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NOTICE OF ALLOWANCE AND FEE(S) DUE

31554 7590 02/11/2020
Carter, DeLuca & Farrell LLP
576 Broad Hollow Road
MELVILLE, NY 11747

EXAMINER

SHIAO, REI TSANG

ART UNIT

PAPER NUMBER

1629

DATE MAILED: 02/11/2020

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/447,300	06/20/2019	Matthew DURING	2262-29 CON B CON TK1	7072

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	UNDISCOUNTED	\$1000	\$0.00	\$0.00	\$1000	05/11/2020

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 02/11/2020
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.
16/447,300	06/20/2019	Matthew DURING	2262-29 CON B CON TK1	7072

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	UNDISCOUNTED	\$1000	\$0.00	\$0.00	\$1000	05/11/2020

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. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

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16/447,300	06/20/2019	Matthew DURING	2262-29 CON B CON TK1	7072
31554	7590	02/11/2020	EXAMINER	
Carter, DeLuca & Farrell LLP			SHIAO, REI TSANG	
576 Broad Hollow Road			ART UNIT	
MELVILLE, NY 11747			PAPER NUMBER	
			1629	
DATE MAILED: 02/11/2020				

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. 16/447,300	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 remarks filed on 1/10/2020.
☐ 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 6-18 . 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 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 16/356,517 03/18/2019 PAT 10363246 which is a CON of 16/013,500 06/20/2018, 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. Applicant's remarks and cancelation of claims 1-5 in the amendment filed on 1/10/2020 is acknowledged. Claims 6-18 are pending in the application.

Reasons for Allowance

3. 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 and 18 under the obviousness-type double patenting has been withdrawn herein.
4. Since During's '500 and '074 have been abandoned, therefore the provisional rejection of claim 6 under the obviousness-type double patenting or under Statutory (35 USC 101) double patenting has been obviated herein.
5. Claims 6-18 are neither anticipated nor rendered obvious over the record, and therefore are allowable. A suggestion for modification of a reference to obtain the instant methods of use has not been found. Claims 6-18 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.

Application/Control Number: 16/447,300
Art Unit: 1629

Page 4

/REI TSANG SHIAO/

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

February 05, 2020

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Matthew DURING

Application No.: 16/447,300

Confirmation No.: 7072

Filed: June 20, 2019

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 FINAL OFFICE ACTION

Sir:

This is a response to the Final Office Action dated January 2, 2020.

Listing of Claims begins on page 2.

Remarks begin on page 4 of this submission.

/REI TSANG SHIAO/

02/05/2020

entered

Electronic Acknowledgement Receipt	
EFS ID:	38259505
Application Number:	16447300
International Application Number:	
Confirmation Number:	7072
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 TK1
Receipt Date:	10-JAN-2020
Filing Date:	20-JUN-2019
Time Stamp:	10:43:18
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_TK1_-_Response_to_Final_OA.pdf	878617 ed35bfc8e385be60f6ae9b9c7ad14297bb259f6	yes	20

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Applicant Arguments/Remarks Made in an Amendment	4	20
	Claims	2	3
	Response After Final Action	1	1
Warnings:			
Information:			
Total Files Size (in bytes):		878617	
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.			

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Matthew DURING

Application No.: 16/447,300

Confirmation No.: 7072

Filed: June 20, 2019

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 FINAL OFFICE ACTION

Sir:

This is a response to the Final Office Action dated January 2, 2020.

Listing of Claims begins on page 2.

Remarks begin on page 4 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 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.

7. (Previously Presented) The method of claim 6, wherein the patient is administered ganaxolone twice daily.

8. (Previously Presented) The method of claim 6, wherein the pharmaceutical composition is an oral capsule.

9. (Previously Presented) The method of claim 6, wherein the pharmaceutical composition is an oral suspension.

10. (Previously Presented) The method of claim 6, wherein the pharmaceutical composition comprises 200 mg ganaxolone.

11. (Previously Presented) The method of claim 6, wherein the pharmaceutical composition comprises 400 mg ganaxolone.

12. (Previously Presented) The method of claim 6, wherein the pharmaceutical composition comprises 450 mg ganaxolone.

