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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/523,650	10/24/2014	John C. BYRD	PIR-88501	1095
	7590 04/22/201 <b>5</b> , LLP (W/PIR)	EXAMINER		
PATENT GROUP, Seaport West 155 SEAPORT BLVD			TRAN, MY CHAU T	
BOSTON, MA	02210		ART UNIT	PAPER NUMBER
			1629	
			NOTIFICATION DATE	DELIVERY MODE
			04/22/2016	ELECTRONIC

### 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):

Patent@foleyhoag.com pair\_foleyhoag@firsttofile.com ABBVIE\_PATENTS\_ABT\_PRK@abbvie.com



	Application No. 14/523,650	Applicant(s) BYRD ET AL.				
Office Action Summary	Examiner MY-CHAU T. TRAN	Art Unit 1629	AIA (First Inventor to File) Status Yes			
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 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.						
<ul> <li>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.</li> <li>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.</li> <li>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).</li> <li>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).</li> </ul>						
Status						
1) Responsive to communication(s) filed on <u>03/08/2016</u> .						
A declaration(s)/affidavit(s) under <b>37 CFR 1.130(b)</b> was/were filed on						
2a) ☐ This action is <b>FINAL</b> . 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 <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims*						
5) Claim(s) 1-20 is/are pending in the application.						
5a) Of the above claim(s) <u>19 and 20</u> is/are withdrawn from consideration.						
6) Claim(s) is/are allowed.						
7) Claim(s) <u>1-18</u> is/are rejected.						
8) Claim(s) is/are objected to.	u alaatian waxaanaa					
9) Claim(s) are subject to restriction and/or election requirement.						
* If any claims have been determined <u>allowable</u> , you may be eligible to benefit from the <b>Patent Prosecution Highway</b> program at a						
participating intellectual property office for the corresponding application. For more information, please see <a href="http://www.uspto.gov/patents/init_events/pph/index.jsp">http://www.uspto.gov/patents/init_events/pph/index.jsp</a> or send an inquiry to PPHfeedback@uspto.gov.						
		and.				
Application Papers	ar					
10) The specification is objected to by the Examiner.  11) The drawing(s) filed on 10/24/2014 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 H.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					
2) N Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date 03/08/2016.  Paper No(s)/Mail Date  4) Other:						
U.S. Patent and Trademark Office PTOL-326 (Rev. 11-13) Office Action	Summary	Part of Paper No	./Mail Date 20160416			



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### **DETAILED ACTION**

### **Application and Claims Status**

- 1. Applicant's response filed on 02/02/2016 is acknowledged and entered.
- 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

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.



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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



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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;  $R_1$  is phenyl-O-phenyl or phenyl-S-phenyl;  $R_2$  and  $R_3$  are independently H;  $R_4$  is  $L_3$ -X- $L_4$ -G, wherein,  $L_3$  is optional, and when present is a bond, optionally substituted or unsubstituted alkyl, optionally substituted or unsubstituted alkenyl, 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)N R10-, heteroaryl-, aryl-, -N R10C(=NR11)N R10-, -N R10C(=NR11)-, -C(=NR11)NR10-, -OC(=NR11)-, or -C(=NR11)O-;  $L_4$  is optional, and when present is a bond, substituted or unsubstituted alkyl, substituted or unsubstituted cycloalkyl, substituted



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