Electronic Acknowledgement Receipt	
EFS ID:	40590105
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/Julie Dascoli
Filer Authorized By:	Jeffrey S. Steen
Attorney Docket Number:	2262-29 CON B CON III
Receipt Date:	17-SEP-2020
Filing Date:	
Time Stamp:	16:03:58
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$785
RAM confirmation Number	E20209GG04171303
Deposit Account	
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	POAasfiled.pdf	3235921 6622558c02f6aec9d82212132e650cc1adfef4a1	no	2
Warnings:					
Information:					
2		CONapp.pdf	914164 80495b93b60f73f089a1eded343ba7e99dfe1f0f	yes	67

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Specification	1	59
	Claims	60	62
	Abstract	63	63
	Drawings-only black and white line drawings	64	67

Warnings:					
Information:					
3	Oath or Declaration filed	DEC.PDF	62143 a3a9857788873ee8c0394e7438ff052f92fb76c5	no	2
Warnings:					
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Information:					
4	Application Data Sheet	ADS.pdf	1819455 0b2920399761a3545b928e8ae0bba1ac64cc1bce	no	7
Warnings:					
Information:					

5	Fee Worksheet (SB06)	fee-info.pdf	35331 37f3c604c4cd417b28a05b4af349c2620e6ff17d	no	2
Warnings:					
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			Total Files Size (in bytes):	6067014	

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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.

WHAT IS CLAIMED IS:

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

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

4. 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. The method of claim 1, wherein the pharmaceutical composition is an oral capsule.

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

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

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

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

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

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

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

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

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

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

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

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

Electronic Acknowledgement Receipt	
EFS ID:	41573577
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/Julie Dascoli
Filer Authorized By:	Jeffrey S. Steen
Attorney Docket Number:	2262-29 CON B CON III
Receipt Date:	06-JAN-2021
Filing Date:	17-SEP-2020
Time Stamp:	16:42:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Information_Disclosure_Statement_Fillable_PDF.pdf	1037491 09d11df9acce8a7175319bb319c279ed40383cd8	no	9

Warnings:

Information:					
2	Transmittal Letter	2262-29_CON_B_CON_III_-_IDS_Transtmittal.pdf	18363 6c03c82d2d4b3742623074f576c820a024902788	no	2
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3	Foreign Reference	WO2016127170A1.pdf	2352162 1ddefa65a96996491c9bf54ea41eb013c3838b4d	no	42
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4	Non Patent Literature	Archer.pdf	1193630 da0b913e54c4d24feaeb145c3d890b6af9ec0738	no	6
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5	Non Patent Literature	Walsh_2009.pdf	619681 5168b8408269855a2e4cb1c69be1f2438a4b4ff3	no	6
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6	Non Patent Literature	Glykys_2007.pdf	586044 f39266be943bcb3b87b114880564cbddd91451ee	no	16
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7	Non Patent Literature	Iber_2007.PDF	3683216 41095d2210161ada94a2068f9b7f9d79b8831e31	no	57
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8	Non Patent Literature	Jennum_2011.pdf	476660 5bb3edde6d38a566a331db5faa02b732c083fcd8	no	15
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9	Non Patent Literature	Jonas_2007.PDF	882893 20c468edab913ebcc21b39211334035b04f8b5d5	no	10
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10	Non Patent Literature	Lennox_Gastaut_Syndrome_-_Wikipedia.pdf	728431 2f14e5a1bebd24693a5d18fe5c97dc360c1e3ceb	no	11
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Information:					
11	Non Patent Literature	Natural_2007.PDF	219237 9952b7ce5c120d1e90e21950700a49fca790e52d	no	3
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12	Non Patent Literature	Tropea_2009.pdf	297303 f1bc42591c62183e088eee0dc3dadb7a7e80b83d	no	6
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13	Non Patent Literature	Vardya_et_al_Neuropharmacology_2012.pdf	1609683 00bef40d41131e24a1dbea66225017b66a4d947b	no	11
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14	Non Patent Literature	ISR_and_Written_Opinion_dated_927.pdf	744499 0b3e5ecee0be677e254d547305aafa8969b4aec0	no	8
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15	Non Patent Literature	ISR_and_Written_Opinion.pdf	531868 d459a9cc9572da45139866024 6f7a5df78aaf0d4	no	9
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16	Non Patent Literature	Intl_Search_Report_and_Written_Opinion_dated_7_18_17.pdf	797654 fcf6f2485cacfef46be3bc69a66ca396d91fc0a1	no	7
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17	Non Patent Literature	DURM_105_PCT_ISR__WO.PDF	221446 72ab6c79007f5af8bead43e9aeb723b1180ff6e37	no	12
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18	Non Patent Literature	Brown_2002.pdf	1317512 a1ba30f510973e197899729924c6707ef82cf62a	no	10
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19	Non Patent Literature	International_Search_Report_and_Written_Opinion_dated_814.pdf	1601300 c668f73fa7dce2f933dbeacd5add7a4d69f4bcc0	no	19
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21	Non Patent Literature	Oakley_et_al.pdf	860952 e7e17d266eaa5a751fb0d3c245b66c2ae224b5aa	no	10
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22	Non Patent Literature	ISR_and_Written_Opinion_dated_103117_PCT_US17_46256.pdf	948406 eaed4d784c6e75c02bf5ec39535b9bcb16da1f97	no	10
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23	Non Patent Literature	2262-29_CON_-_Loescher.pdf	371740 37a8d806635c2bdc10848bbe69837ea8d023f38d	no	10
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24	Non Patent Literature	2262-29_CON_-_Petersen_et_al.pdf	1055644 88a8370f42a575323622b75ad7d1d5d72061bf3a	no	4
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25	Non Patent Literature	2262-3_-_PCT_Notice_dated_21.pdf	709602 02ae68adfc81a068ec23ca6a310e36a2c74e8ba8	no	8
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26	Non Patent Literature	Reagan-Shaw_et_al.pdf	87839 cbba76bb916ae451ea2619e8170a6020bc29a6ea	no	3
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27	Non Patent Literature	2262-33_-_ISR_and_WO_dated_424.pdf	1588417 8980d4d5b07c0cc5ea1f39905e779b26f9745eb8	no	15
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28	Non Patent Literature	2262-29_CON_-_Bahi-Buisson_et_al-2008-Epilepsia.pdf	620327 4ba8099129a14280a522d07629ff1bce23041254	no	11
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29	Non Patent Literature	2262-29_CON_-_Tenney.pdf	615081 1a6f0161ee5e2d11eeb145f618de468c96f7793c	no	13
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30	Non Patent Literature	NPL_-_N_Bahi-Buisson-_CDKL5_Related_Disorders.pdf	1942715 b2c9f28f2ba9d006e3a6285a71ce9856d1ba98cf	no	16
Warnings:					
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31	Non Patent Literature	Monaghan_et_al_Epilepsia_389_1026-1031_1997.pdf	918753 1d8e4c26820aec6f6f5cb879d5a24953b6e8ce38	no	6
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32	Non Patent Literature	2262-29_PCT_EP_DIV_-_European_Search_Report_and_Preliminary_Opinion.pdf	496803 35e02c9edbaf3bf3d78862489b5067febe9f3dd1	no	11
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33	Non Patent Literature	Handforth_reference.pdf	145326 40742a1c20c2160b668f76bfa95c8ae0f4665599	no	1
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34	Non Patent Literature	egawa13.pdf	4153735 d3381589119ae4761629d30ba1451ad8ad49af00	no	15
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New Applications Under 35 U.S.C. 111

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New International Application Filed with the USPTO as a Receiving Office

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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 Confirmation No.: 4361

Filed: September 17, 2020 Art Unit: 1629

For: METHODS AND COMPOSITIONS FOR TREATMENT OF EPILEPTIC DISORDERS Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

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

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98, the attention of the United States Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of the above-identified application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)).

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), copies of U.S. patents and U.S. patent application publications are not submitted. Submitted herewith are copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made. In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in this Information Disclosure Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98, and the Examiner is respectfully requested to consider the listed references.

Applicant believes no fee is due with this submission. However, if a fee is due, please charge our Deposit Account No. 50-2140, under Order No. 2262-29-CON B CON III from which the undersigned is authorized to draw.

Dated: January 6, 2021

Respectfully submitted,

/Jeffrey S. Steen, Reg. #32063/

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Registration No.: 32,063
CARTER, DELUCA & FARRELL LLP
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PTO/SB/08a (02-18)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17024127
Filing Date	2020-09-17
First Named Inventor	Matthew During
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	2262-29-CON B CON III

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	8618087	B2	2013-12-31	Shaw et al.	
	2	9339495		2016-05-17	During	
	3	9351968		2016-05-31	During	
	4	9399034		2016-07-26	During et al.	
	5	9446028		2016-09-20	During	
	6	9629853		2017-04-25	Jones et al.	
	7	9682069		2017-06-20	During	
	8	9717716		2017-08-01	During et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

	9	10071083		2018-09-11	During	
	10	10363246		2019-07-30	During	
	11	10603308		2020-03-31	During	
	12	10799485		2020-10-13	During	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20070032553	A1	2007-02-08	McKernan et al.	
	2	20070112017	A1	2007-05-17	Barlow et al.	
	3	20070141161	A1	2007-06-21	Shaw et al.	
	4	20070259912	A1	2007-11-08	Cooper	
	5	20110034562	A1	2011-02-10	REGAN	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

	6	20110046090	A1	2011-02-24	Barlow et al.	
	7	20130309306	A1	2013-11-21	Rogawski et al.	
	8	20150313913	A1	2015-11-05	CATTERALL et al.	
	9	20150352085	A1	2015-12-10	During	
	10	20160038469	A1	2016-02-11	DURING	
	11	20160228418	A1	2016-08-11	DURING	
	12	20160228454	A1	2016-08-11	Zhang et al.	
	13	20170014392	A1	2017-01-19	During	
	14	20170014393	A1	2017-01-19	DURING	
	15	20170065572	A1	2017-03-09	DURING	
	16	20170348232	A1	2017-12-07	DURING	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

	17	20180042903	A1	2018-02-15	DURING	
	18	20180235942	A1	2018-08-23	DURING et al.	
	19	20180344708	A1	2018-12-06	During	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2016127170	WO	A1	2016-08-11	Marinus Pharmaceuticals, Inc		

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	1	Archer et al., J. of Medical Genetics, 2006, 43(9):729-734.	
	2	James K. Walsh, Ph.D., "Enhancement of Slow Wave Sleep: Implications for Insomnia," Journal of Clinical Sleep Medicine, (2009), Supplement to vol. 5, No. 2; pp. 827-832.	
	3	Glykys et al., "The Main Source of Ambient GABA Responsible for Tonic Inhibition in the Mouse Hippocampus," J Physiol, (2007), vol. 582, No. 3; pp. 1163-1178.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

