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NOTICE OF ALLOWANCE AND FEE(S) DUE

84802 7590 06/20/2017
JONES DAY for Celgene Corporation
250 Vesey Street
NEW YORK, NY 10281-1047

EXAMINER

SHIAO, REI TSANG

ART UNIT

PAPER NUMBER

1628

DATE MAILED: 06/20/2017

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/969,750

12/15/2015

Nathan Andrew BOERSEN

10624-393-999

1040

TITLE OF INVENTION: FORMULATIONS OF
2-(TERT-BUTYLAMINO)-4-((1R,3R,4R)-3-HYDROXY-4-METHYLCYCLOHEXYLAMINO)-PYRIMIDINE-5-CARBOXAMIDE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional

UNDISCOUNTED

\$960

\$0

\$0

\$960

09/20/2017

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

84802 7590 06/20/2017
JONES DAY for Celgene Corporation
250 Vesey Street
NEW YORK, NY 10281-1047

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/969,750	12/15/2015	Nathan Andrew BOERSEN	10624-393-999	1040

TITLE OF INVENTION: FORMULATIONS OF
2-(TERT-BUTYLAMINO)-4-((1R,3R,4R)-3-HYDROXY-4-METHYLCYCLOHEXYLAMINO)-PYRIMIDINE-5-CARBOXAMIDE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	09/20/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
SHIAO, REI TSANG	1628	514-275000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (**Please first reapply any previously paid issue fee shown above**)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____



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EXAMINER	
SHIAO, REI TSANG	

ART UNIT	PAPER NUMBER
1628	

DATE MAILED: 06/20/2017

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/969,750	Applicant(s) BOERSEN ET AL.	
	Examiner REI-TSANG SHIAO	Art Unit 1628	AIA (First Inventor to File) Status Yes

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed on 6/13/2017.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ 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.
3. ☒ The allowed claim(s) is/are 1-7. As a result of the allowed claim(s), 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.
4. ☐ 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)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. ☐ Notice of References Cited (PTO-892) | 5. ☐ Examiner's Amendment/Comment |
| 2. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 6. ☒ Examiner's Statement of Reasons for Allowance |
| 3. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 7. ☐ Other _____. |
| 4. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____. | |

/REI-TSANG SHIAO/
Primary Examiner, Art Unit 1628

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

1. This application claims priority of the provisional applications: 62/196,044 with a filing date 07/23/2015; and 62/092,537 with a filing date 12/16/2014.
2. Amendment including cancelation of claims 8-13 in the amendment filed on 6/13/2017 is acknowledged. Claims 1-7 are pending in the application.

Reasons for Allowance

3. Since claims 8 and 10-13 have been canceled, therefore the rejection of claims 8 and 10-13 under the obviousness-type double patenting over Man et al. '524, or Bennett et al. '534 or '633 have been obviated herein.
4. Claims 1-7 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. A suggestion for modification of a reference to obtain the instant compositions has not been found. Claims 1-7 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts

Art Unit: 1628

to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Winston Shen, can be reached on (571)272-3157. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/REI-TSANG SHIAO/

Rei-tsang Shiao, Ph.D.
Primary Examiner
Art Unit 1628

June 15, 2017

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Boersen *et al.*

Confirmation No.: 1040

Application No.: 14/969,750

Group Art Unit: 1628

Filed: December 15, 2015

Examiner: Rei Tsang Shiao

For: FORMULATIONS OF 2-(TERT-BUTYLAMINO)-4-((1R,3R,4R)-3-HYDROXY-4-METHYLCYCLOHEXYLAMINO)-PYRIMIDINE-5-CARBOXAMIDE

Attorney Docket No.: 10624-393-999
(CAM: 700755-999393)

REPLY TO OFFICE COMMUNICATION UNDER 37 C.F.R. § 1.116

Mail Stop AF

/REI TSANG SHIAO/

06/15/2017

Commissioner for Patents

entered

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

This responds to the Office Action mailed April 13, 2017 in connection with the above-identified application.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 4 of this paper.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Boersen *et al.*

