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NOTICE OF ALLOWANCE AND FEE(S) DUE

101325 7590 12/23/2015 GLOBAL PATENT GROUP - HOR 1005 NORTH WARSON ROAD SUITE 404 SAINT LOUIS, MO 63132 EXAMINER
RAO, SAVITHA M

ART UNIT PAPER NUMBER

1621

DATE MAILED: 12/23/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/816,674	08/03/2015	Bruce Scharschmidt	HOR0026-201TC1-US	9599

TITLE OF INVENTION: METHODS OF THERAPEUTIC MONITORING OF NITROGEN SCAVENGING DRUGS

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	03/23/2016

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

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P.O. Box 1450 Alexandria, Virginia 22313-1450 or <u>Fax</u> (571)-273-2885

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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.

	7590 12/23 TENT GROUP - H YARSON ROAD MO 63132		I her State addr trans	Cer leby certify that this s Postal Service we sesed to the Mail mitted to the USP	tificate is Fee(s vith suff Stop TO (57)	of Mailing or Transt s) Transmittal is being ficient postage for firs ISSUE FEE address 1) 273-2885, on the da	deposited with the United t class mail in an envelope above, or being facsimile te indicated below. (Depositor's name) (Signature) (Date)
APPLICATION NO.	FILING DATE	<u> </u>	FIRST NAMED INVENTOR		ATTO	RNEY DOCKET NO.	CONFIRMATION NO.
14/816,674 08/03/2015 ITTLE OF INVENTION: METHODS OF THERAPEUTIC MONIT		APEUTIC MONITORIN	Bruce Scharschmidt HOR0026-201TC1-US 9599 TORING OF NITROGEN SCAVENGING DRUGS				
APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE PREV. PAID ISS		E FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0		\$960	03/23/2016
EXAMINER ART UNIT		ART UNIT	CLASS-SUBCLASS				
RAO, SAV	VITHA M	1621	424-009200				
"Fee Address" indi PTO/SB/47; Rev 03-0 Number is required. 3. ASSIGNEE NAME A	ondence address (or Cha 3/122) attached. ication (or "Fee Address' 2 or more recent) attach ND RESIDENCE DATA ess an assignee is ident h in 37 CFR 3.11. Comp	nge of Correspondence Indication form ad. Use of a Customer A TO BE PRINTED ON	2. For printing on the part of the part of the part of a single registered attorney or a 2 registered patent attorney in the part of the p	3 registered patenely, e firm (having as a gent) and the namelys or agents. If porinted. e) etent. If an assignessignment.	members of up no nam	er a 2	ocument has been filed for
4a. The following fee(s) a	are submitted: To small entity discount p	4	b. Payment of Fee(s): (Plea A check is enclosed. Payment by credit care The director is hereby overpayment, to Depo	se first reapply and 1. Form PTO-2038 authorized to charg	y prev	iously paid issue fee sched. equired fee(s), any defi	shown above)
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 cer fee payment in the micro NOTE: If the application to be a notification of loss NOTE: Checking this box entity status, as applicable	entity amount will was previously und of entitlement to r will be taken to be	not bé a der mica micro es	accepted at the risk of a ro entity status, checkintity status.	application abandonment. ng this box will be taken
NOTE: This form must b	e signed in accordance v	vith 37 CFR 1.31 and 1.3	33. See 37 CFR 1.4 for signa		and cer	tifications.	
Authorized Signature				Date			





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101325 75	90 12/23/2015	EXAMINER		
GLOBAL PATENT GROUP - HOR 1005 NORTH WARSON ROAD			RAO, SA	VITHA M
SUITE 404	KSON KOAD		ART UNIT	PAPER NUMBER
SAINT LOUIS, MO 63132			1621	

DATE MAILED: 12/23/2015

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.



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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.
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- 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 issuad patent.



Application No. 14/816.674	Applicant(s) SCHARSCHMIDT ET AL.		
Examiner SAVITHA RAO	Art Unit 1621	AIA (First Inventor to File) Status No	

The MAILING DATE of this communication appears on the All claims being allowable, PROSECUTION ON THE MERITS IS (OR REM herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other a NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. To of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPE	MAINS) CLOSED in this application. If not included appropriate communication will be mailed in due course. THIS his application is subject to withdrawal from issue at the initiative			
1. Image: This communication is responsive to 1.1/20/2015 . Image: 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 <u>13-26</u> . 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:				
 Certified copies of the priority documents have been rec 				
2. Certified copies of the priority documents have been rec	···			
3. Copies of the certified copies of the priority documents h	nave 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 connoted below. Failure to timely comply will result in ABANDONMENT of the THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.				
5. CORRECTED DRAWINGS (as "replacement sheets") must be subm	nitted.			
including changes required by the attached Examiner's Amendr Paper No./Mail Date	nent / Comment or in the Office action of			
Identifying indicia such as the application number (see 37 CFR 1.84(c)) sho each sheet. Replacement sheet(s) should be labeled as such in the header				
6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGIC attached Examiner's comment regarding REQUIREMENT FOR THE D				
Attachment(s)				
1. Notice of References Cited (PTO-892)	5. Examiner's Amendment/Comment			
2. 🛮 Information Disclosure Statements (PTO/SB/08),	6. X Examiner's Statement of Reasons for Allowance			
Paper No./Mail Date <u>11/05/2015</u> 3. ☐ Examiner's Comment Regarding Requirement for Deposit	7. Other			
of Biological Material	7. <u>Gallot</u>			
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date				
/SAVITHA RAO/				
Primary Examiner, Art Unit 1621				



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