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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------------------------------------------|-------------|----------------------|----------------------------|------------------|
| 13/340,522 | 12/29/2011 | Joseph J. Buggy | 25922-819.301 | 7251 |
| 116469 | 7590 | 11/01/2013 | EXAMINER | |
| WSGR/Pharmacyclics, Inc. 650 Page Mill Road Palo Alto, CA 94304 | | | RAMACHANDRAN, UMAMAHESWARI | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1627 | |
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| | | | 11/01/2013 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------------------------|-------------------------------------|--------------------------------------------------|
| Office Action Summary | Application No. 13/340,522 | Applicant(s) BUGGY ET AL. | |
| | Examiner UMAMAHESWARI RAMACHANDRAN | Art Unit 1627 | AIA (First Inventor to File) Status No |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 9/17/2013.
 A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) Claim(s) 131, 132, 134-140, 143, 144 and 146-149 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) Claim(s) _____ is/are allowed.
- 7) Claim(s) 131, 132, 134-140, 143, 144 and 146-149 is/are rejected.
- 8) Claim(s) _____ is/are objected to.
- 9) Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) The specification is objected to by the Examiner.
- 11) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) All b) Some * c) None of the:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 3) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____



The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

The office acknowledges Applicants' response to the office action dated 3/13/2013. Claims 1-130, 133, 141, 142, 145 have been cancelled. Claims 131, 132, 134-140, 143, 144, 146-149 are pending. The claims 131, 132, 134-140, 143, 144, 146-149 are examined to the extent they read on the elected species.

Applicants' have amended the Specification to comply with the sequence rules. Applicants' amendment to claim 131 necessitated the withdrawal of 112(1) rejection. Applicants' arguments regarding the ODP and 103 rejections have been fully considered but found not to be persuasive. The arguments are addressed in the Response to Arguments section below. New ODP rejections over 13/747,519 (case docketed to the examiner on 7/17/2013, after non-final mailed on 3/13/2013) and 13/736,812 (case docketed to the examiner on 4/29/2013, after non-final mailed on 3/13/2013) are made. Applicants' amendments to the claims necessitated the modified rejections in this action. Accordingly the action is made Final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

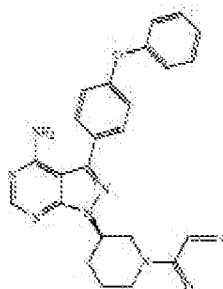
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 131, 132, 134-140, 143, 144, 146-149 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honigberg et al (US 2008/0076921, already of record) in view of PRNewswire (Dec 2009) and Pollyea et al. (Poster Abstracts, Dec 3 2009, 51st ASH Annual Meeting and Exposition) and further in view of Hiddeman et al. (Seminars in Oncology, 30, 1, 2, Feb 2003, p 16-20).

Claims 131, 132, 134-140, 143, 144, 146-149 are drawn towards a method for treating a relapsed or refractory hematological malignancy in an individual comprising

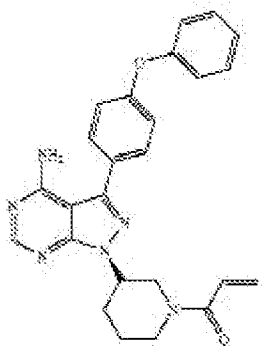
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administering to the individual a therapeutically effective amount of an inhibitor of Bruton's tyrosine kinase (Btk) having the following structure.



Applicants elected the species of lymphoma – mantle cell lymphoma (MCL), species of second cancer agent - rituximab (174722-31-7).

Honigberg teaches the following compound (p 24, [252]).



Honigberg et al. discloses that the compositions comprising this compound may be used in the treatment of disease or conditions that would benefit from inhibition of Bruton's tyrosine kinase or a homolog thereof which involves the administration of the composition in therapeutically effective amounts to the subject wherein the subject is human and the administration is oral ([0027-0029]) wherein the subject in need is suffering from a cancer, which is B-cell proliferative disorder, e.g., diffuse large B cell lymphoma, follicular lymphoma, chronic lymphocytic lymphoma, chronic lymphocytic

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