13. (Previously Presented) The method of claim 6, wherein the pharmaceutical composition comprises 600 mg ganaxolone.
14. (Previously Presented) The method of claim 6, wherein the pharmaceutical composition comprises 900 mg ganaxolone.
15. (Previously Presented) The method of claim 6, wherein the pharmaceutical composition comprises 1800 mg ganaxolone.
16. (Previously Presented) The method of claim 6, wherein the patient is administered oral capsules comprising 200-600 mg ganaxolone twice daily.
17. (Previously Presented) The method of claim 6, wherein the composition provides reduction in the frequency of seizures.
18. (Previously Presented) The method of claim 6, wherein the composition provides reduction in the frequency of seizures, the severity of seizures, or a combination thereof.

REMARKS

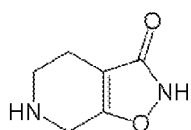
This is a response to the Final Office Action dated January 2, 2020. Currently, claims 6-18 are pending and have been rejected. Applicant notes with appreciation the indication in Office Action that the rejections under 35 U.S.C 112 (a) and 35 U.S.C 103 (a) have been overcome.

According to the Final Office Action, the only remaining rejections are the obviousness-type double patenting rejection of claims 6 and 18 over During et al. '246 and the statutory (35 USC 101) double patenting rejection of claim 6 over During et al. '500. Reconsideration and/or clarification of the present rejections are respectfully requested in view of the following comments.

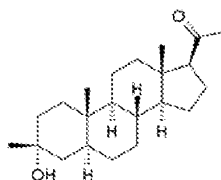
I. Rejection of Claims 6 and 18 Under Obviousness-Type Double Patenting Over Claims 1 and 5 of US Pat. No. 10,363,246 to During

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. The basis for the rejection, as set forth in the previous Office Action dated October 8, 2019, at pages 11-12, paragraph 6.1,¹ is incorrect since it erroneously contends that the claims of the '246 patent involve ganaxolone. The '246 patent claims recite gaboxadol, not ganaxolone.

That gaboxadol and ganaxolone are unrelated is clearly evident from their respective structures:



gaboxadol



ganaxolone

¹ As stated therein: "During's '246 claims a method of method of treating essential tremor (I.e., CDKL5 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 1 mg to 5 mg of ganaxolone, see column 28." (emphasis added)

There is nothing of record that would lead one skilled in the art to substitute gaboxadol for ganaxolone or ganaxolone for gaboxadol in treating CDKL5 deficiency disorder.

Accordingly, the present claims are not obvious over the ‘246 patent.

Moreover, CDKL5 deficiency disorder and essential tremors are different conditions and cannot be equated. Attention is respectfully directed to Exhibit 1 attached hereto which is a publication of the U.S. National Library of Medicine describing CDKL5 deficiency disorder and to Exhibit 2 attached hereto which is a publication of the U.S. National Library of Medicine describing essential tremor. Nowhere in the description of CDKL5 disorder is there any mention of essential tremor. Likewise, nowhere in the description of essential tremor is there any mention of CDKL5 disorder.

Indeed, there is nothing of record that would lead one skilled in the art to equate essential tremor with CDKL5 deficiency disorder. Accordingly, it cannot be obvious to treat CDKL5 deficiency disorder with ganaxolone based on use of gaboxadol to treat essential tremor.

Reconsideration and withdrawal of the rejection of claims 6 and 18 under obviousness-type double patenting over claims 1 and 5 of the ‘246 patent and withdrawal of the requirement for a terminal disclaimer against the ‘246 patent are therefore respectfully requested.

II. Statutory (35 USC 101) Double Patenting Rejection of Claim 6 Over US Application No. 16/013,500 to During

In the Final Office Action at page 3, paragraph 6, it states that, “the provisional rejection of claim 6 under Statutory (35 U.S.C 101) double patenting over During’s ‘500 is maintained.”

However, there is no Statutory (35 U.S.C 101) double patenting rejection over During’s ‘500 application in the previous Office Action dated October 8, 2019.

A review of the previous Office Action, page 14, paragraph 6.3, indicates that the statutory (35 U.S.C 101) double patenting rejection was actually based on During’s U.S. Application No. 16/204,074 and not During ‘500.