	4	Iber et al., "The AASM Manual for the Scoring of Sleep and Associated Events," American Academy of Sleep Medicine (2007); pp. 3-59 (57 pages).	
	5	Jennum et al., "Sleep Disorders in Neurodegenerative Disorders and Stroke," European Handbook of Neurological Management, (2011), vol. 1, 2nd Edition, Chapter 39, Section 6--Sleep Disorders, (Ed. Gilhus et al.) Blackwell Publishing Ltd. 2011; pp.529-543.	
	6	Jonas et al., "Neural Inhibition,", Scholarpedia - http://www.scholarpedia.org/article/Neural_inhibition - (2014); 10 pages.	
	7	Egawa et al., "Pathophysiological power of improper tonic GABA(A) conductances in mature and immature models." Frontiers in Neural Circuits, Oct. 24, 2013, vol. 7, Article 170; pp. 1-15.	
	8	Lennox-gastaut syndrome; Wikipedia article. dated Jul. 10, 2016; 11 pages.	
	9	Natural Patterns of Sleep - Healthy Sleep - (2007) http://healthysleep.med.harvard.edu/healthy/science/what/sleep-patterns-rem-nrem (2007); 3 pages.	
	10	Tropea et al., "Partial Reversal of Rett Syndrome-like Symptoms in MeCP2 Mutant Mice," PNAS, Feb. 10, 2009, vol. 106, No. 6; pp. 2029-2034.	
	11	Vardya et al., "Positive Modulation of .delta.-Subunit Containing GABAA Receptors in Mouse neurons," Neuropharmacology, (2012), vol. 63; pp. 469-479.	
	12	International Search Report and Written Opinion of the International Searching Authority, dated Sep. 27, 2016, corresponding to International Application No. PCT/US16/42238; 8 total pages.	
	13	International Search Report and Written Opinion, dated Oct. 4, 2016, corresponding to International Application No. PCT/US16/50702; 9 total pages.	
	14	International Search Report and Written Opinion of the International Searching Authority, dated Jul. 18, 2017, corresponding to International Application No. PCT/US17/34443; 5 total pages.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

	15	International Search Report and Written Opinion of the International Searching Authority, dated Aug. 26, 2015, corresponding to International Application No. PCT/US15/34018; 12 total pages.	
	16	Brown et al., "Pharmacological Characterization of a Novel Cell Line Expressing Human .alpha.4.beta.3.delta. GABAA Receptors," British Journal of Pharmacology, (2002), vol. 136, No. 7; pp. 965-974.	
	17	International Search Report and Written Opinion of the International Searching Authority, dated Aug. 14, 2015, corresponding to International Application No. PCT/US2015/029155; 19 total pages.	
	18	Cao et al., "Clustered burst firing in FMR1 premutation hippocampal neurons: amelioration with allopregnanolone," Human Molecular Genetics, 2012, vol. 21, No. 13, pp. 2923-2935.	
	19	Oakley et al., "Synergistic GABA-Enhancing Therapy against Seizures in a Mouse Model of Dravet Syndrome," The Journal of Pharmacology and Experimental Therapeutics, May 2013, vol. 345; pp. 215-224.	
	20	International Search Report and Written Opinion of the International Searching Authority, dated Oct. 31, 2017, corresponding to International Patent Application No. PCT/US17/46256; 10 total pages.	
	21	Loescher, W., "Development of Tolerance to the Anticonvulsant Effect of GABA-mimetic Drugs in Animal Models of Seizure States in Tolerance to Beneficial and Adverse Effects of Antiepileptic Drugs," Koella et al. (eds.), (1986); pp. 37-45. cited byapplicant.	
	22	Petersen et al., "THIP: A Single Blind Controlled Trial in Patients with Epilepsy," Acta Neurol. Scand. 67; pp. 114-117 (1983).	
	23	PCT Notice concerning Transmittal of International Preliminary Report on Patentability (Chapter I of the Patent Cooperation Treaty), International Preliminary Report on Patentability and Written Opinion of the International Searching Authority,datedFeb. 1, 2018, corresponding to International Application No. PCT/US2016/042238; 8 total pages.	
	24	Reagan-Shaw et al., "Dose translation from animal to human studies revisited", FASEB J, vol. 22, No. 3, Oct. 17, 2007; pp. 659-661.	
	25	International Search Report and Written Opinion of the International Searching Authority, dated Apr. 24, 2018, corresponding to International Application No. PCT/US18/16602; 15 total pages.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17024127
	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

	26	Bahi-Buisson et al., "The three stages of epilepsy in patients with CDKL5 mutations", Epilepsia, (2008), vol. 49, No. 6; pp. 1027-1037.	
	27	Tenney et al., "The Current State of Absence Epilepsy: Can We Have Your Attention?", Epilepsy Currents, Current Review in Clinical Science, vol. 13, No. 3 (May/Jun. 2013); pp. 135-140.	
	28	Bahi-Buisson et al., "CDKL5-Related Disorders: From Clinical Description to Molecular Genetics," Molecular Syndromology, (2011), vol. 2; pp. 137-152.	
	29	Monaghan et al., "Initial Human Experience with Ganaxolone, A Neuroactive Steroid with Antiepileptic Activity," Epilepsia, (1997), vol. 38, No. 9; pp. 1026-1031.	
	30	European Search Report dated Nov. 18, 2019, corresponding to European Application No. 19190461.4; 11 pages.	
	31	Charles A. Handforth, "GABA Receptor May Present Target for New ET Drug Therapy," Essential Tremor, Jun. 4, 2013; 1 page.	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Application Number	17024127
	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jeffrey S. Steen, Reg. #32063/	Date (YYYY-MM-DD)	2021-01-06
Name/Print	Jeffrey S. Steen	Registration Number	32,063

This collection of information is required by 37 CFR 1.97 and 1.98. 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 1 hour 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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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 the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

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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 inspections or an issued patent.

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Electronic Acknowledgement Receipt	
EFS ID:	41585077
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/Julie Dascoli
Filer Authorized By:	Jeffrey S. Steen
Attorney Docket Number:	2262-29 CON B CON III
Receipt Date:	07-JAN-2021
Filing Date:	17-SEP-2020
Time Stamp:	16:08:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Information_Disclosure_Statement_Fillable_PDF.pdf	1034285 1e4b758bfe464d73a1136694e44055ff90fb9604	no	4

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3	Non Patent Literature	IN_OA_dated_127.pdf	140102 6d8314bc8daad2987b8cd87e2f5fb8c1100b5ae9	no	5
Warnings:					
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Warnings:					
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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

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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 | Confirmation No.: 4361

Filed: September 17, 2020 | Art Unit: 1629

For: METHODS AND COMPOSITIONS FOR TREATMENT OF EPILEPTIC DISORDERS | Examiner: Not Yet Assigned

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)

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

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98, the attention of the United States Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of the above-identified application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)).

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), copies of U.S. patents and U.S. patent application publications are not submitted. Submitted herewith are copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2).

I hereby certify, pursuant to 37 C.F.R. § 1.97(e)(1), that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made. In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in this Information Disclosure Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98, and the Examiner is respectfully requested to consider the listed references.

Applicant believes no fee is due with this submission. However, if a fee is due, please charge our Deposit Account No. 50-2140, under Order No. 2262-29-CON B CON III from which the undersigned is authorized to draw.

Dated: January 7, 2021

Respectfully submitted,

/Jeffrey S. Steen, Reg. #32063/

Jeffrey S. Steen
Registration No.: 32,063
CARTER, DELUCA & FARRELL LLP
576 Broad Hollow Road
Melville, New York 11747
(631) 501-5700
Attorney for Applicant(s)

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	17024127
	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

	1	Indian Examination report dated December 7, 2020, corresponding to counterpart Indian Application No. 201917005079; 5 pages.

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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CERTIFICATION STATEMENT

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OR

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☒ See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jeffrey S. Steen, Reg. #32063/	Date (YYYY-MM-DD)	2021-01-07
Name/Print	Jeffrey S. Steen	Registration Number	32,063

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Electronic Acknowledgement Receipt	
EFS ID:	41868657
Application Number:	17024127
International Application Number:	
Confirmation Number:	4361
Title of Invention:	
First Named Inventor/Applicant Name:	
Correspondence Address:	- - - - - - - - - -
Filer:	Robert H. Underwood/Leilani Legaspi
Filer Authorized By:	Robert H. Underwood
Attorney Docket Number:	
Receipt Date:	08-FEB-2021
Filing Date:	
Time Stamp:	18:26:37
Application Type:	

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$180

RAM confirmation Number	E202128I26320739
Deposit Account	501349
Authorized User	Leilani Legaspi

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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	Information Disclosure Statement (IDS) Form (SB08)	761996-000007_USPTO_Form_List_of_Documents_Cited.pdf	333927 28f68ad56c31231f339d2dbf92e10bd7a5f76afe	no	3
Warnings:					
Information:					
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2	Concise Description of Relevance	Third-Party-Submission-17024127.pdf	125936 1807e2384a57ec107e83adfd24a5fdffc4413ce0	no	17
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Information:					
3	Non Patent Literature	P1-Carter.pdf	693939 f37f5b736d9cb7367e3ea9e994a2f1cec0d81176	no	12
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7	Non Patent Literature	P5-Saporito.pdf	997707 fe7b5a32ce29835c501e4fdc524ffc872ec13b61	no	6
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8	Non Patent Literature	P6-Marinus-Press-Release.pdf	142506 a8af951259f8f51ec50c5c2bf4fc412ce775ee88	no	3
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10	Non Patent Literature	P8-Abstract-Ganaxolone.pdf	1357611 f78a68d80da0ae2cdde48c0176d38820982d1be1	no	2
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11	Concise Description of Relevance	Concise-description-generated.pdf	28074 59097e63f6ae16e89d697451d1979da621135df0	no	3
Warnings:					
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12	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	42867 4f5b64586637e44144eab171b855fc0668ab4474	no	2
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13	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	19984 69063b00008ef9019873038183eec802ed0d163c	no	1
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14	Fee Worksheet (SB06)	fee-info.pdf	29359 b3aa45428beec8c9317f707dbfdfcd425be823b0	no	2
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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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Ovid Therapeutics Inc.
Application No.	:	17/024,127
Filing Date	:	September 17, 2020
Title	:	Methods and Compositions for Treatment of Epileptic Disorders
Examiner	:	To be assigned
Confirmation No.	:	31554

THIRD PARTY PRE-ISSUANCE SUMBISSION UNDER 37 C.F.R. § 1.290

The Examiner is respectfully requested to consider the concise statement of relevance of the documents submitted herewith.

Entry and consideration of this pre-issuance submission is considered proper because the submission is being made before the earlier of: (1) a Notice of Allowance; or (2) the later of either (i) 6-months after publication of the application or (ii) the date of the first rejection.

The party making the submission is not an individual who has a duty to disclose information with respect to the application under 36 C.F.R. § 1.56.

