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NOTICE OF ALLOWANCE AND FEE(S) DUE

31554 7590 06/12/2020
CARTER, DELUCA & FARRELL LLP
576 BROAD HOLLOW ROAD
MELVILLE, NY 11747

EXAMINER

SHIAO, REI TSANG

ART UNIT

PAPER NUMBER

1629

DATE MAILED: 06/12/2020

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/789,709	02/13/2020	Matthew DURING	2262-29 CON B CON II	4611

TITLE OF INVENTION: METHODS AND COMPOSITIONS FOR TREATMENT OF EPILEPTIC DISORDERS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0.00	\$0.00	\$500	09/14/2020

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: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (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)

31554 7590 06/12/2020
CARTER, DELUCA & FARRELL LLP
576 BROAD HOLLOW ROAD
MELVILLE, NY 11747

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.

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 transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/789,709	02/13/2020	Matthew DURING	2262-29 CON B CON II	4611

TITLE OF INVENTION: METHODS AND COMPOSITIONS FOR TREATMENT OF EPILEPTIC DISORDERS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0.00	\$0.00	\$500	09/14/2020

EXAMINER	ART UNIT	CLASS-SUBCLASS
SHIAO, REI TSANG	1629	514-171000

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 03-09 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,

(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.

1 _____

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 must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). 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. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

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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31554 7590 06/12/2020 CARTER, DELUCA & FARRELL LLP 576 BROAD HOLLOW ROAD MELVILLE, NY 11747			EXAMINER SHIAO, REI TSANG	
			ART UNIT	PAPER NUMBER
			1629	
DATE MAILED: 06/12/2020				

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 30 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. 16/789,709	Applicant(s) DURING, Matthew	
	Examiner REI TSANG SHIAO	Art Unit 1629	AIA (FITF) 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 4/20/2020.
☐ 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 6-25 . 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 5/13/20.	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 1629	
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Notice of Pre-AIA or AIA Status

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

Priority and Status of the Claims

1. This application is a CON of 16/447,300 06/20/2019 PAT 10603308, which is a CON of 16/356,517 03/18/2019 PAT 10363246, which is a CON of 16/013,500 06/20/2018 ABN, which is a CON of 15/673,737 08/10/2017 ABN, which claims benefit of 62/490,293 04/26/2017, and claims benefit of 62/373,589 08/11/2016.
2. Amendment including a terminal disclaimer in the amendment filed on 4/20/2020 is acknowledged. Claims 6-25 are pending in the application.

Reasons for Allowance

3. Applicant's arguments regarding the rejection of claims 6-25 under the obviousness-type double patenting over During's '246 have been fully considered and they are persuasive. Since During's '246 does not claim the instant methods of use, therefore it is distinct from the instant invention. The rejection of claims 6-25 under the obviousness-type double patenting over During's '246 have been withdrawn herein.
4. Since the terminal disclaimer against During's '308 has been filed and approved in the Office, therefore the rejection of claims 6-25 under the obviousness-type double patenting over During's '308 has been overcome in the amendment filed on 4/20/2020.

5. Claims 6-25 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 methods of use has not been found. Claims 6-25 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.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Lundgren can be reached on 571-272-5541. 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 1629

June 09, 2020

Electronic Acknowledgement Receipt	
EFS ID:	39204559
Application Number:	16789709
International Application Number:	
Confirmation Number:	4611
Title of Invention:	METHODS AND COMPOSITIONS FOR TREATMENT OF EPILEPTIC DISORDERS
First Named Inventor/Applicant Name:	Matthew DURING
Customer Number:	31554
Filer:	Jeffrey S. Steen/Julie Dascoli
Filer Authorized By:	Jeffrey S. Steen
Attorney Docket Number:	2262-29 CON B CON II
Receipt Date:	20-APR-2020
Filing Date:	13-FEB-2020
Time Stamp:	13:47:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2262-29_CON_B_CON_II_TK1_-_Response_to_OA.pdf	132776	yes	5
			3c39b9a4e6142e6545a3e103b81e9cba692d1ce6		