Confirmation No.: 1040

Application No.: 14/969,750

Group Art Unit: 1628

Filed: December 15, 2015

Examiner: Rei Tsang Shiao

For: FORMULATIONS OF 2-(TERT-BUTYLAMINO)-4-((1R,3R,4R)-3-HYDROXY-4-METHYLCYCLOHEXYLAMINO)-PYRIMIDINE-5-CARBOXAMIDE

Attorney Docket No.: 10624-393-999
(CAM: 700755-999393)

REPLY TO OFFICE COMMUNICATION UNDER 37 C.F.R. § 1.116

Mail Stop AF

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

This responds to the Office Action mailed April 13, 2017 in connection with the above-identified application.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 4 of this paper.

Amendments to the Claims:

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

Listing of claims:

1. (Previously Presented) A pharmaceutical composition comprising about 20-40% by weight of 2-(*tert*-butylamino)-4-((1R,3R,4R)-3-hydroxy-4-methylcyclohexylamino)-pyrimidine-5-carboxamide or a pharmaceutically acceptable salt, stereoisomer, solvate, hydrate, isotopologue or solid form thereof, about 30-50% by weight of microcrystalline cellulose, about 20-40% by weight of mannitol, about 1-10% by weight of carboxymethyl cellulose, about 1-10% by weight of hydroxypropyl methycellulose and about 0.1-2% by weight of magnesium stearate.

2. (Previously Presented) A pharmaceutical composition comprising about 28.57% by weight of 2-(*tert*-butylamino)-4-((1R,3R,4R)-3-hydroxy-4-methylcyclohexylamino)-pyrimidine-5-carboxamide or a pharmaceutically acceptable salt, stereoisomer, solvate, hydrate, isotopologue or solid form thereof, about 37.43% by weight of microcrystalline cellulose, about 26% by weight of mannitol, about 4% by weight of carboxymethyl cellulose, about 3% by weight of hydroxypropyl methycellulose and about 1% by weight of magnesium stearate.

3. (Previously Presented) A pharmaceutical composition comprising about 20-40% by weight of 2-(*tert*-butylamino)-4-((1R,3R,4R)-3-hydroxy-4-methylcyclohexylamino)-pyrimidine-5-carboxamide or a pharmaceutically acceptable salt, stereoisomer, solvate, hydrate, isotopologue or solid form thereof, about 20-40% by weight of microcrystalline cellulose, about 20-40% by weight of mannitol, about 1-20% by weight of carboxymethyl cellulose, about 1-10% by weight of hydroxypropyl methycellulose and about 0.1-2% by weight of magnesium stearate.

4. (Previously Presented) A pharmaceutical composition comprising about 28.57% by weight of 2-(*tert*-butylamino)-4-((1R,3R,4R)-3-hydroxy-4-methylcyclohexylamino)-pyrimidine-5-carboxamide or a pharmaceutically acceptable salt, stereoisomer, solvate, hydrate, isotopologue or solid form thereof, about 33.43% by weight of microcrystalline cellulose, about 26% by weight of mannitol, about 8% by weight of carboxymethyl cellulose, about 3% by weight of hydroxypropyl methycellulose and about 1% by weight of magnesium stearate.

5. (Previously Presented) A pharmaceutical composition comprising about 28.57% by weight of 2-(*tert*-butylamino)-4-((1R,3R,4R)-3-hydroxy-4-methylcyclohexylamino)-pyrimidine-5-carboxamide or a pharmaceutically acceptable salt, stereoisomer, solvate, hydrate, isotopologue or solid form thereof, about 31.93% by weight of microcrystalline cellulose, about 26% by weight of mannitol, about 8% by weight of carboxymethyl cellulose, about 4.5% by weight of hydroxypropyl methycellulose and about 1% by weight of magnesium stearate.

