

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Guoxian Wu et al.

Application No.: 15/048,851

Confirmation No.: 5501

Filed: February 19, 2016

Art Unit: 1627

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

Examiner: S. Wang

AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION UNDER 37 C.F.R.
§ 1.111

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

Dear Commissioner:

INTRODUCTORY COMMENTS

This Amendment and Reply is responsive to the Non-Final Office Action mailed on April 18, 2016. As such, this reply is timely filed, along with a one month extension of time, on or before its due date of August 18, 2016.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 5 of this paper.

Please amend the application as follows.

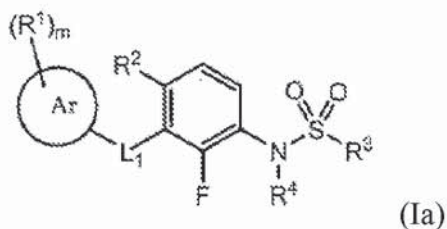
AMENDMENTS TO THE CLAIMS

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

Listing of Claims:

1-20. (Canceled).

21. (Currently Amended) A compound of formula (Ia):



or a pharmaceutically acceptable salt thereof,

wherein:

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

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

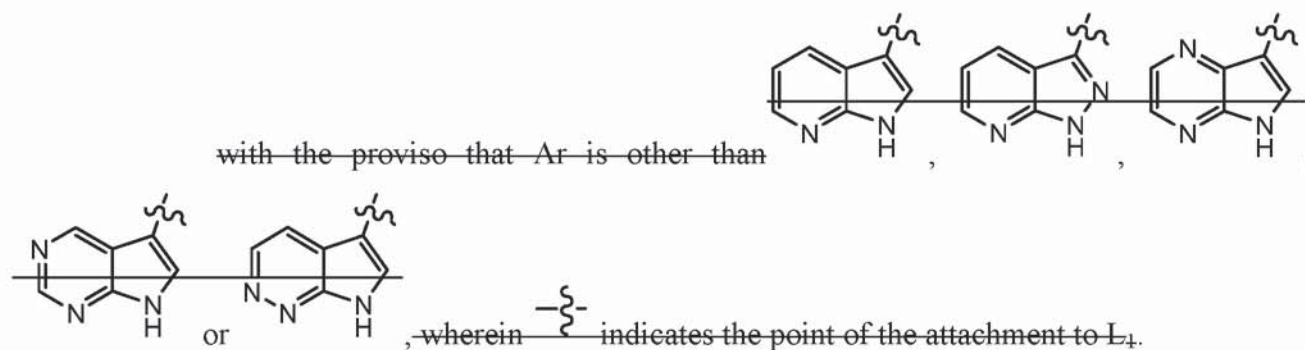
R^2 is hydrogen or halogen;

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.** (Previously presented) The compound of claim **21**, wherein R² is hydrogen.
- 23.** (Previously presented) The compound of claim **21**, wherein R² is halogen.
- 24.** (Previously presented) The compound of claim **21**, wherein R³ is optionally substituted phenyl.
- 25.** (Previously presented) The compound of claim **21**, wherein R³ 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.** (Previously presented) The compound of claim **21**, wherein R³ is phenyl substituted with one or more fluoro.
- 27.** (Previously presented) The compound of claim **21**, wherein each R¹ is optionally substituted lower alkyl.
- 28.** (Previously presented) The compound of claim **21**, wherein each R¹ is optionally substituted heteroaryl.
- 29.** (Canceled).
- 30.** (Previously presented) A pharmaceutical composition comprising a compound of claim **21** and a pharmaceutically acceptable carrier or excipient.

31. (Previously presented) A pharmaceutical composition comprising a compound of claim **21** and another therapeutic agent.

32. (Previously presented) 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. (Previously presented) 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 in the present application.

Claim Amendments

By this paper, claim 21 is amended, and claim 29 is canceled. Upon entry, claims 21-28 and 30-33 are pending. No new matter has been added by these amendments, and as such, Applicant respectfully requests their entry. Applicant reserves the right to pursue canceled subject matter in a continuing application.

Interview Summary

Applicant thanks Examiner Wang and Examiner Padmanabhan for the courtesies extended to Applicant's representatives (Robert Bernstein (Reg. No. 46,020), Lorna Tanner (Reg. No. 50,782), and Joy Lynn Nemirow (Reg. No. 67,163)) during an in person interview conducted July 6, 2016. Possible claim amendments and the pending rejections under 35 U.S.C. § 112 and 35 U.S.C. § 103 were discussed. A copy of the slides discussed during the interview is attached as **Exhibit A**.