Unlike the previous Office Action, there is no reference to a double patenting rejection based on During’s U.S. Application No. 16/204,074 in the Final Office Action. Clarification is respectfully requested.

Regarding During ‘500, according to the previous Office Action, page 13, paragraph 6.2, claim 6 was provisionally rejected under the judicially created doctrine of obviousness-type

double patenting over claims 1 and 18 of During '500. Accordingly, the indication in the Final Office Action that the statutory (35 USC 101) double patenting rejection of claim 6 over During et al. '500 is being maintained appears to be incorrect. Clarification is requested.

III. Express Abandonment

In an effort to facilitate prosecution and allowance of the present application, submitted simultaneously with this Response is an express abandonment of US Application No. 16/013,500 which moots the provisional obviousness-type double patenting rejection of claim 6 over the '500 application. Also submitted simultaneously with this Response is an express abandonment of U.S. Application No. 16/204,074 which moots the statutory double patenting rejection of claim 6.

IV. Conclusion

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: January 10, 2020

Respectfully submitted,

/Jeffrey S. Steen, Reg. #32063/

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/447,300	06/20/2019	Matthew DURING	2262-29 CON B CON TK1	7072
31554	7590	01/02/2020	EXAMINER	
Carter, DeLuca & Farrell LLP 576 Broad Hollow Road MELVILLE, NY 11747			SHIAO, REI TSANG	
			ART UNIT	PAPER NUMBER
			1629	
			NOTIFICATION DATE	DELIVERY MODE
			01/02/2020	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

Office Action Summary	Application No. 16/447,300	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 --

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 10/24/2019.
☐ 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) 6-18 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.

6) ☐ Claim(s) ____ is/are allowed.

7) ☒ Claim(s) 6-18 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 6/20/2019 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)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date 12/18/19.

3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.

4) ☐ Other: ____.

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 16/356,517 03/18/2019 PAT 10363246 which is a CON of 16/013,500 06/20/2018, 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 of claim 6 and cancelation of claims 1-5 in the amendment filed on 10/24/2019 is acknowledged. Claims 6-18 are pending in the application.

Responses to Amendments/Arguments

3. The rejection of claim 6 under 35 U.S.C.112 (a) has been overcome in the amendment filed on 10/24/2019.
4. Since Shaw et al. '087, Jones et al. '853 in view of Bahi-Buisson et al. and Archer et al. does not disclose the instant methods of use, therefore they are distinct from the instant invention. The rejection of claims 6-18 under 35 U.S.C. 103 (a) over Shaw et al. '087, Jones et al. '853 in view of Bahi-Buisson et al. and Archer et al. has been overcome in the amendment filed on 10/24/2019.
5. Since a terminal disclaimer against During's et al. '246 has not been filed to the Office, therefore the rejection of claims 6 and 18 under the obviousness-type double patenting over During's et al. '246 is maintained. Applicants are requested to file a terminal disclaimer to the Office.

6. Since claims 1 and 18 of During's et al. '500 has not been amended, therefore the provisional rejection of claim 6 under Statutory (35 USC 101) double patenting over During's et al. '500 is maintained.

7. 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 appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. 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.

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: 16/447,300
Art Unit: 1629

Page 5

/REI TSANG SHIAO/

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

December 24, 2019

Electronic Acknowledgement Receipt	
EFS ID:	37548930
Application Number:	16447300
International Application Number:	
Confirmation Number:	7072
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 TK1
Receipt Date:	24-OCT-2019
Filing Date:	20-JUN-2019
Time Stamp:	12:08:11
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_TK1_-_Response_to_OA.pdf	201539	yes	7
			6b14dab335c25c9afd635746105b76db14ca85f3		

Multipart Description/PDF files in .zip description					
Document Description			Start	End	
Amendment/Req. Reconsideration-After Non-Final Reject			1	1	
Claims			2	3	
Applicant Arguments/Remarks Made in an Amendment			4	7	
Warnings:					
Information:					
2	Non Patent Literature	American_Epilepsy_Society_Ab stract_2018_01392663xB7E30. pdf	156293 a5c373d3383d2c2aab9aa5503c6bab3ece8 69d4f	no	3
Warnings:					
Information:					
3	Non Patent Literature	GEBN_Article_01392846xB7E30 .pdf	1375254 cb432165e8c32ab8774da7469bc864ed46 8181a	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			1733086		
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.					