The submission complies with the requirements of 35 U.S.C § 122 (e) and 37 C.F.R. § 1.290.

This submission is accompanied by a fee of $180.00, as set forth in §1.17(o), for the submission of eight publications.

List of Documents

Publication 1: Carter et al., Characterization of the Anticonvulsant Properties of Ganaxolone (CCD 1042; 3α-Hydroxy-3β-methyl-5α-pregnan-20-one), a Selective, High-Affinity, Steroid Modulator of the γ-Aminobutyric $Acid_A$ Receptor, The Journal of Pharmacology and Experimental Therapeutics, 280(3):1284-1295 (1997).

Publication 2: WIPO, Marinus Pharmaceuticals, Inc., WO 2016/127170 (International Application No.: PCT/US2016/016977) published August 11, 2016.

Publication 3: WIPO, Marinus Pharmaceuticals, WO 2007/062266 (International Application No.: PCT/US2006/045626), published May 31, 2007.

Publication 4: Saporito et al., Intravenous Administration of Ganaxolone Attenuates Electroencephalographic Seizures in a Diazepam Resistant Model of Status Epilepticus, Neurobiology, 86 (16 supplement), published April 4, 2016.

Publication 5: Saporito et al., Ganaxolone Administered Intravenously Prevents Behavioral Seizures and Promotes Survival in the Rat Lithium-Pilocarpine Model of Status Epilepticus, Neurology, 86 (16 Supplement), published April 4, 2016.

Publication 6: Press Release: "Marinus Pharmaceuticals Doses First Subject in Phase 1 Clinical Trial for Ganaxolone IV," Published on June 22, 2016, Available at: https://ir.marinuspharma.com/news/news-details/2016/Marinus-Pharmaceuticals-Doses-First-Subject-in-Phase-1-Clinical-Trial-for-Ganaxolone-IV/default.aspx.

Publication 7: Press Release: "Marinus Pharmaceuticals Receives FDA Orphan Drug Designation for Ganaxolone IV to Treat Status Epilepticus," Published April 15, 2016, Available at: https://ir.marinuspharma.com/news/news-details/2016/Marinus-Pharmaceuticals-Receives-FDA-Orphan-Drug-Designation-for-Ganaxolone-IV-to-Treat-Status-Epilepticus/default.aspx.

Publication 8: Chez, "Ganaxolone Therapy Improves Interictal EEG and Seizure Control in Lennox Gastaut Syndrome in Patients with PCDH19 and CDKL5," Annals of Neurol. 80 (suppl 20)published October 26, 2016.

CONCISE STATEMENT OF RELEVANCE

The party making the submission, submits herewith 8 publications (Publications 1-8). Publications 1-8 demonstrate that, well before the earliest possible effective filing date of U.S. Application No. 17/024,127 (the "'127 Application"), it was known in the art that ***ganaxolone*** can effectively ***treat status epilepticus*** ("SE"). Before the earliest possible effective filing date of the '127 Application, pre-clinical studies for treating SE had been completed and the results disclosed (Publications 2, 4, and 5), and a human clinical trial of ganaxolone for treating SE had started (Publication 6). A concise statement of relevance for each of the publications is provided below along with a claim chart to highlight sections of the Publications that disclose the subject matter of pending claims 1-20 of the '127 Application.

1. Publication 1 is relevant because it discloses *in vivo* data demonstrating that ganaxolone exerts potent anticonvulsant effects in numerous models of epilepsy disorders more than 20 years before the '127 Application

Publication 1 published in March 1997, which is ***more than 20 years before*** the earliest possible priority date of the '127 Application (emphasis added). Publication 1 is prior art under section 102(a)(1).

Publication 1 is a prior art reference that demonstrates that ***more than 20 years before*** the filing of '127 Application, it was known that "***ganaxolone exerts potent anticonvulsant effects in a broad range of animal model seizure models with predictive validity for a number of different human epileptic disorders***" (*see*, p. 1290, right col.) (emphasis added). Publication 1 presents *in vivo* data clearly demonstrating that ganaxolone exhibited "***potent anticonvulsant activity***" against numerous established animal models having chemically induced seizures, maximal electroshock induced seizures, or cornea-kindled seizures (*see*, e.g., Abstract, p. 1289, right col., and p. 1290, left col., Tables 5 and 6) (emphasis added).

2. Publication 2 is relevant because it discloses ganaxolone formulations for treating status epilepticus, and presents *in vivo* data showing ganaxolone effectively treats status epilepticus

Publication 2 was filed on February 8, 2016, and has an earliest claimed priority date of February 6, 2015, and is prior art under section 102(a)(2). By contrast, the earliest possible priority date of the '127 Application is August 11, 2016, well after the filing date and priority date of Publication 1.

Publication 2 is directed to intravenous ***ganaxolone*** formulations and discloses the use of ganaxolone for ***treating SE*** (*see*, *e.g.*, ¶¶ [0069] and [0078]) (emphasis added). This is the ***same compound*** and the ***same disease*** recited in the pending claims of the '127 Application (emphasis added).

Publication 2 includes *in vivo* data demonstrating that ***ganaxolone*** has a ***therapeutic effect*** in a well-known and predictive ***rodent model of SE*** (*see*, *e.g.*, Example 8 at ¶¶ [0117]-[0136]). Example 8 discloses that SE was induced in the Sprague-Dawley rat model by administration of lithium chloride and pilocarpine (*see*, ¶ [0117]). Ganaxolone was administered intravenously to one group at 12 mg/kg or 15 mg/kg at 15 minutes or 60 minutes after the onset of SE. *Id.* Allopregnanolone was administered to another group at 15 mg/kg as a comparison at the same time intervals. *Id.* The study results showed that both doses of ganaxolone elicited SE suppression at each time point analyzed, with antiepileptic activity observed for up to 5 hours (*see*, *e.g.*, ¶¶ [0133]-[0136], Table 6, Table 7, Figure 3 and Figure 4). As a comparison, allopregnanolone did not have sustain antiepileptic activity for durations longer than 1 hour, and by 2 hours post dosing SE returned and was equivalent to the vehicle control. *Id.* Accordingly, Publication 2 demonstrates a positive therapeutic effect for ***treating SE*** using ***ganaxolone*** in a well-known and predictive model (emphasis added).

The '127 Application discloses a preclinical study that is very similar to the study in Publication 2. Example 3 of the '127 Application discloses ***same rodent model of SE that is disclosed in Example 8*** of Publication 2, and the use of the rodent model to evaluate the effects of the ***same compounds disclosed in Publication 2 (ganaxolone and allopregnanolone)*** and an additional compound (gaboxadol) (*see, e.g.*, ¶ [0176] of the '127 Application) (emphasis added). Example 3 of the '127 application merely corroborates the data that was previously disclosed in Publication 2. It is observed that Example 3 of the '127 Application was first disclosed in U.S. Application No.: 15/673,737 filed on August 10, 2017, which is well after the effective filing date of Publication 2.

Thus, Publication 2 discloses ***treating SE using ganaxolone*** administered intravenously, and clearly demonstrates a positive therapeutic effect *in vivo* well before the earliest possible effective filing date of the '127 Application.

3. Publication 3 is relevant because it discloses oral formulations of ganaxolone for use in treating epileptic disorders, including status epilepticus

Publication 3 was filed on November 28, 2006, and has an earliest claimed priority date of November 28, 2005, which is ***more than 15 years before*** than the earliest possible effective filing date of the '127 Application (emphasis added). Publication 3 is prior art under section 102(a)(1).

Publication 3 is directed to formulations of ***ganaxolone*** that can be used for treating epileptic disorders, including ***SE*** (*see, e.g.*, ¶¶ [0019] (aa) and [00418]) (emphasis added). Again, this is the ***same compound*** and the ***same disease*** recited in the pending claims of the '127 Application (emphasis added).

Publication 3 describes oral formulations of ganaxolone formulated as an ***oral capsule*** or as an ***oral suspension*** for treating epileptic disorders, including ***SE*** (*see, e.g.*, (¶¶ [0018], [0019] [0042], [0044], [0068], [00164], [00174], and [00179]). Publication 3 also discloses that the ganaxolone formulations can be administered ***twice a day or three times a day*** (*see, e.g.*, ¶¶ [0019], [00174], [00289] and [00290]). The concentration of ganaxolone in the oral suspension and dosage amounts recited in pending claims 7, 8 and 10-18 of the '127 Application are encompassed by the disclosure in Publication 3 (*see, e.g.*, ¶¶ [0011], [0018], [0027], [0065], [00200], [00255], and [00287]-[00289]). Publication 3 further provides 64 examples relating to the disclosed ganaxolone formulations.

Accordingly, Publication 3 demonstrates that ***more than 15 years before*** the '127 Application, that ***ganaxolone*** had already been formulated in oral dosage forms for ***treating*** epileptic disorders, including ***SE***, and the ***ganaxolone concentrations in the oral suspension*** and ***dose amounts*** for oral ganaxolone had been disclosed.

4. Publication 4 is relevant because it discloses *in vivo* data showing that ganaxolone effectively treats status epilepticus

Publication 4 published on April 4, 2016, which is before the earliest possible priority date of the '127 Application, and is prior art under section 102(a)(1).

Publication 4 is another prior art publication that presents pre-clinical *in vivo* data clearly demonstrating that ***ganaxolone*** can effectively ***treat SE*** in a well-known and predictive rodent model of SE. The study presented in Publication 4 corresponds to the study disclosed in Example 8 of Publication 2. Publication 4 discloses that ganaxolone (12 mg/kg or 15 mg/kg) or allopregnanolone (15 mg/kg) were intravenously administered 15 or 60 minutes after SE onset and seizure response was measured for 5 hours in the rodent model of SE. Publication 4 reports

that both doses of ganaxolone elicited a "***complete block of SE***" at all time points, with antiepileptic activity observed for at least five hours.

Publication 4 is further evidence that before the '127 Application ***ganaxolone*** had already been administered to rodent models of ***SE*** and demonstrated effective therapeutic results (i.e., suppression of SE with ganaxolone) (emphasis added).

5. Publication 5 is relevant because it discloses additional *in vivo* data showing that ganaxolone effectively treats status epilepticus

Publication 5 published on April 4, 2016, which is before the earliest possible effective filing date of the '127 Application, and is prior art under section 102(a)(1).

Publication 5 presents additional *in vivo* data showing that ***ganaxolone*** is ***effective in treating SE*** in the well-known and predictive rat lithium-pilocarpine model of convulsive SE (emphasis added). Publication 5 discloses that ganaxolone (6, 9, 12 mg/kg) or allopregnanolone (15 mg/kg) were administered as an intravenous bolus injection at the time of convulsive SE onset (time 0), or 15, 30, or 60 minutes after convulsive SE onset. Publication 5 further discloses that ganaxolone "***was able to halt***" convulsive SE and produced a dose-dependent reduction in SE at all time intervals. Publication 5 concludes that intravenous bolus administration of ***ganaxolone produced a dose dependent anti-convulsant effect*** (emphasis added).