Regarding the rejection under 35 U.S.C. § 112, the Office agreed that the application provides support for L₁ as amide or a bond and support for Ar as a monocyclic or bicyclic nitrogen-containing heteroaryl as discussed below and during the prosecution of the parent application, U.S. Application No. 13/926,959 ("the '959 Application"). As suggested by the Office, Applicant also hereby amends L₁ of claim 21 to be directed to "a bond or -N(H)C(O)-."

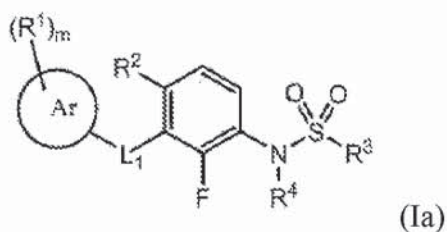
Regarding the rejection under 35 U.S.C. § 103, a declaration to antedate the cited reference was discussed and is submitted concurrently herewith.

While the Office requested the Applicant to point out references relating to the bicyclic heteroaryls encompassed by the proviso of claim 21, Applicant respectfully submits that the present amendments render this request moot.

Rejection under 35 U.S.C. § 112, Written Description

Claims 21-33 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office alleges that substantial structural variation exists in the claimed genus/subgenus, there is no disclosure of species supporting the genus, and common structural attributes of the claimed genus/subgenus, combined with a correlation between structure and function is neither disclosed in the present application or commonly known in the art. Office Action at p. 6.

Without acquiescing to the rejection, but in sincere attempt to expedite prosecution, Applicant has amended claim 21 to be directed to compounds of formula (Ia):



or a pharmaceutically acceptable salt thereof, wherein L_1 is a bond or $-N(H)C(O)-$, Ar is a monocyclic heteroaryl containing 5 to 6 atoms wherein at least one atom is nitrogen, and the remaining variables are as delineated in claim 21.

Exemplary disclosure in the present application demonstrates that Applicant had clear possession of the claimed compounds at the time of filing. For example, numerous embodiments for claimed L_1 , including L_1 is a bond, can be found throughout the specification, including but not limited to paragraphs [0007], [0009], [0011], and [0021]. Further, for embodiments when L_1 is a bond, Scheme 2 provides exemplary methods of making compounds where L_1 is a bond. Based on Scheme 2, one of ordinary skill in the art would have understood that the Applicant had possession of these claimed compounds.

Paragraph [0091] of the present application also provides that “heteroaryl” refers to “a monocyclic aromatic ring structure containing 5 or 6 ring atoms . . . containing one or more . . .

heteroatoms independently selected from the group consisting of O, S, and N.” The present application further includes numerous exemplary compounds falling within the claimed genus, such as throughout Examples 1, 2, 9, and 10.

For at least the foregoing reasons, Applicant respectfully submits that the present application sufficiently describes the claimed subject matter to reasonably convey to one of ordinary skill in the art that the Applicant had possession of the claimed invention. Applicant requests that the rejection be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 21-32 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Dimauro et al (WO 2007/022380). Claim 33 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Dimauro et al. and in further view of Samowitz et al. (Cancer Research, 2005, Vol. 65, No. 14, p. 6063- 6070).

Applicant submits concurrently herewith a Declaration under 37 C.F.R. § 1.131. This declaration provides evidence of Applicant’s conception and reduction to practice of at least one compound within the scope of the claims prior to the earliest filing date of Dimauro et al. Accordingly, Applicant conceived and reduced to practice the claimed invention prior to the earliest filing date of Dimauro et al. As such, Dimauro et al. cannot serve as a reference for an obviousness rejection.

Thus, for at least the foregoing reasons, Applicant respectfully requests that the rejection be withdrawn.

Conclusion

Applicant believes that the present application is now in condition for allowance. Accordingly, reconsideration and favorable action on all claims are respectfully requested. In the event any issues remain to be resolved in view of this communication, the Examiner is invited to

contact the undersigned at the telephone number set forth below so that a prompt disposition of the present application can be achieved.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-6219. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-6219.

Dated: July 20, 2016

Respectfully submitted,

By Joy Lynn Nemirow/

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