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Matthew DURING

Application No.: 16/447,300

Confirmation No.: 7072

Filed: June 20, 2019

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 non-final Office Action dated October 8, 2019.

Amendments to the **Claims** begin on page 2.

Remarks begin on page 4 of this submission.

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. (Currently Amended) 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.
7. (Previously Presented) The method of claim 6, wherein the patient is administered ganaxolone twice daily.
8. (Previously Presented) The method of claim 6, wherein the pharmaceutical composition is an oral capsule.
9. (Previously Presented) The method of claim 6, wherein the pharmaceutical composition is an oral suspension.
10. (Previously Presented) The method of claim 6, wherein the pharmaceutical composition comprises 200 mg ganaxolone.
11. (Previously Presented) The method of claim 6, wherein the pharmaceutical composition comprises 400 mg ganaxolone.
12. (Previously Presented) The method of claim 6, wherein the pharmaceutical composition comprises 450 mg ganaxolone.

13. (Previously Presented) The method of claim 6, wherein the pharmaceutical composition comprises 600 mg ganaxolone.
14. (Previously Presented) The method of claim 6, wherein the pharmaceutical composition comprises 900 mg ganaxolone.
15. (Previously Presented) The method of claim 6, wherein the pharmaceutical composition comprises 1800 mg ganaxolone.
16. (Previously Presented) The method of claim 6, wherein the patient is administered oral capsules comprising 200-600 mg ganaxolone twice daily.
17. (Previously Presented) The method of claim 6, wherein the composition provides reduction in the frequency of seizures.
18. (Previously Presented) The method of claim 6, wherein the composition provides reduction in the frequency of seizures, the severity of seizures, or a combination thereof.

REMARKS

This is a response to the non-final Office Action dated October 8, 2019. Claims 6-18 are pending and have been rejected. Claim 6 has been amended to recite the treatment of CDKL5 deficiency disorder. No new matter has been added. Reconsideration and allowance of the pending claims in view of these Remarks are respectfully requested.

Claim Rejections Under 35 U.S.C. § 112

Claim 6 has been rejected under 35 U.S.C §112(a) first paragraph as not providing enablement of treatment of CDKL5 disorder. The Office Action indicates that CDKL5 disorder is not a named disease or disorder and includes a number of disorders or diseases including seizure, epilepsy, regression or autonomic feature disorder, which are associated with CDKL5 mutation. Applicant has amended claim 6 to recite the treatment of CDKL5 deficiency disorder. Applicant submits with this response an abstract presented at the American Epilepsy Society in 2018 that describes CDKL5 deficiency disorder (CDD) and the treatment with ganaxolone. The Conclusions state the “CDD is a recently recognized distinct clinical entity with significant unmet medical need.” Accordingly, Applicant respectfully submits that CDKL5 deficiency disorder (CDD) is a distinct disorder and the currently amended claims are sufficiently enabled. Reconsideration and withdrawal of the rejection of claim 6 under 35 U.S.C §112 is respectfully requested.

Claim Rejections Under 35 U.S.C. § 103

Claims 6-18 have been rejected under 35 U.S.C §103 as obvious over Shaw *et al.*, U.S. Patent 8,618,087 (“Shaw”) and Jones *et al.*, U.S. 9,629,853 (“Jones”) in view of Bahi-Buisson *et al.*, Epilepsia. 2008 Jun;49(6):1027-37 (“Bahi-Buisson”) and Archer *et al.*, J of Medical Genetics 2006, 43(9);729-734 (“Archer”).