As a comparison, Example 3 in the '127 Application is an equivalent experiment to that carried out in Publication 5. Example 3 describes evaluating the effects of the ***same*** compounds, in the ***same*** rodent model, using ***similar*** doses, and ***similar*** administration route (emphasis added). Example 3 merely confirms the observations published in the art.

Publication 5 is again further evidence that, before the '127 Application, it was established that ***ganaxolone*** can effectively ***treat SE*** (emphasis added).

6. Publication 6 is relevant because it discloses that a human was administered ganaxolone as part of the Phase I clinical trial of ganaxolone for treating status epilepticus

Publication 6 published on June 22, 2016, which is again before the earliest possible effective filing date of the '127 Application, and is prior art under section 102(a)(1).

Publication 6 announced on June 16, 2016, that Marinus Pharmaceuticals, Inc. had "dosed the first [human] ***subject*** in its ***Phase I clinical trial*** of ***ganaxolone*** IV … for the ***treatment of status epilepticus (SE)***" (emphasis added). Publication 6 demonstrates that before the earliest possible effective filing date of the '127 application that human clinical studies of ganaxolone for treating SE were underway and that the first subject in the study had already been dosed.

7. Publication 7 is relevant because the U.S. Food Administration granted orphan drug designation to Marinus Pharmaceuticals, Inc before the '127 Application

Publication 7 was published on April 15, 2016, which again published before the earliest possible effective filing date of the '127 Application, and is prior art under section 102(a)(1).

Publication 7 announces that the U.S. Food and Drug Administration granted Orphan Drug Designation to the intravenous formulation of ***ganaxolone for the treatment of SE*** (emphasis added). Publication 7 provides further evidence that persons of skill in the art expected that ganaxolone could be used to treat SE. It is noted that the FDA cannot grant an orphan designation if there is insufficient information about the drug "to establish a medically plausible basis ***for expecting the drug to be effective*** in the prevention, diagnosis, or treatment of that disease of condition." 37 C.F.R. § 316.25(a)(2) (emphasis added).

8. Publication 8 is relevant because it demonstrates that ganaxolone had been administered to patients at a dose of up to 1,800 mg per day

Dependent claims 4 and 9 of the '127 application disclose administering to a patient up to 1,800 mg of ganaxolone per day. Administering up to 1,800 mg of ganaxolone per day is not disclosed in the two provisional applications to which the '127 application claims priority. Administering up to 1,800 mg of ganaxolone per day is first disclosed in U.S. Application No. 15/673,737, filed on ***August 10, 2017***. *See e.g.*, ¶¶ [0032] and [0033]. Publication 8 published on October 26, 2016, and is prior art under section 102(a)(1) with respect to claims that recite administering up to 1,800 mg of ganaxolone per day.

Publication 8 is an exemplary publication that discloses that ganaxolone was known to have been administered at a maximum dose of ***1,800 mg of ganaxolone per day*** in an open label trial of ganaxolone in patients with genetic epileptic disorders. *See*, Methods at lines 1-4. Publication 8 demonstrates that before the '127 Application administering up to 1,800 mg of ganaxolone to human patients was known in the art.

9. The relevance of the cited publications is further explained in the below claim chart

Claim Chart for U.S. Application No. 17/024,127

Claim in U.S. Application No. 17/024,127	Support in Publications
1. A method of ***treating status epilepticus***	**Publication 2:** is directed to ***treating SE***. "The disclosure includes methods of ***treating status epilepticus***, refractory status epilepticus, super-refractory status epilepticus, PCDH19 female pediatric epilepsy, and other seizure disorders comprising administering an effective amount of the substituted β-cyclodextrin-ganaxolone injectable formulation to a patient suffering from any of these seizure disorders." *See*, ¶ [0069]. "The disclosure includes methods of ***treating*** a seizure disorder wherein the seizure disorder ***is status epilepticus, refractory status epilepticus, super refractory status epilepticus***, or PCDH19 female pediatric epilepsy comprising administering an effective amount of the ganaxolone/ sulfobutyl ether-β-cyclodextrin formulation to a patient." *See*, ¶ [0078]. *See also*, ¶¶ [0070], Example 8, claim 31. **Publication 3**: generally discloses treating epileptic disorders, including SE. "[T]he ganaxolone is used to ***treat status epilepticus*** . . . ." *See*, ¶ [0019]. The ganaxolone formulations described herein can be administered in therapeutically effective amounts for the ***treatment*** of a subject that has had or is anticipating a convulsive state including, but not limited to, ***status epilepticus***, epileptic seizures or spasms. *See*, ¶ [00418]. **Publication 4**: is directed to ***treating SE*** in well-known and predictive rodent models. Publication 4 demonstrates that SE was effectively treated in clinically translatable rodent models. "These studies were designed to evaluate the potential of ganaxolone (GNX) for the ***treatment of status epilepticus*** (SE)." *See*, lines 1-2. "Conclusion: GNX produced an anti-epileptic response in a diazepam resistant model of SE with IV injection." *See*, lines 17-18 **Publication 5**: is directed to ***treating SE*** in well-known and predictive rodent models. Publication 5 demonstrates that status epilepticus was effectively treated in clinically translatable rodent models. "OBJECTIVE: To test IV ganaxolone in a clinically translatable rodent model of SE." Line 1. **Publication 6**: is directed to ***treating SE*** in a Phase I clinical study. "[T]oday announced that it has ***dosed the first subject in its Phase I clinical trial of ganaxolone IV*** . . . for the ***treatment of status epilepticus*** (SE)" Lines 2-3. **Publication 7**: is directed to ***treating SE***. "[T]he U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to the intravenous (IV) formulation of its CNS-selective $GABA_A$ modulator, ganaxolone, for the ***treatment of status epilepticus***."

comprising administering to a patient in need thereof a pharmaceutical composition comprising ***ganaxolone*** or a pharmaceutically acceptable salt thereof.	**Publication 2:** discloses administering an intravenous ***ganaxolone*** formulation comprising sulfobutyl ether-β-cyclodextrin to treating SE. Publication 2 demonstrates a positive therapeutic effect of ganaxolone in an *in vivo* rodent model of SE. Ganaxolone intravenously administered at 12 mg/kg and 15 mg/kg at 15 minutes and 60 minutes after the onset of SE elicited anti-epileptic activity for up to 5 hours. *See*, Example 8 at ¶¶ [0117]-[0135], Figure 3 and Figure 4. "The disclosure provides an injectable ***ganaxolone formulation*** comprising ganaxolone, sulfobutyl ether-β-cyclodextrin; and water." *See*, Abstract. "The disclosure includes methods of treating a seizure disorder wherein the seizure disorder is status epilepticus, refractory status epilepticus, super refractory status epilepticus, or PCDH19 female pediatric epilepsy comprising ***administering an effective amount of the ganaxolone***/sulfobutyl ether-β-cyclodextrin formulation to a patient." *See*, ¶ [0078]. *See also*, ¶¶ [0005], [0007], [0029], [0030], [0032]-[0067], [0069], [0074]-[0078], [0080]-[0089], Claims 1-23, and Figures 1-4. **Publication 3:** discloses ***administering to a patient in need thereof*** a therapeutically effective amount of the ***ganaxolone formulations*** disclosed in Publication 3. "[T]he **ganaxolone** is used to ***treat status epilepticus*** . . . ." *See*, ¶ [0019]. "The **ganaxolone** formulations described herein can be administered in therapeutically effective amounts for the ***treatment*** of a subject that has had or is anticipating a convulsive state including, but not limited to, ***status epilepticus***, epileptic seizures or spasms." *See*, ¶ [00418]. **Publication 4**: is directed to a treating SE in a rodent model by ***administering ganaxolone***. Publication 4 demonstrates a positive therapeutic effect of ganaxolone in an *in vivo* rodent model of SE. Ganaxolone (12 or 15 mg/kg) was administered via intravenous injection into the rodent model. Lines 7 and 11. "**GNX** (12 or 15 mg/kg; bolus IV) elicited a complete block of SE when administered 15 or 60 min after SE onset. The GNX antiepileptic activity was durable, with activity observed for at least 5 hours." Lines 11-14. **Publication 5**: is directed to a treating SE in a rodent model by ***administering ganaxolone***. Publication 5 demonstrates a positive therapeutic effect of ganaxolone in an *in vivo* rodent model of SE. "**GNX** (6, 9, 12 mg/kg) or ALLO (15 mg/kg) were administered via IV bolus injections at the time of CSE onset (time 0) or 15, 30, or 60 minutes after CSE onset, as measured by the first observed Racine Stage 3 seizure." Lines 6-8. "IV bolus **ganaxolone** produced a dose-dependent anti-convulsant effect." Lines 17-18. **Publication 6**: is directed to ***treating SE*** in a Phase I clinical study. "[T]oday announced that it has ***dosed the first subject in its Phase I clinical trial of ganaxolone IV …*** for the ***treatment of status epilepticus*** (SE)"

	Lines 2-3. **Publication 7**: is directed to ***treating SE***. "[T]he U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to the intravenous (IV) formulation of its CNS-selective $GABA_A$ modulator, ganaxolone, for the ***treatment of status epilepticus***."
2. The method of claim 1, wherein the patient is administered ganaxolone or a pharmaceutically acceptable salt thereof ***twice daily***.	**Publication 2:** Discloses that multiple injections of the ganaxolone formulation can be administered and that injections may be given at intervals of 1 to 24 hours. *See*, ¶ [0074]. **Publication 3**: Discloses that ganaxolone can be administered twice daily. "(s) the ganaxolone is administered ***twice a day*** . . . ." *See*, ¶ [0019]. "In other embodiments, the ganaxolone particles are dispersed in an ***aqueous dispersion for b.i.d. administration***" *See*, ¶ [00174]. "b.i.d" is defined as ***twice-a-day*** administration. *Id.* *See also*, ¶¶ [00287], [00289], and [00290].
3. The method of claim 1, wherein the patient is administered ganaxolone or a pharmaceutically acceptable salt thereof ***three times daily***.	**Publication 2:** Discloses that multiple injections of the ganaxolone formulation can be administered and that injections may be given at intervals of 1 to 24 hours. *See*, ¶ [0074]. **Publication 3**: Discloses that ganaxolone can be administered three times daily. "In one aspect, the ***aqueous oral suspension*** can be administered ***three times a day*** (ti.d)." *See*, ¶ [00289]. "Contemplated compositions of the present invention provide a therapeutically effective amount of ***ganaxolone*** over an interval of about 30 minutes to about 8 hours after administration, enabling, for example, once-a-day, twice-a-day, ***three times a day***, and etc. administration if desired. *See*, ¶ [00290]. *See also*, ¶ [00174].
4. The method of claim 6, wherein the patient is administered ganaxolone or a pharmaceutically acceptable salt in ***an amount of up to 1,800 mg/day***.	**Publication 8:** Discloses administering to the patient ganaxolone an amount of up to 1,800 mg/day. "Dosages were ***up to 1,800 mg/day***." See, Methods at lines 3-4.
5. The method of claim 1, wherein the pharmaceutical composition is an ***oral capsule***.	**Publication 3**: teaches oral capsule formulations of ganaxolone. "(ai) the formulation is in the form of a ***pharmaceutically-acceptable tablet or capsule*** . . . ." *See*, ¶ [0018]. "In some embodiments, the entire dose of the ***ganaxolone*** formulation is delivered in a ***capsule form***" *See*, ¶ [00200]. "When administering ***ganaxolone capsules***, both test capsule and reference capsules are given in a dose of about 10 mg/kg. ***Capsules are administered orally as is typical***." *See*, ¶ [00443]. "The ganaxolone particles generated by the methods described herein can be utilized in solid or aqueous liquid dosage formulations, such as controlled release formulations, solid dose fast melt formulations, lyophilized formulations, tablets, ***capsules***, aqueous dispersions, or aerosol