6. (Previously Presented) A pharmaceutical composition comprising about 20-40% by weight of 2-(*tert*-butylamino)-4-((1R,3R,4R)-3-hydroxy-4-methylcyclohexylamino)-pyrimidine-5-carboxamide or a pharmaceutically acceptable salt, stereoisomer, solvate, hydrate, isotopologue or solid form thereof, about 20-50% by weight of microcrystalline cellulose, about 20-40% by weight of mannitol, about 1-10% by weight of carboxymethyl cellulose, about 1-10% by weight of hydroxypropyl methycellulose and about 0.1-2% by weight of magnesium stearate.

7. (Previously Presented) A pharmaceutical composition comprising about 28.57% by weight of 2-(*tert*-butylamino)-4-((1R,3R,4R)-3-hydroxy-4-methylcyclohexylamino)-pyrimidine-5-carboxamide or a pharmaceutically acceptable salt, stereoisomer, solvate, hydrate, isotopologue or solid form thereof, about 35.93% by weight of microcrystalline cellulose, about 26% by weight of mannitol, about 4% by weight of carboxymethyl cellulose, about 4.5% by weight of hydroxypropyl methycellulose and about 1% by weight of magnesium stearate.

8-13. (Canceled)

REMARKS

Upon entry of the presently made amendments, claims 1-7 will be pending.

Claim 8 and 10-13 are canceled, without prejudice.

No new matter has been added.

Applicant reserves their right to prosecute the subject matter of any canceled claim, any amended claim, any withdrawn claim or any unclaimed subject matter in one or more related applications.

Applicant acknowledges with thanks the Examiner's indication that claims 1-7 are allowable.

I. Claim Rejections

- A. Claims 8 and 10-13 are rejected under obviousness-type double patenting over claims 1-9 and 10-14 of US 9,365,524 to Man *et al.*, claims 1 and 45 of US 9,139,534 to Bennett *et al.*, or claims 21 and 40-43 of copending US Application No. 14/814,633 to Bennett *et al.*

Without acquiescing in the rejection and solely to expedite prosecution of the present application, Applicant has canceled claims 8 and 10-13, without prejudice.

Applicant respectfully submits that the rejection of claims 8 and 10-13 under obviousness-type double patenting is moot and should be withdrawn.

CONCLUSION

Applicant respectfully requests that the above remarks and amendments be entered in the present application file. If the Examiner has any comments or concerns or otherwise believes a telephone call could help resolve any remaining issues, the Examiner is invited to call the undersigned attorney at (404) 581-8614. No fee is estimated to be due in connection with this Response; however, in the event that any fee is due, please charge the required fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

Date: June 13, 2017

/Michael J. Bruner/

By: Michael J. Bruner (Reg. No. 47,458)

JONES DAY
250 Vesey Street
New York, New York 10281
(404) 581-8614



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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NEW YORK, NY 10281-1047

EXAMINER

SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
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1628

MAIL DATE	DELIVERY MODE
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04/13/2017

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. 14/969,750	Applicant(s) BOERSEN ET AL.	
	Examiner REI-TSANG SHIAO	Art Unit 1628	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.

- 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 2/2/2017.
☐ 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) 1-8 and 10-13 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 1-7 is/are allowed.
- 7) ☒ Claim(s) 8 and 10-13 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 12/15/2015 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. ____. |
| 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____. | 4) ☐ Other: ____. |

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

1. This application claims priority of the provisional applications: 62/196,044 with a filing date 07/23/2015; and 62/092,537 with a filing date 12/16/2014.
2. Amendment of claims 1-8 and 10-13, and cancelation of claim 9 in the amendment filed on 2/2/2017 is acknowledged. Claims 1-8 and 10-13 are pending in the application.

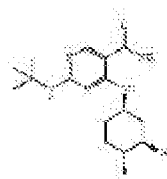
Responses to Amendments/Arguments

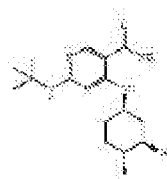
3. The rejection of claims 1-8, 10 and 12-13 under 35 U.S.C. 112 (a) or (b) has been overcome in the amendment filed on 2/02/2017. Since claim 9 has been canceled, the rejection of claim 9 under 35 U.S.C. 112 (a) or (b) has been obviated herein.
4. Applicant's arguments regarding the rejection of claims 8 and 10-13 under the obviousness-type double patenting over Man et al. '524, or Bennett et al. '534 or '633 have been fully considered but they are not persuasive.