Shaw is directed to novel compositions of ganaxolone. Jones is directed to the treatment of absence epilepsy. Shaw and Jones disclose only that ganaxolone may be effective for treating infantile spasms and epilepsy. As noted in the abstract presented at the American Epilepsy Society (“Specchio”), CDKL5 deficiency disorder (CDD) is a distinct disorder and there is significant need for antiepileptic drugs that reduce seizure frequency with safe and durable action. Bahi-Buisson teaches that the management of CDKL5 is mainly symptomatic and epileptic drugs like valproate or vigabatrin may be used to treat infantile spasms, levetiracetam may be used to treat myoclonic seizures, or topiramate may be used to treat tonic seizures. Archer discloses that CDKL5 mutations cause infantile spasms, early onset seizures and severe mental retardation. Neither Bahi-Buisson nor Archer disclose ganaxolone. The prior art provides no teaching or suggestion to replace the recommended treatments provided by Bahi-Buisson with ganaxolone. Bahi-Buisson explicitly recognizes that “[e]pilepsy is one of the main problems in most CDKL5 mutation patients and is largely refractory to medication.” Bahi-Buisson page 149, col. 2. Thus, one skilled in the art would conclude from Bahi-Buisson that most treatments are likely to be ineffective.

Furthermore, an obviousness determination requires finding both “that a skilled artisan would have been motivated to combine the teachings of the prior art . . . and that the skilled artisan would have had a reasonable expectation of success in doing so.” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016). Given the unpredictability in treating CDKL5, the prior art fails to provide a reasonable expectation of success as required to establish obviousness. One skilled in the art would not conclude that ganaxolone is effective for all seizure disorders based on the disclosure of Shaw and Jones. For example, Shaw states that ganaxolone could be effective in treating numerous seizure types, including tonic-clonic (Grand Mal), partial (Focal) seizures, catamenial seizures, acute repetitive seizure, psychomotor (complex partial) seizures. However, ganaxolone has been clinically tested and failed in the treatment of adult focal-onset seizures. *See, Genetic Engineering & Biotechnology News* (June 16, 2016) (copy attached). This reported clinical failure would lead one skilled in the art away from the use of ganaxolone for a difficult to treat seizure disorder such as CDKL5. Accordingly, as of the filing date, the prior art could not provide an expectation that the claimed invention would be successful as required to establish obviousness. Despite this unpredictability, clinical study results, published in 2018, demonstrate that ganaxolone administered up to 1800 mg per

day is effective in treating CDKL5 disorder. *See* Specchio¹ These results could not have been expected before the priority date of the present application and would be considered surprising and unexpected to one skilled in the art.

Accordingly, Bahi-Buisson alone or in view of Shaw or Jones does not establish a *prima facie* case of obviousness. Reconsideration and withdrawal of the rejection under 35 U.S.C §103 is respectfully requested.

Double Patenting

Claims 6 and 18 have been provisionally rejected under the doctrine of obviousness-type double patenting in view of U.S. Patent 10,363,246 Claim 6 has also been provisionally rejected under the doctrine of obviousness-type double patenting in view Application 16//013,500. Applicant will file a terminal disclaimer once allowable subject matter has been identified.

Claim 6 has been rejected under 35 USC 101 ad claiming the same invention as U.S. application 16/204,074. Applicant will abandon or amend the claims of the '074 Patent once allowable subject matter has been identified.

¹ Abstract submitted herewith and published at
https://www.aesnet.org/meetings_events/annual_meeting_abstracts/view/506062.

Conclusion

In view of the foregoing remarks, Applicant respectfully submits that the claims of the present application are in condition for allowance. Favorable and early reconsideration of this application are respectfully requested.

Should the Examiner believe that a telephone interview may facilitate prosecution of this application, the Examiner is respectfully requested to call applicant's 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: October 23, 2019

Respectfully submitted,

/Jeffrey S. Steen, Reg. #32063/

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/447,300	06/20/2019	Matthew DURING	2262-29 CON B CON TK1	7072
31554 7590 10/08/2019 Carter, DeLuca & Farrell LLP 576 Broad Hollow Road MELVILLE, NY 11747			EXAMINER SHIAO, REI TSANG	
			ART UNIT 1629	PAPER NUMBER
			NOTIFICATION DATE 10/08/2019	DELIVERY MODE 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):

bpuchaczewska@carterdeluca.com
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 16/356,517 03/18/2019 PAT 10363246 which is a CON of 16/013,500 06/20/2018, 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 6-18 are pending in the application.