	formulations." *See*, ¶ [00389]. *See also*, ¶¶ [0018], [0041], [0042], [0044], [0068], [0090], [00174], [00179], [00180], [00200]-[00208], [00389], Example 11 at [00443], Example 53 at [00519]-[00523], Example 54 [00524]-[00425] Example 55 [00526]-[00527]
6. The method of claim 1, wherein the pharmaceutical composition is an ***oral suspension***.	**Publication 3**: teaches oral suspension formulations of ganaxolone. "(n) the ***ganaxolone*** is administered as an ***oral suspension*** to infants about every 6 hours, about every 8 hours, about every 12 hours, as needed" *See*, ¶ [0019]. "In still other aspects, the invention is directed to a liquid pharmaceutical ***oral suspension comprising ganaxolone*** . . . ." *See*, ¶ [0068]. "Ganaxolone oral solid dosage forms and ***oral aqueous suspensions*** are included herein." *See*, ¶ [00164]. "Liquid ganaxolone formulation dosage forms for ***oral administration*** can be ***aqueous suspensions*** selected from the group including, but not limited to, pharmaceutically acceptable aqueous oral dispersions, emulsions, solutions, and syrups." *See*, ¶ [00256]. *See also*, ¶¶ [0018], [00174], [00253], [00253], [00255], [00289], [00426], Example 11 at [00443], Example 13 at [00446], Example 14 at [00447]-[00448], Example 15 at [00449], Example 16 at [00450]-[00451]-[00452], Example 18 at [00453]-[00455], Example 23 at [00465]-[00467], Example 53 at [00546]-[00547].
7. The method of claim 1, wherein the pharmaceutical composition is an ***oral suspension comprising 50 mg/ml*** ganaxolone or a pharmaceutically acceptable salt thereof.	**Publication 3**: discloses that ganaxolone is an oral suspension comprising 50 mg/ml of ganaxolone. "In another embodiment, a ***ganaxolone formulation*** is administered as an aqueous ***oral suspension*** at a concentration of about ***50 mg/ml*** final concentration." *See*, ¶ [0289]. "(ae) the formulation is in the form of an aqueous dispersion wherein the concentration of ***ganaxolone*** is between about 25 to ***50 mg/ml*** of solution . . . ." *See*, ¶ [0018]. "In yet another embodiment, the ***aqueous oral dispersions*** described herein comprise ganaxolone particles or ***ganaxolone*** complex at a concentration of about ***50 mg/ml of suspension***. *See*, ¶ [00255]. *See also*, Example 21 at [00459]-[00460], Example 64 at [00546]-[00547].
8. 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***.	**Publication 3**: discloses that ganaxolone can be an oral suspension comprising 50 mg/ml ganaxolone and can be administered three times daily. "In another embodiment, ***a ganaxolone formulation*** is administered as an ***aqueous oral suspension*** at a concentration of about ***50 mg/ml final concentration***. The aqueous oral suspensions comprising a ganaxolone formulation described herein can be administered both as a single dose per day or given multiple times within a 24 hour period. In one aspect, the aqueous oral suspension can be administered ***three times a day*** (ti.d)." ¶ [00289].
9. The method of claim 1, wherein the pharmaceutical composition is an ***oral suspension comprising 50***	**Publication 3**: discloses that ganaxolone is an oral suspension comprising 50 mg/ml of ganaxolone.

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***.	"In another embodiment, a ***ganaxolone formulation*** is administered as an aqueous ***oral suspension*** at a concentration of about ***50 mg/ml*** final concentration. The aqueous oral suspensions comprising a ganaxolone formulation described herein can be administered both as a single dose per day or given multiple times within a 24 hour period. In one aspect, the aqueous oral suspension can be administered ***three times a day*** (ti.d)." *See*, ¶ [0289]. *See also*, [0018], [00255], Example 21 at [00459]-[00460], Example 64 at [00546]-[00547]. **Publication 8:** Discloses administering to the patient ganaxolone an amount of up to 1,800 mg/day. "Dosages were ***up to 1,800 mg/day***." See, Methods at lines 3-4.
10. The method of claim 1, wherein the patient is administered ***600 mg ganaxolone*** or a pharmaceutically acceptable salt thereof.	**Publication 3**: discloses that the ganaxolone formulation comprises 600 mg of ganaxolone. "In some embodiments, the entire dose of ganaxolone is delivered in capsule form. For example, 100 mg to about ***600 mg of ganaxolone***." ¶ [00200]. "In various other embodiments of the present invention, the ***amount ganaxolone administered*** to a subject via a solid dosage form to achieve a therapeutically effective concentration ganaxolone is typically in the range of about 50 mg to about 800 mg or from about 300 mg to about 700 mg. In one embodiment, a ***ganaxolone*** formulation is ***administered*** in a solid dosage form at a concentration of about ***250 mg to about 650 mg***." ¶ [00287]. *See also*, ¶¶ [0011] and [00206]
11. The method of claim 1, wherein the patient is administered ***600 mg ganaxolone*** or a pharmaceutically acceptable salt thereof ***three times daily***.	**Publication 3**: discloses that 600 mg of ganaxolone can be administered and discloses that the ganaxolone formulation can be administered three times per day. "In one embodiment, a ***ganaxolone*** formulation is ***administered*** in a solid dosage form at a concentration of about ***250 mg to about 650 mg***." ¶ [00287]. "In one aspect, the ***aqueous oral suspension*** can be administered ***three times a day*** (ti.d)." *See*, ¶ [00289]. *See also*, ¶¶ [0011], [00174], [00200], [00206], and [00290].
12. The method of claim 1, wherein the patient is administered ***50 mg ganaxolone*** or a pharmaceutically acceptable salt thereof.	**Publication 3**: discloses that 50 mg of ganaxolone can be administered. "In various other embodiments of the present invention, the amount ***ganaxolone administered to a subject*** via a solid dosage form to achieve a therapeutically effective concentration ganaxolone is typically in the range of about ***50 mg*** to about 800 mg or from about 300 mg to about 700 mg." *See*, ¶ [00288].
13. The method of claim 1, wherein the patient is administered ***100 mg ganaxolone*** or a pharmaceutically acceptable salt thereof.	**Publication 3**: discloses that 100 mg of ganaxolone can be administered. "In some embodiments, the entire dose of the ganaxolone formulation is delivered in a capsule form. For example, the capsule may comprise between about ***100 mg*** to about 600 mg of ganaxolone. In some

	embodiments, the capsule may comprise between ***about 100 to about 500 mg of ganaxolone***." *See*, ¶ [00200]. "In various other embodiments of the present invention, the amount ganaxolone administered to a subject via a solid dosage form to achieve a therapeutically effective concentration ***ganaxolone is typically in the range of about 50 mg*** to about 800 mg or from about 300 mg to about 700 mg." *See*, ¶ [00288].
14. The method of claim 1, wherein the patient is administered ***200 mg ganaxolone*** or a pharmaceutically acceptable salt thereof.	**Publication 3**: discloses that 200 mg of ganaxolone can be administered. "In another aspect, the invention is directed to a pharmaceutical composition comprising particles comprising ganaxolone, the composition providing a mean blood plasma AUC(0-24) from about 100 to about 300 ng*h/mL after ***200 to about 500 mg*** of ganaxolone is administered to adult subjects in the fasted state." See, ¶ [0027]. "A liquid pharmaceutical oral suspension comprising ganaxolone, the suspension providing a mean blood plasma Cmax of about 30 to 45 ng/mL and a mean blood plasma AUC (0-24) of about 160 to about 210 ng*h/mL, based on a dose of ***200 mg ganaxolone*** to subjects in the fasted state" Claim 160. *See also*, ¶¶ [0011], [0028]-[0030], [0062]-[0066], [00200], [00288], [00360], [00426], and Claim 163.
15. The method of claim 1, wherein the patient is administered ***300 mg ganaxolone*** or a pharmaceutically acceptable salt thereof.	**Publication 3**: discloses that 300 mg of ganaxolone can be administered. "In another embodiment, the ***ganaxolone*** formulation is ***administered*** in a solid dosage form at concentration of about ***300-400 mg***." *See*, ¶ [00288] *See also*, ¶¶ [0011], [0027]-[0030], [0062]-[0066], [00200], and [00360].
16. The method of claim 1, wherein the patient is administered ***400 mg ganaxolone*** or a pharmaceutically acceptable salt thereof.	**Publication 3**: discloses that 400 mg of ganaxolone can be administered. "In another embodiment, the ***ganaxolone*** formulation is ***administered*** in a solid dosage form at concentration of about ***300-400 mg***." *See*, ¶ [00288] *See also*, ¶¶ [0011], [0027]-[0030], [0062]-[0066], [00200], and [00360].
17. The method of claim 1, wherein the patient is administered ***500 mg ganaxolone*** or a pharmaceutically acceptable salt thereof.	**Publication 3**: discloses that 500 mg of ganaxolone can be administered. "In another aspect, the invention is directed to a pharmaceutical composition comprising particles comprising ganaxolone, the composition providing a mean blood plasma AUC(0-24) from about 100 to about 300 ng*h/mL after 200 to ***about 500 mg*** of ganaxolone is administered to adult subjects in the fasted state." *See*, ¶ [0027]. *See also*, ¶¶ [0011], [0028]-[0030], [0062]-[0066], [00200], [00288], [00360], and claims 148-151, and 158.
18. The method of claim 1, wherein the patient is administered ***oral capsules*** comprising ***200-600 mg ganaxolone*** or a pharmaceutically acceptable salt thereof.	**Publication 3**: discloses that 200-600 mg of ganaxolone can be administered. "In various other embodiments of the present invention, the amount ganaxolone administered to a subject via a solid dosage form to achieve a therapeutically effective concentration ganaxolone is typically in the range of about ***50 mg to about 800 mg or from about 300 mg to about 700 mg***."