Applicants claim methods of use for inhibiting JNK pathway and treating liver fibrotic disorder, interstitial pulmonary fibrosis, systemic sclerosis, or chronic allograft nephropathy using a composition comprising 20-40% by weight of a compound 2-(*tert*-butylamino)-4-((1R,3R,4R)-3-hydroxy-4-methylcyclohexylamino)-pyrimidine-5-carboxamide, and microcrystalline (i.e., pharmaceutical acceptable carrier), see claims 8, 10 and 12-13. Applicants also claim a salt of 2-(*tert*-butylamino)-4-((1R,3R,4R)-3-hydroxy-4-methylcyclohexyl amino)-pyrimidine-5-carboxamide, wherein the salt is a

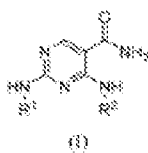
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hydrochloride salt, a sulfate salt, a phosphate salt, an tartrate salt, a succinate salt or a p-toluenesulfate salt, see claim 11.



Man et al. '524 claims a compound, i.e., , and its method of use for inhibiting JNK1 or JNK2 kinase and treating liver fibrotic disorder, interstitial pulmonary fibrosis, systemic sclerosis, or chronic allograft nephropathy, see columns 125-128.

Bennett et al. '633 claims a compound/composition of formula (I) or its salts, i.e.,

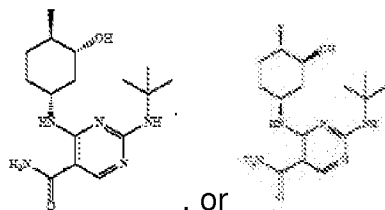


, wherein R1 is alkyl, R2 is substituted cycloalkyl, see claims 21 and 40, and methods of use for treating liver fibrotic disorder, see claims 41-42.

The difference between the instant claims and Man et al. '524 or Bennett et al. '633 is that the instant claims represent a species of Bennett et al. '633 compounds of formula (I). Man et al. '524 or Bennett et al. '633 methods of use overlap with the instant invention. It is noted that the instant the compound 2-(tert-butylamino)-4-((1R,3R,4R)-3-hydroxy-4-methylcyclohexylamino)-pyrimidine-5-carboxamide would release from the carrier or excipient (i.e., microcrystalline cellulose, mannitol or magnesium stearate) as an active ingredient for treatment after administration in the body fluid, and there is no distance from the administration of Man et al. '524 or Bennett et al. '633 methods of use for treating same diseases or disorders using the same compound. Without un-expected results, Man et al. '524 or Bennett et al. '633

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methods of use still render obviousness over the instant invention of claims 8, 10 and 12-13.



Bennett et al. '534 claims a compound , or , or its salt

or stereoisomer, see columns 501, 533, and 583. The salt is selected from hydrochloric, isethionic, lactic, maleic, malic, mandelic, methanesulfonic, mucic, nitric, pamoic, pantothenic, phenylacetic, phosphoric, propionic, salicylic, stearic, succinic, sulfanilic, sulfuric, tartaric acid, or p-toluenesulfonic acid, see line 14-25 in column 8. Therefore the instant salts of the compound of claim 11 are embraced within the scope of Bennett et al. '534 compound and its salt.

The rejection of claims 8 and 10-13 under the obviousness-type double patenting over Man et al. '524, or Bennett et al. '534 or '633 is maintained. Applicants are requested to file a terminal disclaimer to overcome the rejection. Since claim 9 has been canceled, therefore the rejection of claim 9 under the obviousness-type double patenting has been obviated herein.

5. Claims 1-7 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable.

6. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Patent Trial and Appeal Board or to an amendment complying with the requirements set forth below.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Winston Shen, can be reached on (571)272-3157. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from

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the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rei-tsang Shiao/

Rei-tsang Shiao, Ph.D.
Primary Examiner
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March 28, 2017