

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Guoxian Wu et al.

Application No.: Not Yet Assigned

Confirmation No.: N/A

Filed: Concurrently Herewith

Art Unit: N/A

For: COMPOUNDS AND METHODS FOR KINASE
MODULATION, AND INDICATIONS
THEREFOR

Examiner: Not Yet Assigned

PRELIMINARY AMENDMENT UNDER 37 CFR 1.115

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Prior to examination of the present Application, Applicant respectfully requests that the application be amended as follows:

Amendments to the Specification begin on page 2 of this document.

Amendments to the Claims are reflected in the listing of claims that begin on page 3 of this document.

Remarks/Arguments begin on page 5 of this document.

Please amend the application as follows:

Amendments to the Specification:

Please amend the specification as follows:

Please replace the first paragraph, paragraph [0001], with the following amended paragraph:

--This application is a continuation of U.S. Application No. 13/926,959, filed June 25, 2013, which is a continuation application of U.S. Application No. 13/866,353, filed April 19, 2013, which is a continuation application of 12/669,450, filed January 15, 2010, which application is a National Phase application under 35 U.S.C. § 371 of PCT/US2008/070124, filed July 16, 2008, which claims the benefit under 35 U.S.C. § 119(e) from U.S. Application No. 60/959,907, filed July 17, 2007, which applications are hereby incorporated by reference in their entirety.--

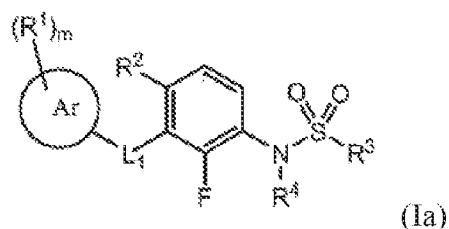
Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-20. (Canceled).

21. (New) A compound of formula (Ia):



or a pharmaceutically acceptable salt thereof,

wherein:

L_1 is a bond, $-N(H)C(O)-$, $-N(H)-$, $-N(H)-S(O)_2-$, or $-N(H)-C(NH)-$;

each R^1 is optionally substituted lower alkyl or optionally substituted heteroaryl;

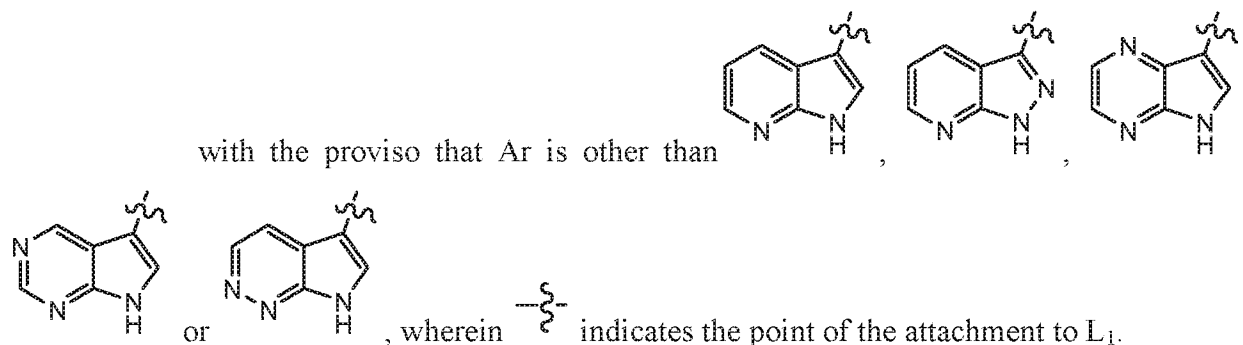
R^2 is hydrogen or halogen;

R^4 is hydrogen;

R^3 is optionally substituted lower alkyl or optionally substituted aryl;

m is 0, 1, 2, 3, 4, or 5; and

Ar is a monocyclic heteroaryl containing 5 to 6 atoms or a bicyclic heteroaryl containing 8 to 10 atoms wherein at least one atom is nitrogen,



22. (New) The compound of claim 21, wherein R^2 is hydrogen.

- 23.** (New) The compound of claim **21**, wherein R^2 is halogen.
- 24.** (New) The compound of claim **21**, wherein R^3 is optionally substituted phenyl.
- 25.** (New) The compound of claim **21**, wherein R^3 is phenyl substituted with one or more substituents selected from the group consisting of fluoro, lower alkyl, fluoro substituted lower alkyl, lower alkoxy, fluoro substituted lower alkoxy, lower alkylthio, and fluoro substituted lower alkylthio.
- 26.** (New) The compound of claim **21**, wherein R^3 is phenyl substituted with one or more fluoro.
- 27.** (New) The compound of claim **21**, wherein each R^1 is optionally substituted lower alkyl.
- 28.** (New) The compound of claim **21**, wherein each R^1 is optionally substituted heteroaryl.
- 29.** (New) The compound of claim **21**, wherein Ar is a monocyclic heteroaryl containing 5 to 6 atoms.
- 30.** (New) A pharmaceutical composition comprising a compound of claim **21** and a pharmaceutically acceptable carrier or excipient.
- 31.** (New) A pharmaceutical composition comprising a compound of claim **21** and another therapeutic agent.
- 32.** (New) A method for treating a subject suffering from melanoma, thyroid cancer or colorectal cancer, said method comprising administering to the subject an effective amount of a compound of claim **21**.
- 33.** (New) The method of claim **32**, wherein the melanoma is melanoma having a mutation encoding a V600E amino acid substitution.