	See, ¶ [00288]. *See also*, ¶¶ [0011] and [00200].
19. The method of claim 1, wherein the pharmaceutical composition provides ***reduction in the frequency of seizures***.	**Publication 1:** demonstrates that ganaxolone exerts anticonvulsant effects in numerous animal models of epileptic disorders."***[G]anaxolone*** exerts ***potent anticonvulsant effects*** in a broad range of animal model seizure models with predictive validity for a number of different human epileptic disorders" (see, p. 1290, right col.)." "***Ganaxolone*** also exhibited ***potent anticonvulsant activity against seizures*** induced by s.c. bicuculline (ED50 of 4.6 mg/kg i.p.), i.p. TBPS (ED50 of 11.7 mg/kg i.p.) and i.p. aminophylline (ED50 of 11.5 mg/kg i.p.) in mice." *See,* Abstract. **Publication 2**: demonstrates a positive therapeutic effect of ganaxolone in an *in vivo* rodent model of SE. Ganaxolone intravenously administered at 12 mg/kg and 15 mg/kg at 15 minutes and 60 minutes after the onset of SE ***elicited anti-epileptic activity for at least 5 hours***. *See*, Example 8 at ¶¶ [0117]-[0135], Figure 3 and Figure 4. **Publication 4:** demonstrates that ganaxolone suppressed SE in a clinically translatable rodent model of SE. "GNX (12 or 15 mg/kg; bolus IV) elicited a ***complete block of SE*** when administered 15 or 60 min after SE onset. The ***GNX antiepileptic activity was durable***, with activity observed for at least 5 hours." Lines 11-14." **Publication 5**:demonstrates that ganaxolone stopped SE and reduced seizure activity when administration was delayed. "GNX was able to ***halt CSE and produced a dose-dependent reduction in CSE at all time points***." Lines 13-14. "***GNX reduced seizure activity*** when administration was delayed until 30 min and up to at least 60 minutes after CSE onset, a period of SE typically refractory to benzodiazepines." Lines 20-22.
20. The method of claim 1, wherein the pharmaceutical composition provides ***reduction in the frequency of seizures, the severity of seizures***, or a combination thereof.	**Publication 1:** demonstrates that ganaxolone exerts anticonvulsant effects in numerous animal models of epileptic disorders."***[G]anaxolone*** exerts ***potent anticonvulsant effects*** in a broad range of animal model seizure models with predictive validity for a number of different human epileptic disorders" (see, p. 1290, right col.)." "***Ganaxolone*** also exhibited ***potent anticonvulsant activity against seizures*** induced by s.c. bicuculline (ED50 of 4.6 mg/kg i.p.), i.p. TBPS (ED50 of 11.7 mg/kg i.p.) and i.p. aminophylline (ED50 of 11.5 mg/kg i.p.) in mice." *See,* Abstract. **Publication 3**: demonstrates a positive therapeutic effect of ganaxolone in an *in vivo* rodent model of SE. "Ganaxolone intravenously administered at 12 mg/kg and 15 mg/kg at 15 minutes and 60 minutes after the onset of status epilepticus ***elicited anti-epileptic activity for up to 5 hours***. *See*, Example 8 at ¶¶ [0117]-[0135], Figure 3 and Figure 4. **Publication 4:** demonstrates that ganaxolone suppressed SE in a clinically translatable rodent model of SE.

	"GNX (12 or 15 mg/kg; bolus IV) elicited a ***complete block of SE*** when administered 15 or 60 min after SE onset. The ***GNX antiepileptic activity was durable***, with activity observed for at least 5 hours." Lines 11-14." **Publication 5**:demonstrates that ganaxolone stopped SE and reduced seizure activity when administration was delayed. "GNX was able to ***halt CSE and produced a dose-dependent reduction in CSE at all time points***." Lines 13-14. "***GNX reduced seizure activity*** when administration was delayed until 30 min and up to at least 60 minutes after CSE onset, a period of SE typically refractory to benzodiazepines." Lines 20-22. "Administration of GNX promoted survival with activity similar to that observed with ALLO in a rat model of CSE." Lines 17-19.

Respectfully submitted,

HOGAN LOVELLS US LLP

/Robert H. Underwood, Reg. No. 45,170/

Robert H. Underwood
Registration No. 45,170

Please recognize our Customer No. 24633 as our correspondence address

Date: February 8, 2021

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THIRD-PARTY SUBMISSION UNDER 37 CFR 1.290 CONCISE DESCRIPTION OF RELEVANCE	
Application Number	17024127

U.S. PATENTS

Cite No	Patent Number	Concise Description of Relevance

U.S. PATENT APPLICATION PUBLICATION

Cite No	Publication Number	Concise Description of Relevance

FOREIGN PATENT DOCUMENTS		
CiteNo	**Foreign Document Number**	**Concise Description of Relevance**
1	2007062266	see attached
2	2016127170	see attached

NON-PATENT PUBLICATIONS		
Cite No	**Reference**	**Concise Description of Relevance**

PTO/SB/429(08-12)
Approved for use through 07/31/2015. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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THIRD-PARTY SUBMISSION UNDER 37 CFR 1.290	Application Number	17024127

U.S. PATENTS				
Cite No	Patent Number	Kind Code[1]	Issue Date (YYYY-MM-DD)	First Named Inventor

U.S. PATENT APPLICATION PUBLICATIONS				
Cite No	Publication Number	Kind Code[1]	Publication Date (YYYY-MM-DD)	First Named Inventor

FOREIGN PATENTS AND PUBLISHED FOREIGN PATENT APPLICATIONS						
Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[1]	Publication Date (YYYY-MM-DD)	Applicant, Patentee or First Named Inventor	T[5]
1	2016127170	WO	A1	2016-08-11	Marinus Pharmaceuticals, Inc.	☐
2	2007062266	WO	A1	2007-05-31	Marinus Pharmaceuticals	☐

NON-PATENT PUBLICATIONS (e.g., journal article, Office action)			
Cite No	Author (if any), title of the publication, page(s) being submitted, publication date, publisher (where available), place of publication (where available).	T[5]	E[6]

THIRD-PARTY SUBMISSION UNDER 37 CFR 1.290	Application Number	17024127

		☐	☐

STATEMENTS

The party making the submission is not an individual who has a duty to disclose information with respect to the above-identified application under 37 CFR 1.56.

This submission complies with the requirements of 35 U.S.C. 122(e) and 37 CFR 1.290.

☒ The fee set forth in 37 CFR 1.290(f) has been submitted herewith.

☐ The fee set forth in 37 CFR 1.290(f) is not required because this submission lists three or fewer total items and, to the knowledge of the person signing the statement after making reasonable inquiry, this submission is the first and the only submission under 35 U.S.C 122(e) filed in the above-identified application by the party making the submission or by a party in privity with the party.

☐ This resubmission is being made responsive to a notification of non-compliance issued for an earlier filed third-party submission. The corrections in this resubmission are limited to addressing the non-compliance. As such, the party making this resubmission: (1) requests that the Office apply the previously-paid fee set forth in 37 CFR 1.290(f), or (2) states that no fee is required to accompany this resubmission as the undersigned is again making the fee exemption statement set forth in 37 CFR 1.290(g).

Signature	/Robert H. Underwood/		
Name/Print	Robert H. Underwood	Registration Number (if applicable)	45170

Examiner Signature		Date Considered	

*EXAMINER: Signature indicates all documents listed above have been considered,except for citations through which a line is drawn. Draw line through citation if not considered. Include a copy of this form with next communication to applicant. 1. If known, enter kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16. See MPEP 901.04(a). 2. Enter the country or patent office that issued the document, by two-letter code under WIPO standard ST.3. See MPEP 1851. 3. For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 4. If known, enter the kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 . See MPEP 901.04(a). 5. Check mark indicates translation attached. 6. Check mark indicates evidence of publication attached.

Doc Code: IDS.3P
Document Description: Information Disclosure Statement Filed

PTO/SB/429 (06-15)
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THIRD-PARTY SUBMISSION UNDER 37 CFR 1.290

(Do **not** submit this form electronically via EFS-Web)

Application Number (required):

17/024,127

U.S. PATENTS AND U.S. PATENT APPLICATION PUBLICATIONS

Cite No.	Document Number Number-Kind Code[1]	Issue Date or Publication Date MM/DD/YYYY	First Named Inventor
	US-		
	US-		
	US-		
	US-		
	US-		
	US-		
	US-		
	US-		
	US-		

FOREIGN PATENTS AND PUBLISHED FOREIGN PATENT APPLICATIONS

Cite No.	Country or Patent Office and Document Number Country Code[2]-Number[3]-Kind Code[4]	Publication Date MM/DD/YYYY	Applicant, Patentee or First Named Inventor	Translation Attached
2	WO2016/127170	08/11/2016	Marinus Pharmaceuticals, Inc.	☐
3	WO007/062266	05/31/2007	Marinus Pharmaceuticals, Inc.	☐
				☐
				☐
				☐
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This collection of information is required by 35 U.S.C. 122(e) and 37 CFR 1.290. The information is required to obtain or retain a benefit by the public, which is to update (and by the USPTO to process) the file of a patent or reexamination proceeding. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 10 hours 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.**

Doc Code: IDS.3P
Document Description: Information Disclosure Statement Filed

PTO/SB/429 (06-15)
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THIRD-PARTY SUBMISSION UNDER 37 CFR 1.290

(Page 2 of 2)

Application Number (required): 17/024,127

NON-PATENT PUBLICATIONS (e.g., journal article, Office action)

Cite No.	Author (if any), title of the publication, page(s) being submitted, publication date, publisher (where available), and place of publication (where available)	Translation Attached	Evidence of Publication Attached
1	Carter et al., Characterization of the Anticonvulsant Properties of Ganaxolone (CCD 1042; 3α-Hydroxy-3β-methyl-5α-pregnan-20-one), a Selective, High-Affinity, Steroid Modulator of the γ-Aminobutyric AcidA Rec	☐	☑
4	Saporito et al., Intravenous Administration of Ganaxolone Attenuates Electroencephalographic Seizures in a Diazepam Resistant Model of Status Epilepticus, Neurobiology, 86 (16 supplement), published April 4, 2	☐	☑
5	Saporito et al., Ganaxolone Administered Intravenously Prevents Behavioral Seizures and Promotes Survival in the Rat Lithium-Pilocarpine Model of Status Epilepticus, Neurology, 86 (16 Supplement), published A	☐	☑
6	Press Release: "Marinus Pharmaceuticals Doses First Subject in Phase 1 Clinical Trial for Ganaxolone IV," Published on June 22, 2016, Available at: https://ir.marinuspharma.com/news/news-details/2016/Marinus	☐	☑
7	Press Release: "Marinus Pharmaceuticals Receives FDA Orphan Drug Designation for Ganaxolone IV to Treat Status Epilepticus," Published April 15, 2016, Available at: https://ir.marinuspharma.com/news/news-	☐	☑
8	Chez, Ganaxolone Therapy Improves Interictal EEG and Seizure Control in Lennox Gastaut Syndrome in Patients with PCDH19 and CDKL5," Child Society for Neuroscience published October 26, 2016	☐	☑
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

STATEMENTS

The party making the submission is not an individual who has a duty to disclose information with respect to the above-identified application under 37 CFR 1.56.