Claim Rejections - 35 USC § 112

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

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

Claim 6 is rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112, first paragraph (pre-AIA), because the specification does not reasonably provide enablement of treatment of CDKL5 disorder without limitation (i.e., no named disease or disorder), see claim 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first

paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case:

The nature of the invention

The nature of the invention of claim 6 is drawn to methods of use for treating CDKL5 disorder in a patient with a compound ganaxolone, wherein CDKL5 disorder is without limitation (i.e., no named disease or disorder), see claim 6.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening *in vitro* and *in vivo* to determine which compound ganaxolone exhibit the desired pharmacological activities (i.e. what compound ganaxolone can treat which specific diseases by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. In Bahi-Buisson et al., Molecular

Syndromology, 2011, 2: 137-152, it disclose a number of disorders or diseases including seizure, epilepsy, regression, or autonomic feature disorder, which are associated with CDKL5 mutation, see Table 1 on page 138.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

Applicants are claiming intent methods of use using the instant for treating CDKL5 disorder without limitation (i.e., no named disease or disorder). As such, the specification fails to enable the skilled artisan to use for treating CDKL5 disorder without limitation (i.e., no named disease or disorder).

In addition, there is no established correlation between *in vitro* or *in vivo* activity and accomplishing treatment of CDKL5 disorder without limitation (i.e., no named disorder or disease), and those skilled in the art would not accept allegations in the instant specification to be reliable predictors of success, and those skilled in the art would not be able to use for treating CDKL5 disorders without limitation (i.e., no named disease or disorder) in a host is treated.

Hence, one of skill in the art is unable to fully predict possible results from the administration of the instant compound due to the unpredictability of treatment of CDKL5 disorders without limitation (i.e., no named disorder). The “treatment without limitation of CDKL5 disorders (i.e., no named disease or disorder)” is known to have

many obstacles that would prevent one of ordinary skill in the art from accepting treating regimen on its face.

The amount of direction or guidance present and the presence or absence of working examples

The only direction or guidance present in the instant specification is the description of treating a number of CDKL5 disorders, see page 3 of the specification. There are no *in vitro* or *in vivo* working examples present for the treatment without limitation (i.e., no named disease or disorder) by the administration of the instant invention.

The breadth of the claims

The breadth of the claims is methods of use of the instant treatment of CDKL5 disorder without limitation (i.e., no named disease or disorder).

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine how treatment of CDKL5 disorders without limitation (i.e., no named disease or disorder) would be benefited (i.e., treated) by the administration of the instant invention and would furthermore then have to determine which of the claimed methods of use would provide treatment of CDKL5 disorder without limitation (i.e., no named disease or disorder), if any.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be

individually assessed for physiological activity by successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

in vitro and *in vivo* screening to determine which methods of use exhibit the desired pharmacological activity and which would benefit from this activity. Thus, the specification fails to provide sufficient support of the broad use of the pharmaceutical composition of the instant claims for the various diseases or disorders.

As a result necessitating one of skill to perform an exhaustive search for which metabolic-related diseases can be treated or prevented by what pharmaceutical compound ganaxolone of the instant claims in order to practice the claimed invention. Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instantly claimed methods. In view of the breadth of the claim, the chemical nature of the invention, and the lack of working examples regarding the activity of the claimed compound ganaxolone in regards to the treatment of the many diseases, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation, with no assurance of success. This rejection can be overcome by incorporation of named disease or disorders supported by the specification (i.e., see claim 18) into claim 6 would obviate the rejection.

4. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-18 are rejected under 35 U.S.C. 103(a) as being obvious over Shaw et al. US 8,618,087, Jones et al. US 9,629,853 in view of Bahi-Buisson et al., Molecular Syndromology, 2011, 2: 137-152, and Archer et al., J. of Medical Genetics, 2006, 43(9):729-734. It is noted that Jones et al. '853 is 102 (a)(2) reference.

