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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Matthew During

Application No.: 17/024,127

Examiner: R. T. Shiao

Filed: September 17, 2020

Art Unit: 1629

For: METHODS AND COMPOSITIONS FOR TREATMENT OF EPILEPTIC DISORDERS

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

Filed via EFS-Web
Confirmation No. 4361

SUPPLEMENTAL RESPONSE

In response to a non-Final Office Action dated April 4, 2022, setting a shortened period for reply expiring on July 4, 2022, and further to Applicant's response submitted on April 19, 2022, please enter the following:

Amendments to the Claims are reflected in the **Listing of Claims** which begins on page 2; and

Remarks begin on page 6.

Any required fee will be paid at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees due to Deposit Account No. **50-2140**.

MARINUS 1047
Marinus v. Ovid
PGR2023-00020

AMENDMENTS TO THE CLAIMS

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

1. (Original) A method of treating status epilepticus comprising administering to a patient in need thereof a pharmaceutical composition comprising ganaxolone or a pharmaceutically acceptable salt thereof.

2. (Original) The method of claim 1, wherein the patient is administered ganaxolone or a pharmaceutically acceptable salt thereof twice daily.

3. (Original) The method of claim 1, wherein the patient is administered ganaxolone or a pharmaceutically acceptable salt thereof three times daily.

4. (Original) 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.

5. (Original) The method of claim 1, wherein the pharmaceutical composition is an oral capsule.

6. (Original) The method of claim 1, wherein the pharmaceutical composition is an oral suspension.

7. (Original) The method of claim 1, wherein the pharmaceutical composition is an oral suspension comprising 50 mg/ml ganaxolone or a pharmaceutically acceptable salt thereof.

8. (Original) The method of claim 1, 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.

9. (Original) The method of claim 1, 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

10. (Original) The method of claim 1, wherein the patient is administered 600 mg ganaxolone or a pharmaceutically acceptable salt thereof.

11. (Original) The method of claim 1, wherein the patient is administered 600 mg ganaxolone or a pharmaceutically acceptable salt thereof three times daily.

12. (Original) The method of claim 1, wherein the patient is administered 50 mg ganaxolone or a pharmaceutically acceptable salt thereof.

13. (Original) The method of claim 1, wherein the patient is administered 100 mg ganaxolone or a pharmaceutically acceptable salt thereof.

14. (Original) The method of claim 1, wherein the patient is administered 200 mg ganaxolone or a pharmaceutically acceptable salt thereof.

15. (Original) The method of claim 1, wherein the patient is administered 300 mg ganaxolone or a pharmaceutically acceptable salt thereof.

16. (Original) The method of claim 1, wherein the patient is administered 400 mg ganaxolone or a pharmaceutically acceptable salt thereof.

17. (Original) The method of claim 1, wherein the patient is administered 500 mg ganaxolone or a pharmaceutically acceptable salt thereof.

18. (Original) The method of claim 1, wherein the patient is administered oral capsules comprising 200-600 mg ganaxolone or a pharmaceutically acceptable salt thereof.

19. (Original) The method of claim 1, wherein the pharmaceutical composition provides reduction in the frequency of seizures.

20. (Original) The method of claim 1, wherein the pharmaceutical composition provides reduction in the frequency of seizures, the severity of seizures, or a combination thereof.

21. (New) A method of treating status epilepticus comprising administering to a patient in need thereof a pharmaceutical composition comprising ganaxolone or a pharmaceutically acceptable salt thereof wherein the pharmaceutical composition is administered intravenously.

22. (New) The method of claim 21 wherein the pharmaceutical composition provides improvement to the patient after administration for more than 8 hours.

23. (New) The method of claim 21 wherein the pharmaceutical composition comprises about 30 mg ganaxolone.

24. (New) The method of claim 21 wherein the patient is administered about 150 mg to 1000 mg/day ganaxolone.

25. (New) The method of claim 21 wherein the patient is administered about 500 mg to 1000 mg/day ganaxolone.

26. (New) The method of claim 21 wherein the patient is administered about 625 mg to 650 mg/day ganaxolone.

27. (New) The method of claim 21 wherein the patient is administered about 650 mg to 675 mg/day ganaxolone.

28. (New) The method of claim 21 wherein the patient is administered about 675 mg to 700 mg/day ganaxolone.

29. (New) The method of claim 21 wherein the patient is administered about 625 mg to 700 mg/day ganaxolone.

30. (New) The method of claim 21 wherein the patient is administered about 700 mg to 725 mg/day ganaxolone.

31. (New) The method of claim 21 wherein the patient is administered about 1025 mg to 1050 mg ganaxolone.

REMARKS

The present application has been reviewed in light of the non-Final Office Action dated April 4, 2022. New claims 21 through 31 are added herein. Support for the new claims can be found generally throughout the specification and specifically, e.g., at paragraphs 32, 33, 72, 78, and 111. Accordingly, no new matter is entered into the application by virtue of the present amendment.

Applicant respectfully submits that the claims of the present application are in condition for allowance. Favorable and early reconsideration of this application is respectfully requested.

Applicant does not concede that the subject matter encompassed by the claims prior to this Response is unpatentable over the art cited by the Office Action. Indeed, Applicant traverses the rejections and preserves all rights and arguments. To the extent that any particular statement or argument by the Office in the pending Office Action has not been explicitly addressed herein, the same should not be construed as an acquiescence or admission by the Applicant that such statements or arguments by the Office are accurate and proper.

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.

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

Respectfully submitted,

Dated: May 11, 2022

By: /Jeffrey S. Steen, Reg. #32063/

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Electronic Patent Application Fee Transmittal

Application Number:	17024127
Filing Date:	17-Sep-2020
Title of Invention:	METHODS AND COMPOSITIONS FOR TREATMENT OF EPILEPTIC DISORDERS
First Named Inventor/Applicant Name:	Matthew DURING
Filer:	Jeffrey S. Steen/Julie Dascoli
Attorney Docket Number:	2262-29 CON B CON III

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	2202	11	50	550
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**550**

Electronic Acknowledgement Receipt

EFS ID:	45684311
Application Number:	17024127
International Application Number:	
Confirmation Number:	4361
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/Sarah Schlie
Filer Authorized By:	Jeffrey S. Steen
Attorney Docket Number:	2262-29 CON B CON III
Receipt Date:	11-MAY-2022
Filing Date:	17-SEP-2020
Time Stamp:	11:15:46
Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	yes
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Payment was successfully received in RAM	$550
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Deposit Account	502140
Authorized User	Sarah Schlie

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.21 (Miscellaneous fees and charges)

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_III_-_Supplemental_Response.pdf	153365 dd7e237c47036ba89933617ce27299424139b518	yes	6

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Supplemental Response or Supplemental Amendment	1	1
Claims	2	5
Applicant Arguments/Remarks Made in an Amendment	6	6

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	37926 6a10c803d90bf9b6f84605f07e50aeec4ef42db3	no	2

Warnings:

Information:

Total Files Size (in bytes):	191291

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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.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/024,127	Filing Date 09/17/2020	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

AMENDMENT	05/11/2022	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 31	Minus	** 20	= 11		x $100 =	1100
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	1100

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/CHRISTINE V MOORE/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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