

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

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755 Page Mill Road
Palo Alto, California 94304-1018
United States of America

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)
25 July 2012

Applicant's or agent's file reference
701832000341

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US2012/XXXXXX

International filing date (*day/month/year*)

17 May 2012

Priority date (*day/month/year*)

17 May 2011

International Patent Classification (IPC) or both national classification and IPC

C07D 405/12 (2006.01)

Applicant

ABC THERAPEUTICS, INC. et al.

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input checked="" type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43 <i>bis</i> .1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | 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 66.1*bis*(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

AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606,
AUSTRALIA
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Date of completion of this opinion

18 July 2012

Authorised Officer

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2012/XXXXXX

Box No. I 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 (under 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 43*bis*.1(b))
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:
 - a. forming part of the international application as filed:
 - in the form of an Annex C/ST.25 text file.
 - on paper or in the form of an image file.
 - b. furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. furnished subsequent to the international filing date for the purposes of international search only:
 - in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
 - on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
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 forming part of 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/US2012/XXXXXX**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:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International Application No.

PCT/US2012/XXXXXX

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 1-30	YES
	Claims NONE	NO
Inventive step (IS)	Claims 1-30	YES
	Claims NONE	NO
Industrial applicability (IA)	Claims 1-30	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS:**CITATIONS**

D1: WO 1999/009016 A1 (AMERICAN CYANAMID COMPANY) 25 February 1999

NOVELTY (N)

D1 discloses quinazoline derivates and their use as tyrosine kinase inhibitors (see abstract). The compounds exemplified in this document do not fall within the scope of the present claims (see Examples of D1), therefore claims 1-30 meet the criteria set forth in PCT Article 33(2) for novelty.

INVENTIVE STEP (IS)

D1 discloses substituted quinazoline derivatives for use as tyrosine kinase inhibitors. The generic structure disclosed in D1 differs from present claim 1 at a number of different moieties (see, for example, groups R2 and R3 in claim 1 of D1). This document does not obviously teach the compounds as defined in the present claims. Claims 1-30 meet the criteria set out in PCT Article 33(3) with regard to the requirement of inventive step.

INDUSTRIAL APPLICABILITY (IA)

The invention defined in the claims is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT because it can be made by, or used in, industry.

P Category Document/s listed in Box VI:

There is a document(s) listed as a P category document in Box VI because it:

- discloses subject matter that is of particular relevance to this application and
- is published before the international filing date but after the priority date of this application.

Under the PCT, only documents published before the priority date of the instant application can deprive the claims of that application of novelty or inventive step.

However, the relevance of a document published after the priority date of the application under consideration is dependent on national law in individual countries.

P category document/s may become significant in the National Phase.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International Application No.

Box No. VI Certain documents cited**PCT/US2012/XXXXXX**1. Certain published documents (Rules 43*bis*.1 and 70.10)

Application No. Patent No.	Publication date (<i>day/month/year</i>)	Filing date (<i>day/month/year</i>)	Priority date (valid claim) (<i>day/month/year</i>)
P,X : WO 2011/084796 A2	14 July 2011	21 December 2010	21 December 2009
P,X : WO 2012/027960 A1	08 March 2012	30 August 2011	30 August 2010

See Supplemental Box for Details2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

Kind of non-written disclosure	Date of non-written disclosure (<i>day/month/year</i>)	Date of written disclosure referring to non-written disclosure (<i>day/month/year</i>)
_____	_____	_____

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International Application No.

Supplemental Box

PCT/US2012/XXXXXXContinuation of: **Box VI**

WO 2011/084796 discloses compounds that fall within the scope of the present claims where Ar is substituted phenyl, L is CH₂, and M is a substituted bicyclic heterocycle, see in particular page 37, which discloses the following compounds:

(E)-N-(4-(3-chloro-4-fluorophenyl-(N-D)-amino)-7-((2-methyloctahydrocyclopenta[c]pyrrol-5-yl)methoxy)quinazolin-6-yl)-4-(dimethylamino)but-2-enamide

(E)-4-(dimethylamino)-N-(4-(3-(2-D-ethynyl)phenylamino)-7-((2-methyl-octahydrocyclopenta[c]pyrrol-5-yl)methoxy)quinazolin-6-yl)but-2-enamide

(E)-N-(4-(3-chloro-4-(3-fluorobenzyloxy)phenyl-(N-D)-amino)-7-((2-methyl-octahydrocyclopenta[c]pyrrol-5-yl)methoxy)quinazolin-6-yl)-4-(dimethylamino)but-2-enamide

These compounds are relevant to claims 1-6, 9, 10 and 19-27. WO 2011/084796 also discloses that these compounds inhibit EGF receptor tyrosine kinases and are used to treat hyperproliferative disorders (see abstract).

WO 2012/027960 discloses compound 20 (page 18) which falls within the scope of the present claims where Ar is 3-chloro, 4-fluorophenyl, L is CH₂ and M is a bicyclic heterocycle, and is relevant to claims 1-6, 9, 10 and 19-27. This document also discloses similar compounds including compounds 21-23 (page 19), compound 33 (page 69), and compounds 38, 39 and 42-45 (page 70). WO 2012/027960 discloses the use of these compounds in pharmaceutical compositions to treat diseases such as hyperplasia (see abstract).