Applicants claim a method of method of treating CDKL5 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, see claim 6. Dependent claims 7-18 further limit the scope of methods of use, i.e., the administration strategy in claims 7-9, the composition comprises 200-1800 mg ganaxolone in claims 10-16, and reduction of frequency of seizure or its severity in claims 17-18.

Determination of the scope and content of the prior art (MPEP §2141.01)

Shaw et al. '087 discloses that ganaxolone is used for treating epileptic seizure, infantile spasms, and the dose is from 200 mg to 500 mg by oral administration composition. The composition can be formulated as tablet or capsule, see columns 120-124.

Jones et al. '853 discloses that ganaxolone is used for treating epileptic seizure, and the dose is from 2 mg to 160 mg in a pediatric subject, see column 24. The composition can be formulated as tablet or capsule, see column 9.

Bahi-Buisson et al. disclose a number of disorders or diseases including seizure, epilepsy, regression, or autonomic feature disorder, which are associated with CDKL5 mutation, see Table 1 on page 138.

Archer et al. disclose that CDKL5 mutation cause infantile spasm, early onset seizure and severe mental retardation in patients.

Determination of the difference between the prior art and the claims (MPEP §2141.02)

The difference between instant claims and Shaw et al. '087 or Jones et al. '853 is that the instant claims are silent on the scope of CDKL5 disorders.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the claims 6-18 prima facie obvious because one would be motivated to employ the methods of use of Shaw et al. '087, Jones et al. '853 in view of Bahi-Buisson et al. and Archer et al. to obtain instant invention. Although Shaw et al. '087 and Jones et al. '853 does not disclose the instant working mechanism targeting CDKL5, however, the teachings from Bahi-Buisson et al.

and Archer et al. provide rationales for inhibiting CDKL5 activity in a subject leading to inhibition of the frequency or severity of seizure in a patient. It is *prima facie* obvious to use the methods of use from Shaw et al. '087, Jones et al. '853 in view of Bahi-Buisson et al. and Archer et al., which provide rationale, i.e., for inhibiting of the frequency or severity of seizure in a patient of a subject using a compound ganaxolone, to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), see MPEP 2144.06.

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 of ganaxolone from Shaw et al. '087, Jones et al. '853 to reach the instant composition of claims 6 and 10-16.

The motivation to make the claimed methods of use derived from the known methods of use of Shaw et al. '087, Jones et al. '853 in view of Bahi-Buisson et al. and Archer et al. would possess similar activity to that which is claimed in the reference.

Double Patenting

6. 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).

6.1 Claims 6 and 18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable independently over claims 1 and 5 of Durning's US 10,363,246. 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 method of treating CDKL5 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, see claim 6.

During's '246 claims a method of method of treating essential tremor (i.e., CDKL5 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 1 mg to 5 mg of ganaxolone, see column 28.

The difference between instant claims and During's '246 is that the instant claims are silent on the scope of CDKL5 disorders.

One having ordinary skill in the art would find the claims 6 and 18 *prima facie* obvious because one would be motivated to employ the methods of use of During's '246 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 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 would possess same yields to that which is claimed in the reference.

6.2 Claim 6 is provisionally rejected under the judicially created doctrine of obviousness- type double patenting as being unpatentable independently over claims 1 and 18 of During's co-pending application No. 16/013,500. 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 method of treating CDKL5 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, see claim 6.

During's '500 claims a method of treating CDKL5 disorder comprising administering to a patient in need thereof a pharmaceutical composition comprising ganaxolone or a pharmaceutically acceptable salt thereof, wherein the composition comprises 1,800 mg of ganaxolone.

The difference between instant claims and During's '500 is that the instant claims are administration with a dose up to 1,800 mg per day.