This submission complies with the requirements of 35 U.S.C. 122(e) and 37 CFR 1.290.

☑ The following fee set forth in 37 CFR 1.290(f) is submitted herewith: ☒ regular undiscounted ☒ small entity*

☐ The fee set forth in 37 CFR 1.290(f) is not required because this submission lists three or fewer total items and, to the knowledge of the person signing the statement after making reasonable inquiry, this submission is the first and only submission under 35 U.S.C. 122(e) filed in the above-identified application by the party making the submission or by a party in privity with the party.

☐ This resubmission is being made responsive to a notification of non-compliance issued for an earlier filed third-party submission. The corrections in this resubmission are limited to addressing the non-compliance. As such, the party making this resubmission: (1) requests that the Office apply the previously-paid fee set forth in 37 CFR 1.290(f), or (2) states that no fee is required to accompany this resubmission as the undersigned is again making the fee exemption statement set forth in 37 CFR 1.290(g).

Signature	/Robert H. Underwood, Reg. No. 45,170/	Date	February 8, 2021
Name (Printed/Typed)	Robert H. Underwood	Reg. No., if applicable	45,170

Examiner Signature**		Date Considered	

*SUBMITTER: By selecting the "small entity" box and paying the applicable small entity fee, the party making the submission asserts that the party qualifies as a small entity. A third party is not eligible for the micro entity discount.

**EXAMINER: Signature indicates all items listed have been considered, except for citations through which a line is drawn. Draw line through citation if not considered. Include a copy of this form with next communication to applicant.

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.

Electronic Acknowledgement Receipt	
EFS ID:	43154369
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/Julie Dascoli
Filer Authorized By:	Jeffrey S. Steen
Attorney Docket Number:	2262-29 CON B CON III
Receipt Date:	01-JUL-2021
Filing Date:	17-SEP-2020
Time Stamp:	18:40:41
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	2262-29_-_WO2015189744A1.pdf	3182648 15934cb031415b5009e55814cb93c0ee5cdb88a3	no	85

Warnings:

Information:					
2	Non Patent Literature	jpoa.pdf	54778 c67c3c1b739eb7a6c80183366a074f80adf5feea	no	3
Warnings:					
Information:					
3	Non Patent Literature	D5_Brain_A_Journal_of_Neurology_2012_Vol_135_pp_105-116.pdf	1451549 3165b31d11fe3d6ad255214a46d2d8d2c2a79116	no	12
Warnings:					
Information:					
4	Transmittal Letter	Supp_IDS_Tranmsittal.pdf	20650 d7fc2ff400328cb18aa1a0cd99c883b3195ccb93	no	2
Warnings:					
Information:					
5	Information Disclosure Statement (IDS) Form (SB08)	SB08.pdf	1034547 e9f05d03fd4a979c10bb3d2544a1a95b6e763041	no	4
Warnings:					
Information:					
6	Non Patent Literature	Handforth.PDF	250898 cff5bb34e6a35d2c3192ed2c7f799e80be75d3ba	no	4
Warnings:					
Information:					
7	Non Patent Literature	ILOA.PDF	249464 0da2f7ab5b2238e927ccc896308744415081d316	no	4
Warnings:					
Information:					
		Total Files Size (in bytes):	6244534		

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

New Applications Under 35 U.S.C. 111

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

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

Docket 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 Confirmation No.: 4361

Filed: September 17, 2020 Art Unit: 1629

For: METHODS AND COMPOSITIONS FOR TREATMENT OF EPILEPTIC DISORDERS Examiner: Not Yet Assigned

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)

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

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98, the attention of the United States Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of the above-identified application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)).

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), copies of U.S. patents and U.S. patent application publications are not submitted. Submitted herewith are copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made. In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in this Information Disclosure Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

I hereby certify, pursuant to 37 C.F.R. § 1.97(e)(1), that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

I hereby certify, pursuant to 37 C.F.R. 1.704(d)(1), that each item of information contained in the information disclosure statement:

> (i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement; or
> (ii) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98, and the Examiner is respectfully requested to consider the listed references.

Applicant believes no fee is due with this submission. However, if a fee is due, please charge our Deposit Account No. 50-2140, under Order No. 2262-29-CON B CON III from which the undersigned is authorized to draw.

Dated: July 1, 2021

Respectfully submitted,

/Jeffrey S. Steen, Reg. #32063/

Jeffrey S. Steen
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CARTER, DELUCA & FARRELL LLP
576 Broad Hollow Road
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Attorney for Applicant(s)

PTO/SB/08a (02-18)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17024127
Filing Date	2020-09-17
First Named Inventor	Matthew During
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	2262-29-CON B CON III

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20070259912	A1	2007-11-08	Cooper	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2015189744	WO	A1	2015-12-17	Pfizer Ltd		

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

	1	English translation of Japanese Office Action dated June 1, 2021, corresponding to Japanese Application No. 2019-507328;	
	2	Charles A. Handforth, "A Delta GABA Receptor as a Target for Essential Tremor Therapy," National Institutes of Health, June 10, 2015; 4 pages.	
	3	Paris-Robidas et al., "Defective dentate nucleus GABA receptors in essnetial tremor," Brain: A Journal of Neurology, 2012, Vol. 135; pages 105-116.	
	4	English tranlsation of Israeli Office Action dated April 12, 2021, corresponding to counterpart Israeli Application No. 264510; 4 pages.	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jeffrey S. Steen, Reg. #32063/	Date (YYYY-MM-DD)	2021-07-01
Name/Print	Jeffrey S. Steen	Registration Number	32,063

This collection of information is required by 37 CFR 1.97 and 1.98. 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 1 hour 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.**

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 the Freedom of Information Act requires disclosure of these record s.

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 inspections 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.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Number	17024127
Filing Date	2020-09-17
First Named Inventor	Matthew During
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	2262-29-CON B CON III

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20150359756	A1	2015-12-17	GUY ET AL.	
	2	20150335659	A1	2015-11-26	JONES et al.	

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Electronic Acknowledgement Receipt	
EFS ID:	43390052
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/Julie Dascoli
Filer Authorized By:	Jeffrey S. Steen
Attorney Docket Number:	2262-29 CON B CON III
Receipt Date:	30-JUL-2021
Filing Date:	17-SEP-2020
Time Stamp:	13:56:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Information_Disclosure_Statement_Fillable_PDF.pdf	1034605 0c6a612d808bfa7cb0d37648159b62d0369efaa7	no	4

Warnings:

Information:					
2	Non Patent Literature	MX_OA_dated_71.pdf	682192 e9819f710e33a434336306c09692018cfa648bf1	no	9
Warnings:					
Information:					
3	Non Patent Literature	Saporito_et_al_Intravenous.pdf	251961 52ab1300c694e9cd9cde43a6d0fffe3e00e4e72d	no	6
Warnings:					
Information:					
4	Non Patent Literature	BROA.pdf	147550 c81cfff61021ec59c261bb342f50fdebf735bb6a	no	5
Warnings:					
Information:					
5	Transmittal Letter	2262-29_CON_B_CON_III_-_Supp_IDS_Transmittal.pdf	20756 3493a6d8c71e00b9f36ca64b787816f952751291	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2137064		

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

New Applications Under 35 U.S.C. 111

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

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

I hereby certify, pursuant to 37 C.F.R. 1.704(d)(1), that each item of information contained in the information disclosure statement:

> (i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement; or
> (ii) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made. In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in this Information Disclosure Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98, and the Examiner is respectfully requested to consider the listed references.

Applicant believes no fee is due with this submission. However, if a fee is due, please charge our Deposit Account No. 50-2140, under Order No. 2262-29-CON B CON III from which the undersigned is authorized to draw.

Dated: July 30, 2021

Respectfully submitted,

/Jeffrey S. Steen, Reg. #32063/

Jeffrey S. Steen
Registration No.: 32,063
CARTER, DELUCA & FARRELL LLP
576 Broad Hollow Road
Melville, New York 11747
(631) 501-5700
Attorney for Applicant(s)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17024127
	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Mexican Office Action dated July 1, 2021, corresponding to counterpart Mexican Application No. MX/a/2019/001669; 9 pages.	
	2	Saporito et al., "Intravenous Administration of Ganaxolone Attenuates Electroencephalographic Seizures in a Diasepam Resistant Model of Status Epilepticus (P4.212)," Neurology, April 4, 2016; 6 pages.	
	3	Brazilian Office Action dated July 1, 2021, corresponding to counterpart Brazilian Application No. BR112019002538-3; 5 pages.	

If you wish to add additional non-patent literature document citation information please click the Add button Add

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Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

CERTIFICATION STATEMENT

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OR

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☒ See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jeffrey S. Steen, Reg. #32063/	Date (YYYY-MM-DD)	2021-07-30
Name/Print	Jeffrey S. Steen	Registration Number	32,063

This collection of information is required by 37 CFR 1.97 and 1.98. 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 1 hour 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.**

Privacy Act Statement

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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 the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

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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.

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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.

Electronic Acknowledgement Receipt	
EFS ID:	45066482
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/Elyssa Berger
Filer Authorized By:	Jeffrey S. Steen
Attorney Docket Number:	2262-29 CON B CON III
Receipt Date:	24-FEB-2022
Filing Date:	17-SEP-2020
Time Stamp:	10:09:30
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Information_Disclosure_Statement_Fillable_PDF.pdf	1034240 80d957c3a0741a64925d5ce7311b2109de158463	no	4

Warnings:

Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
2	Non Patent Literature	EP_Communication.pdf	315529 cd9e59a3254d462070b4810eeb2a663f1d581e6b	no	8
Warnings:					
Information:					
3	Transmittal Letter	2262-29_CON_B_CON_III_-_Supp_IDS_Transmittal.pdf	20712 2ec6e6c2caa94a468884dc38df0fbec11c6ba67e	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1370481		

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

New Applications Under 35 U.S.C. 111

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

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

Docket 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 | Confirmation No.: 4361

Filed: September 17, 2020 | Art Unit: 1629

For: METHODS AND COMPOSITIONS FOR TREATMENT OF EPILEPTIC DISORDERS | Examiner: R. T. Shiao

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)

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

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98, the attention of the United States Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of the above-identified application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)).

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), copies of U.S. patents and U.S. patent application publications are not submitted. Submitted herewith are copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2).

I hereby certify, pursuant to 37 C.F.R. § 1.97(e)(1), that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

I hereby certify, pursuant to 37 C.F.R. 1.704(d)(1), that each item of information contained in the information disclosure statement:

> (i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement; or
> (ii) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made. In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in this Information Disclosure Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98, and the Examiner is respectfully requested to consider the listed references.