REMARKS

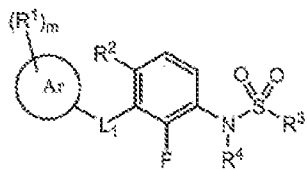
Applicant respectfully requests that the foregoing amendments be made prior to examination of the present application.

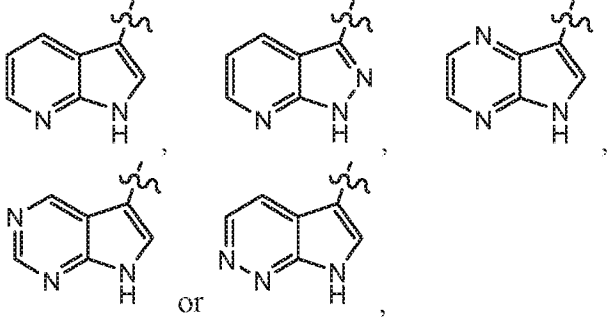

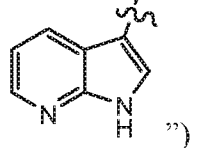
Amendments to the Specification

In the specification, paragraph [0001] has been amended to update the priority claim. No new matter is added by the amendment, and its entry is respectfully requested.

Claim Amendments

Claims 1-20 are canceled, and claims 21-33 are newly added. Support for these claims can be found throughout the original specification and priority application as summarized in the Table below.

Claim(s)	Claim Limitation	Exemplary Support in Present Application	Exemplary Support in Priority Application
21	Compounds of Formula (Ia) 	Para. [0006]	Para. [0008]
21	L ₁ is a bond, -N(H)C(O)-, -N(H)-, -N(H)-S(O) ₂ -, or -N(H)-C(NH)-	Para. [0005], [0007], [0009],	Para. [0007], [0009], and [0010]
21, 27, 28	each R ¹ is optionally substituted lower alkyl or optionally substituted heteroaryl	Para. [0005]	Para. [0007]
21, 22, 23	R ² is hydrogen or halogen	Para. [0009]	Para. [0010]
21	R ³ is optionally substituted lower alkyl or optionally substituted aryl	Para. [0005]	Para. [0007]

21	R ⁴ is hydrogen	Para. [0007]-[0009]	Para. [0009]-[0010]
21	m is 0, 1, 2, 3, 4, or 5	Para. [0005]	Para. [0007]
21, 29	Ar is a monocyclic heteroaryl containing 5 to 6 atoms or a bicyclic heteroaryl containing 8 to 10 atoms wherein at least one atom is nitrogen	Para. [0005], [0043]-[0044], and [0091]	Para. [0007], [0025], [0027], and [0074]
21	<p>with the proviso that Ar is other than</p>  <p>wherein  indicates the point of the attachment to L₁</p>	Para. [0005]	<p>Para. [0007]</p> <p>(Ar is not “7-azaindol-3-yl, i.e. is not  ”)</p>
24	R ³ is optionally substituted phenyl	Para. [0048]	Para. [0029]
25, 26	R ³ is phenyl substituted with one or more substituents selected from the group consisting of fluoro, lower alkyl, fluoro substituted lower alkyl, lower alkoxy, fluoro substituted lower alkoxy, lower alkylthio, and fluoro substituted lower alkylthio.	Para. [0048]	Para. [0029]
30, 31	Pharmaceutical compositions comprising compounds of formula (Ia)	Para. [0143]-[0151]	Para. [0362]-[0372]
32, 33	Methods of treatment comprising administering compounds of formula (Ia)	Para. [0053] and [0077]	Para. [0035] and [0058]-[0061]

No new matter is added by this amendment, and as such, Applicant respectfully requests its entry. Further, Applicant reserves the right to pursue canceled subject matter in a continuing application.

Applicant respectfully requests the Office review the Interview Summary of parent application, U.S. App. No. 13/926,959 (“the ‘959 application”), filed on even date herewith. Additionally, as noted in an Applicant-Initiated Interview Summaries dated January 22, 2016, and February 4, 2016, of the ‘959 application, the Office agreed that the application has support for L1 as amide or a bond, and Ar as nitrogen-containing bicyclic heteroaryl and monocyclic heteroaryl. Further, the Applicant-Initiated Interview Summary dated January 22, 2016, provides that “[t]he examiner further indicate that compounds with L1 is –NH-C(O)- and Ar is nitrogen containing bicyclic heteroaryl, with the proviso therein, are allowable.”

Early examination of the application as amended is respectfully requested, and the Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Dated: February 19, 2016

Respectfully submitted,

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