Multipart Description/PDF files in .zip description			
Document Description		Start	End
Amendment/Req. Reconsideration-After Non-Final Reject		1	1
Claims		2	4
Applicant Arguments/Remarks Made in an Amendment		5	5

Warnings:

Information:

Total Files Size (in bytes):	132776
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Docket: 2262-29 CON B CON II TK1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Matthew DURING

Application No.: 16/789,709

Confirmation No.: 4611

Filed: February 13, 2020

Art Unit: 1629

For: METHODS AND COMPOSITIONS FOR
TREATMENT OF EPILEPTIC DISORDERS

Examiner: Shiao, Rei Tsang

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION

Sir:

This is a response to the Office Action dated April 17, 2020.

Listing of Claims begins on page 2.

Remarks begin on page 5 of this submission.

LISTING OF CLAIMS

The following listing of claims will replace all prior versions, and listings, of claims in the present application:

Claims 1-5 (Cancelled).

6. (Previously presented) A method of treating PCDH19 related epilepsy comprising administering to a patient in need thereof a pharmaceutical composition comprising ganaxolone or a pharmaceutically acceptable salt thereof.
7. (Previously presented) The method of claim 6, wherein the patient is administered ganaxolone or a pharmaceutically acceptable salt thereof twice daily.
8. (Previously presented) The method of claim 6, wherein the patient is administered ganaxolone or a pharmaceutically acceptable salt thereof three times daily.
9. (Previously presented) The method of claim 6, wherein the patient is administered ganaxolone or a pharmaceutically acceptable salt thereof in an amount of up to 1,800 mg/day.
10. (Previously presented) The method of claim 6, wherein the pharmaceutical composition is an oral capsule.
11. (Previously presented) The method of claim 6, wherein the pharmaceutical composition is an oral suspension.
12. (Previously presented) The method of claim 6, wherein the pharmaceutical composition is an oral suspension comprising 50 mg/ml ganaxolone or a pharmaceutically acceptable salt thereof.

13. (Previously presented) The method of claim 6, wherein the pharmaceutical composition is an oral suspension comprising 50 mg/ml ganaxolone or a pharmaceutically acceptable salt thereof and is administered three times daily.

14. (Previously presented) The method of claim 6, wherein the pharmaceutical composition is an oral suspension comprising 50 mg/ml ganaxolone or a pharmaceutically acceptable salt thereof administered three times daily wherein the patient is administered an amount of up to 1,800 mg/day

15. (Previously presented) The method of claim 6, wherein the patient is administered 600 mg ganaxolone or a pharmaceutically acceptable salt thereof.

16. (Previously presented) The method of claim 6, wherein the patient is administered 600 mg ganaxolone or a pharmaceutically acceptable salt thereof three times daily.

17. (Previously presented) The method of claim 6, wherein the patient is administered 50 mg ganaxolone or a pharmaceutically acceptable salt thereof.

18. (Previously presented) The method of claim 6, wherein the patient is administered 100 mg ganaxolone or a pharmaceutically acceptable salt thereof.

19. (Previously presented) The method of claim 6, wherein the patient is administered 200 mg ganaxolone or a pharmaceutically acceptable salt thereof.

20. (Previously presented) The method of claim 6, wherein the patient is administered 300 mg ganaxolone or a pharmaceutically acceptable salt thereof.

21. (Previously presented) The method of claim 6, wherein the patient is administered 400 mg ganaxolone or a pharmaceutically acceptable salt thereof.

22. (Previously presented) The method of claim 6, wherein the patient is administered 500 mg ganaxolone or a pharmaceutically acceptable salt thereof.

23. (Previously presented) The method of claim 6, wherein the patient is administered oral capsules comprising 200-600 mg ganaxolone or a pharmaceutically acceptable salt thereof.

24. (Previously presented) The method of claim 6, wherein the pharmaceutical composition provides reduction in the frequency of seizures.

25. (Previously presented) The method of claim 6, wherein the pharmaceutical composition provides reduction in the frequency of seizures, the severity of seizures, or a combination thereof.