One having ordinary skill in the art would find the claim 6 prima facie obvious because one would be motivated to employ the methods of use of During's '500 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 '500 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 '500 would possess same yields to that which is claimed in the reference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Statutory (35 USC 101) Double Patenting

6.3. Claim 6 is directed to the same invention as that of claim 1 of During's co-pending application No. 16/204,074, which are commonly assigned Ovid Therapeutics Inc. The issue of priority under pre-AIA 35 U.S.C. 102(g) and possibly pre-AIA 35 U.S.C. 102(f) of this single invention must be resolved.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application having common ownership (see

MPEP Chapter 2300). Either the applicant must amend or cancel claims such that the reference and the instant application no longer contain claims directed to the same invention, or the assignee must state which entity is the prior inventor of the commonly claimed subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under pre-AIA 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

Claim 6 is provisionally rejected under Statutory (35 USC 101) Double Patenting as being unpatentable over claim 1 of During's co-pending application No. 16/204,074.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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

October 02, 2019

Electronic Acknowledgement Receipt	
EFS ID:	36362112
Application Number:	16447300
International Application Number:	
Confirmation Number:	7072
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
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RAM confirmation Number	062119INTEFSW15291600
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The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	2262-29_CON_B_CON_-_POA_as_filed.pdf	935781	no	2
			717057e3e7e5692ec3e892ce2bfa174dc8335069		
Warnings:					
Information:					
2		2262-29_CON_B_CON_-_Preliminary_Amendmnet.pdf	148574	yes	4
			e6c95c6eefaaaf871b982ec8bbf0470b50aeb355		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Preliminary Amendment		1	1	
	Claims		2	3	
	Applicant Arguments/Remarks Made in an Amendment		4	4	
Warnings:					
Information:					
3	Application Data Sheet	2262-29_CON_B_CON_-_Application_Data_Sheet.pdf	1819301	no	7
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Warnings:					
Information:					
4	TrackOne Request	2262-29_CON_B_CON_-_Cert_and_Request_for_Prioritized_Exam.pdf	140528	no	2
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Warnings:					
Information:					
5		2262-29_CON_B_CON_-_Continuation_Application_as_filed.pdf	805632	yes	62
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Multipart Description/PDF files in .zip description					
Document Description			Start	End	
Specification			1	56	
Claims			57	57	
Abstract			58	58	
Drawings-only black and white line drawings			59	62	
Warnings:					
Information:					
6	Oath or Declaration filed	2262-29_CON_B_-_Executed_Declaration.pdf	62143	no	2
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Warnings:					
The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	40384	no	2
			d674149898980fb83859ea8afc2001ac839cc9d9		
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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. <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.					

Docket No.: 2262-29 CON B CON
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Matthew DURING

Application No.: To Be Assigned

Confirmation No.: 3649

Filed: Concurrently Herewith

Art Unit: 1629

For: METHODS AND COMPOSITIONS FOR
TREATMENT OF EPILEPTIC DISORDERS

Examiner: Schmitt, Michael J

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 Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.

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

LISTING OF CLAIMS:

Claims 1-5 (Cancelled).

6. (New) A method of treating CDKL5 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.
7. (New) The method of claim 6, wherein the patient is administered ganaxolone twice daily.
8. (New) The method of claim 6, wherein the pharmaceutical composition is an oral capsule.
9. (New) The method of claim 6, wherein the pharmaceutical composition is an oral suspension.
10. (New) The method of claim 6, wherein the pharmaceutical composition comprises 200 mg ganaxolone.
11. (New) The method of claim 6, wherein the pharmaceutical composition comprises 400 mg ganaxolone.
12. (New) The method of claim 6, wherein the pharmaceutical composition comprises 450 mg ganaxolone.
13. (New) The method of claim 6, wherein the pharmaceutical composition comprises 600 mg ganaxolone.

14. (New) The method of claim 6, wherein the pharmaceutical composition comprises 900 mg ganaxolone.
15. (New) The method of claim 6, wherein the pharmaceutical composition comprises 1800 mg ganaxolone.
16. (New) The method of claim 6, wherein the patient is administered oral capsules comprising 200-600 mg ganaxolone twice daily.
17. (New) The method of claim 6, wherein the composition provides reduction in the frequency of seizures.
18. (New) The method of claim 6, wherein the 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 6-18 have been added. Applicants respectfully requests early and favorable reconsideration of this application.

Support for the amendment may be found generally throughout the specification. Applicant submits that no new matter has been added by the present Amendment.

Should the Examiner believe 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.

An early and favorable response on the merits is earnestly solicited.

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: June 20, 2019

Respectfully submitted,

/Jeffrey S. Steen, Reg. #32063/

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