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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes details for application 14/523,650, inventor John C. BYRD, and attorney FOLEY HOAG, LLP.

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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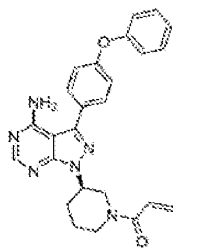
DETAILED ACTION

Application and Claims Status

1. Applicant's response filed on 02/02/2016 is acknowledged and entered.
2. Claims 1-20 were pending. No claims were amended, added, and/or cancelled. Therefore, claims 1-20 are currently pending.
3. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Election/Restrictions

4. Applicant's election without traverse of a species for a pharmaceutical composition in the reply filed on 02/02/2016 is acknowledged. The elected species is as follows: "*Applicant respectfully elects without traverse claims drawn to (R)-1-(3-(4-amino-3-(4-phenoxyphenyl)-1H-pyrazolo[3,4-d]pyrimidin-1-yl)piperidin-1-yl)prop-2-en-one, also known as ibrutinib,*



represented by the structural formula *ibrutinib* ”.

5. Claims 19 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to *nonelected species*, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 02/02/2016. Accordingly, claims 1-18 are under consideration in this Office Action.

Priority

6. This instant application claims for domestic priority under 35 U.S.C. 119(e) to four provisional applications. They are as follows: 61/895,981 that was filed on 10/25/2013; 61/910,945 that was filed on 12/02/2013; 61/973,173 that was filed on 03/31/2014; and 61/973,176 that was filed on 03/31/2014. Thus, the effective filing date of this instant application is 10/25/2013.

Information Disclosure Statement

7. The information disclosure statement (IDS) that was filed on 03/18/2016 has been reviewed, and the references that have been considered are initialed as recorded in PTO-1449 forms.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

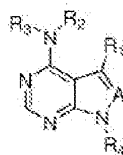
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person

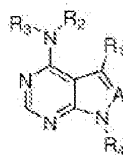
Art Unit: 1629

skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1 and 3-18 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a scope of enablement rejection.

First, claim 1 recites “A method of preventing the occurrence of graft versus host disease (GVHD) or reducing the severity of GVHD occurrence in a patient requiring cell transplantation, comprising administering to the patient a therapeutically effective amount of a



compound of Formula (A) having the structure:  Formula (A); wherein: A is N; R₁ is phenyl-O-phenyl or phenyl-S-phenyl; R₂ and R₃ are independently H; R₄ is L₃-X-L₄-G, wherein, L₃ is optional, and when present is a bond, optionally substituted or unsubstituted alkyl, optionally substituted or unsubstituted cycloalkyl, optionally substituted or unsubstituted alkenyl, optionally substituted or unsubstituted alkynyl; X is optional, and when present is a bond, -O-, -C(=O)-, -S-, -S(=O)-, -S(=O)₂-, -NH-, -NR₉-, -NHC(O)-, -C(O)NH-, -NR₉C(O)-, -C(O)NR₉-, -S(=O)₂NH-, -NHS(=O)₂-, -S(=O)₂NR₉-, -NR₉S(=O)₂-, -OC(O)NH-, -NHC(O)O-, -OC(O)NR₉-, -NR₉C(O)O-, -CH=NO-, -ON=CH-, -NR₁₀C(O)NR₁₀-, heteroaryl-, aryl-, -NR₁₀C(=NR₁₁)NR₁₀-, -NR₁₀C(=NR₁₁)-, -C(=NR₁₁)NR₁₀-, -OC(=NR₁₁)-, or -C(=NR₁₁)O-; L₄ is optional, and when present is a bond, substituted or unsubstituted alkyl, substituted or unsubstituted cycloalkyl, substituted

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