REMARKS

This is a response to the Office Action dated April 17, 2020. Currently, claims 6-25 are pending and have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable independently over claims 1-5 of During's US 10,363,246, (the “‘246 patent”) and over claims 1-13 of During's US 10,603,308 respectively. Submitted herewith is a terminal disclaimer in connection with US 10,603,308.

Reconsideration of the double patenting rejection over the ‘246 patent is respectfully requested.

It is respectfully submitted that this rejection is improper because the respective claims of the ‘246 patent and the claims of the present application are directed to unrelated drugs and different indications. Applicant respectfully notes that the basis for the rejection, as set forth in the Office Action, at page 3, is incorrect since it erroneously contends that the claims of the ‘246 patent involve ganaxolone. The ‘246 patent claims recite gaboxadol, not ganaxolone. Reconsideration and withdrawal of the rejection under obviousness-type double patenting over the ‘246 patent is therefore respectfully requested.

A good faith effort has been made to place the present application in condition for allowance. Should the Examiner believe that a telephone interview may facilitate prosecution of this application, the Examiner is respectfully requested to call Applicants’ representative at the number indicated below.

Please charge any deficiency as well as any other fees that may become due under 37 C.F.R. § 1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fees, to Deposit Account No. 50-2140.

Dated: April 20, 2020

Respectfully submitted,

/Jeffrey S. Steen, Reg. #32063/

Jeffrey S. Steen
Registration No.: 32,063
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/789,709	02/13/2020	Matthew DURING	2262-29 CON B CON II	4611
31554	7590	04/17/2020	EXAMINER	
CARTER, DELUCA & FARRELL LLP			SHIAO, REI TSANG	
576 BROAD HOLLOW ROAD				
MELVILLE, NY 11747				
			ART UNIT	PAPER NUMBER
			1629	
			NOTIFICATION DATE	DELIVERY MODE
			04/17/2020	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):

docket@carterdeluca.com

Notice of Pre-AIA or AIA Status

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

Priority and Status of the Claims

1. This application is a CON of 16/447,300 06/20/2019 PAT 10603308, which is a CON of 16/356,517 03/18/2019 PAT 10363246, which is a CON of 16/013,500 06/20/2018 ABN, which is a CON of 15/673,737 08/10/2017 ABN, which claims benefit of 62/490,293 04/26/2017, and claims benefit of 62/373,589 08/11/2016.
2. Claims 6-25 are pending in the application.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (c) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable independently over claims 1-5 of During's US 10,363,246, and over claims 1-13 of During's US 10,603,308 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim a method of treating PCDH19 related epilepsy comprising administering to a patient in need thereof a pharmaceutical composition comprising ganaxolone or a pharmaceutically acceptable salt thereof, see claim 6. Dependent claims 7-25 further limit the scope of methods, i.e., a dose range and strategy in claims 7-25.

During's '246 claims a method of method of treating essential tremor (i.e., CDKL5 disorder or epilepsy) comprising administering to a patient in need thereof a pharmaceutical composition comprising ganaxolone or a pharmaceutically acceptable salt thereof wherein the patient is administered 0.05 mg to 30 mg of ganaxolone, see column 38.

During's '308 claims a method of treating CDKL5 deficiency disorder comprising administering to a patient in need thereof a pharmaceutical composition comprising

ganaxolone or a pharmaceutically acceptable salt thereof wherein the patient is administered up to 1,800 mg of ganaxolone per day. The CDKL5 deficiency disorder is frequency of seizures, the severity of seizures, or a combination thereof (i.e., epilepsy), see columns 38-39.

The difference between instant claims and During's '246 and '308 is that the instant claims are silent on the scope of dose of ganaxolone.

One having ordinary skill in the art would find the claims 6-25 *prima facie* obvious because one would be motivated to employ the methods of use of During's '246 and '308 to obtain instant invention.

