-04-2007	AU 2006302179 A1 CA 2623768 A1 EP 1931645 A2 KR 20080068651 A	19-04-2007 19-04-2007 18-06-2008 23-07-2008
WO 2008021389 A	21-02-2008	NONE	
WO 2008101979 A	28-08-2008	NONE	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/004570

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2007023186 A	01-03-2007	AU 2006283846 A1 CA 2618479 A1 KR 20080049767 A	01-03-2007 01-03-2007 04-06-2008
WO 2007044729 A	19-04-2007	AU 2006302179 A1 CA 2623768 A1 EP 1931645 A2 KR 20080068651 A	19-04-2007 19-04-2007 18-06-2008 23-07-2008
WO 2008021389 A	21-02-2008	NONE	
WO 2008101979 A	28-08-2008	NONE	