Moreover, the amount of a specific amount ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize, optimization of parameters (dose, time, or weight ratio) is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results based on factors such as the expected amount up to 1800 mg of ganaxolone. In the instant case, a person would modify the amount or dose of ganaxolone from During's '246 and '308 to reach the instant dose of claim 6.

The motivation to make the claimed methods of use derived from the known methods of use of During's '246 and '308 would possess same yields to that which is claimed in the reference.

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.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Lundgren can be reached on 571-272-5541. 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.

Application/Control Number: 16/789,709
Art Unit: 1629

Page 6

/REI TSANG SHIAO/

Rei-tsang Shiao, Ph.D.
Primary Examiner, Art Unit 1629

April 14, 2020

Electronic Acknowledgement Receipt	
EFS ID:	38577801
Application Number:	16789709
International Application Number:	
Confirmation Number:	4611
Title of Invention:	METHODS AND COMPOSITIONS FOR TREATMENT OF EPILEPTIC DISORDERS
First Named Inventor/Applicant Name:	Matthew DURING
Customer Number:	31554
Filer:	Jeffrey S. Steen/Kathleen Dugo-Sandvik
Filer Authorized By:	Jeffrey S. Steen
Attorney Docket Number:	2262-29 CON B CON II TK1
Receipt Date:	13-FEB-2020
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Authorized User	Kathleen Dugo-Sandvik
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.17 (Patent application and reexamination processing fees) 37 CFR 1.19 (Document supply fees)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	TrackOne Request	01560775.PDF	267336	no	2
			a10aee59b5fd7a8ad055260e8634e252c2f3dba		

Warnings:**Information:**

2		01560787.PDF	5995909	yes	58
			fcde9106ee0db387baf454d12cc02d7e2ebb185d		

Multipart Description/PDF files in .zip description

	Document Description	Start	End
	Specification	1	56
	Claims	57	57
	Abstract	58	58

Warnings:**Information:**

3	Drawings-only black and white line drawings	01560788.PDF	433422	no	4
			5fb6c039bd1a1518098422ec3bdf26eb0e82e495		

Warnings:**Information:**

4	Application Data Sheet	01560781.PDF	742342	no	7
			447d01cc7f11fbac97503781a4ca42a989b37d7		

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This is not an USPTO supplied ADS fillable form

5	Oath or Declaration filed	01560783.PDF	137731	no	1
			84650a2db01c502ae5eb495eb6e97ef20f1d16d1		
Warnings:					
Information:					
6	Power of Attorney	01560782.PDF	196678	no	1
			c3de581a369c136667ac73e3dc839fe07472039b		
Warnings:					
Information:					
7	Preliminary Amendment	01560785.PDF	300447	no	6
			edc843104ffe719e2bb366d1fcec32dd5e8f3b2		
Warnings:					
Information:					
8	Fee Worksheet (SB06)	fee-info.pdf	40602	no	2
			a3cbc886e7263df76cb9561fd7f1931f995f5d9f		
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Total Files Size (in bytes):			8114467		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Matthew DURING

Application No.:

Confirmation No.: 7072

Filed:

Art Unit: 1629

For: METHODS AND COMPOSITIONS FOR
TREATMENT OF EPILEPTIC DISORDERS

Examiner: Shiao, Rei Tsang

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Sir:

Prior to examination on the merits, please amend the above-identified application as follows:

Amendments to the Specification are at page 2 of this submission.

Amendments to the Claims are at page 3 of this submission

Remarks begin on page 7 of this submission.

AMENDMENTS TO SPECIFICATION

Please amend page 1, paragraph [0001], as follows:

-- CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation application of U.S. Patent Application No. 16/447,300, filed June 20, 2019, which is a continuation of U.S. Patent Application No. 16/356,517, filed March 18, 2019, which is a continuation of U.S. Patent Application No. 16/013,500, filed June 20, 2018, which is a continuation of U.S. Patent Application No. 15/673,737, filed August 10, 2017, which claims benefit of and priority to U.S. Provisional Application No. 62/490,293, filed April 26, 2017 and U.S. Provisional Application No. 62/373,589, filed August 11, 2016, and all of which are incorporated herein by reference in their respective entireties.

AMENDMENTS TO THE CLAIMS

The following listing of claims will replace all prior versions, and listings, of claims in the present application:

Claims 1-5 (Cancelled).

6. (New) A method of treating PCDH19 related epilepsy comprising administering to a patient in need thereof a pharmaceutical composition comprising ganaxolone or a pharmaceutically acceptable salt thereof.

7. (New) The method of claim 6, wherein the patient is administered ganaxolone or a pharmaceutically acceptable salt thereof twice daily.

8. (New) The method of claim 6, wherein the patient is administered ganaxolone or a pharmaceutically acceptable salt thereof three times daily.

9. (New) The method of claim 6, wherein the patient is administered ganaxolone or a pharmaceutically acceptable salt thereof in an amount of up to 1,800 mg/day.

10. (New) The method of claim 6, wherein the pharmaceutical composition is an oral capsule.

11. (New) The method of claim 6, wherein the pharmaceutical composition is an oral suspension.

12. (New) The method of claim 6, wherein the pharmaceutical composition is an oral suspension comprising 50 mg/ml ganaxolone or a pharmaceutically acceptable salt thereof.

13. (New) The method of claim 6, wherein the pharmaceutical composition is an oral suspension comprising 50 mg/ml ganaxolone or a pharmaceutically acceptable salt thereof and is administered three times daily.

14. (New) The method of claim 6, wherein the pharmaceutical composition is an oral suspension comprising 50 mg/ml ganaxolone or a pharmaceutically acceptable salt thereof administered three times daily wherein the patient is administered an amount of up to 1,800 mg/day
15. (New) The method of claim 6, wherein the patient is administered 600 mg ganaxolone or a pharmaceutically acceptable salt thereof.
16. (New) The method of claim 6, wherein the patient is administered 600 mg ganaxolone or a pharmaceutically acceptable salt thereof three times daily.
17. (New) The method of claim 6, wherein the patient is administered 50 mg ganaxolone or a pharmaceutically acceptable salt thereof.
18. (New) The method of claim 6, wherein the patient is administered 100 mg ganaxolone or a pharmaceutically acceptable salt thereof.
19. (New) The method of claim 6, wherein the patient is administered 200 mg ganaxolone or a pharmaceutically acceptable salt thereof.
20. (New) The method of claim 6, wherein the patient is administered 300 mg ganaxolone or a pharmaceutically acceptable salt thereof.
21. (New) The method of claim 6, wherein the patient is administered 400 mg ganaxolone or a pharmaceutically acceptable salt thereof.
22. (New) The method of claim 6, wherein the patient is administered 500 mg ganaxolone or a pharmaceutically acceptable salt thereof.
23. (New) The method of claim 6, wherein the patient is administered oral capsules comprising 200-600 mg ganaxolone or a pharmaceutically acceptable salt thereof.

24. (New) The method of claim 6, wherein the pharmaceutical composition provides reduction in the frequency of seizures.

25. (New) The method of claim 6, wherein the pharmaceutical composition provides reduction in the frequency of seizures, the severity of seizures, or a combination thereof.

REMARKS

Applicant respectfully requests that the amendments to the above-identified application, presented herein, be entered prior to examination.

Claims 1-5 have been cancelled. New Claims 6-25 have been added. Support may be found throughout the specification and originally filed claims, *see, e.g.*, paragraphs 7, 20, 32, 33, and 83. Applicant submits that no new matter has been added by the present Amendment.

If the Examiner believes that a telephone interview may facilitate prosecution of this application, or resolve any outstanding matters, the Examiner is sincerely invited to contact the Applicant's undersigned representative at the number indicated below.

Applicant respectfully requests early and favorable consideration of this application on the merits.

Please charge any deficiency as well as any other fee(s) that may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s), to Deposit Account No. 50-2140. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 50-2140 therefor.

Dated: February 13, 2020

Respectfully submitted,

/Jeffrey S. Steen, Reg. #32063/

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