Applicant believes no fee is due with this submission. However, if a fee is due, please charge our Deposit Account No. 50-2140, under Order No. 2262-29-CON B CON III from which the undersigned is authorized to draw.

Dated: February 24, 2022

Respectfully submitted,

/Jeffrey S. Steen, Reg. #32063/

Jeffrey S. Steen
Registration No.: 32,063
CARTER, DELUCA & FARRELL LLP
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(631) 501-5700
Attorney for Applicant(s)

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	17024127
	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	R. T. Shiao
	Attorney Docket Number	2262-29-CON B CON III

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							
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NON-PATENT LITERATURE DOCUMENTS			Remove
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17024127
	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	R. T. Shiao
	Attorney Docket Number	2262-29-CON B CON III

	1	European Communication dated February 17, 2022 corresponding to counterpart European Application No. 19190461.4; 8 pages.

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17024127
	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	R. T. Shiao
	Attorney Docket Number	2262-29-CON B CON III

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jeffrey S. Steen, Reg. #32063/	Date (YYYY-MM-DD)	2022-02-24
Name/Print	Jeffrey S. Steen	Registration Number	32,063

This collection of information is required by 37 CFR 1.97 and 1.98. 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 1 hour 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.**

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 the Freedom of Information Act requires disclosure of these record s.

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 inspections 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.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/024,127	09/17/2020	Matthew DURING	2262-29 CON B CON III	4361

31554 7590 04/04/2022

CARTER, DELUCA & FARRELL LLP
576 BROAD HOLLOW ROAD
MELVILLE, NY 11747

EXAMINER	
SHIAO, REI TSANG	

ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
04/04/2022	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.** 17/024,127	**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 9/17/2020.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-20 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) 1-20 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 9/17/2020 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 2/24/22,1/6/21, 1/7/21, 2/8/21, 7/1/21,7/30/21.

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 16/789,709 02/13/2020 PAT 10799485, which is a CON of 16/447,300 06/20/2019 PAT 10603308, which is a CON of 16/356,517 03/18/2019 PAT 10363246, which is a CON of 16/013,500 06/20/2018 ABN, which is a CON of 15/673,737 08/10/2017 ABN, which claims benefit of 62/490,293 04/26/2017, and claims benefit of 62/373,589 08/11/2016.

2. Claims 1-20 are pending in the application.

Double Patenting

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

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

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

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

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable independently over claim 1 of During's US 10,799,485, and over claims 1-13 of During's US 10,603,308 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicant claim 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, see claim 1.

During's '485 claims a method of treating PCDH19 related epilepsy comprising administering to a patient in need thereof a pharmaceutical composition comprising ganaxolone or a pharmaceutically acceptable salt thereof, see column 38.

During's '308 claims a method of treating CDKL5 deficiency disorder comprising administering to a patient in need thereof a pharmaceutical composition comprising ganaxolone or a pharmaceutically acceptable salt thereof wherein the patient is administered up to 1,800 mg of ganaxolone per day. The CDKL5 deficiency disorder is

frequency of seizures, the severity of seizures, or a combination thereof (i.e., epilepsy), see columns 38-39.

The difference between instant claims and During's '485 and '308 is that the instant claims are silent on the scope of dose of ganaxolone.

One having ordinary skill in the art would find the claims 1-20 prima facie obvious because one would be motivated to employ the methods of use of During's '485 and '308.

The motivation to make the claimed methods of use derived from the known methods of use of During's '485 and '308 would possess same yields to that which is claimed in the reference.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REI TSANG SHIAO whose telephone number is (571)272-0707. The examiner can normally be reached on 8:30 am-5:00 pm.

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

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/REI TSANG SHIAO/

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

March 29, 2022

Notice of References Cited	Application/Control No. 17/024,127	Applicant(s)/Patent Under Reexamination DURING, Matthew	
	Examiner REI TSANG SHIAO	Art Unit 1629	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-10603308-B2	03-2020	During; Matthew	A61K31/57	1/1
*	B	US-10799485-B2	10-2020	During; Matthew	A61K31/195	1/1
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	Art Unit
	REI TSANG SHIAO	1629

CPC - Searched*		
Symbol	Date	Examiner
A61K 31/437	02/18/2022	RS

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
STN, structure, inventors, text	12/29/2021	RS
EAST group/subgroup	02/18/2022	RS
PALM inventors	02/18/2022	RS

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629	

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L3	483,112	A61K 31/437	US-PGPUB; USPAT	OR	OFF	2022/02/18 15:45

EAST Search History (Interference)

<This search history is empty>

2/18/2022 3:45:38 PM

Doc Code: IDS.3P
Document Description: Information Disclosure Statement Filed

PTO/SB/429 (06-15)
Approved for use through 09/30/2021. OMB 0651-0062
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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THIRD-PARTY SUBMISSION UNDER 37 CFR 1.290

(Do **not** submit this form electronically via EFS-Web)

Application Number (required):

17/024,127

U.S. PATENTS AND U.S. PATENT APPLICATION PUBLICATIONS

Cite No.	Document Number Number-Kind Code[1]	Issue Date or Publication Date MM/DD/YYYY	First Named Inventor
	US-		
	US-		
	US-		
	US-		
	US-		
	US-		
	US-		
	US-		
	US-		

FOREIGN PATENTS AND PUBLISHED FOREIGN PATENT APPLICATIONS

Cite No.	Country or Patent Office and Document Number Country Code[2]-Number[3]-Kind Code[4]	Publication Date MM/DD/YYYY	Applicant, Patentee or First Named Inventor	Translation Attached
2	WO2016/127170	08/11/2016	Marinus Pharmaceuticals, Inc.	☐
3	WO007/062266	05/31/2007	Marinus Pharmaceuticals, Inc.	☐
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1. If known, enter kind of document by the appropriate symbols indicated on the document under WIPO Standard ST.16. See MPEP 901.04(a). 2. Enter the country or patent office that issued the document by two-letter country code under WIPO Standard ST.3. See MPEP 1851. 3. For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 4. If known, enter kind of document by the appropriate symbols indicated on the document under WIPO Standard ST.16. See MPEP 901.04(a).

This collection of information is required by 35 U.S.C. 122(e) and 37 CFR 1.290. The information is required to obtain or retain a benefit by the public, which is to update (and by the USPTO to process) the file of a patent or reexamination proceeding. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 10 hours 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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S/

Doc Code: IDS.3P
Document Description: Information Disclosure Statement Filed

PTO/SB/429 (06-15)
Approved for use through 09/30/2021. OMB 0651-0062
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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THIRD-PARTY SUBMISSION UNDER 37 CFR 1.290

(Page 2 of 2)

Application Number (required): 17/024,127

NON-PATENT PUBLICATIONS (e.g., journal article, Office action)

Cite No.	Author (if any), title of the publication, page(s) being submitted, publication date, publisher (where available), and place of publication (where available)	Translation Attached	Evidence of Publication Attached
1	Carter et al., Characterization of the Anticonvulsant Properties of Ganaxolone (CCD 1042; 3α-Hydroxy-3β-methyl-5α-pregnan-20-one), a Selective, High-Affinity, Steroid Modulator of the γ-Aminobutyric AcidA Rec	☐	☑
4	Saporito et al., Intravenous Administration of Ganaxolone Attenuates Electroencephalographic Seizures in a Diazepam Resistant Model of Status Epilepticus, Neurobiology, 86 (16 supplement), published April 4, 2	☐	☑
5	Saporito et al., Ganaxolone Administered Intravenously Prevents Behavioral Seizures and Promotes Survival in the Rat Lithium-Pilocarpine Model of Status Epilepticus, Neurology, 86 (16 Supplement), published A	☐	☑
6	Press Release: "Marinus Pharmaceuticals Doses First Subject in Phase 1 Clinical Trial for Ganaxolone IV," Published on June 22, 2016, Available at: https://ir.marinuspharma.com/news/news-details/2016/Marinus	☐	☑
7	Press Release: "Marinus Pharmaceuticals Receives FDA Orphan Drug Designation for Ganaxolone IV to Treat Status Epilepticus," Published April 15, 2016, Available at: https://ir.marinuspharma.com/news/news-	☐	☑
8	Chez, Ganaxolone Therapy Improves Interictal EEG and Seizure Control in Lennox Gastaut Syndrome in Patients with PCDH19 and CDKL5," Child Society for Neuroscience published October 26, 2016	☐	☑
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

STATEMENTS

The party making the submission is not an individual who has a duty to disclose information with respect to the above-identified application under 37 CFR 1.56.

This submission complies with the requirements of 35 U.S.C. 122(e) and 37 CFR 1.290.

☑ The following fee set forth in 37 CFR 1.290(f) is submitted herewith: ☐ regular undiscounted ☐ small entity*

☐ The fee set forth in 37 CFR 1.290(f) is not required because this submission lists three or fewer total items and, to the knowledge of the person signing the statement after making reasonable inquiry, this submission is the first and only submission under 35 U.S.C. 122(e) filed in the above-identified application by the party making the submission or by a party in privity with the party.

☐ This resubmission is being made responsive to a notification of non-compliance issued for an earlier filed third-party submission. The corrections in this resubmission are limited to addressing the non-compliance. As such, the party making this resubmission: (1) requests that the Office apply the previously-paid fee set forth in 37 CFR 1.290(f), or (2) states that no fee is required to accompany this resubmission as the undersigned is again making the fee exemption statement set forth in 37 CFR 1.290(g).

Signature	/Robert H. Underwood, Reg. No. 45,170/	Date	February 8, 2021
Name (Printed/Typed)	Robert H. Underwood	Reg. No., if applicable	45,170

Examiner Signature**	/REI TSANG SHIAO/	Date Considered	02/18/2022

*SUBMITTER: By selecting the "small entity" box and paying the applicable small entity fee, the party making the submission asserts that the party qualifies as a small entity. A third party is not eligible for the micro entity discount.

**EXAMINER: Signature indicates all items listed have been considered, except for citations through which a line is drawn. Draw line through citation if not considered. Include a copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S/

Privacy Act Statement

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17024127
Filing Date	2020-09-17
First Named Inventor	Matthew During
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	2262-29-CON B CON III

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20150359756	A1	2015-12-17	GUY ET AL.	
	2	20150335659	A1	2015-11-26	JONES et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17024127
	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	Not Yet Assigned. R T Shiao
	Attorney Docket Number	2262-29-CON B CON III

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Mexican Office Action dated July 1, 2021, corresponding to counterpart Mexican Application No. MX/a/2019/001669; 9 pages.	
	2	Saporito et al., "Intravenous Administration of Ganaxolone Attenuates Electroencephalographic Seizures in a Diasepam Resistant Model of Status Epilepticus (P4.212)," Neurology, April 4, 2016; 6 pages.	
	3	Brazilian Office Action dated July 1, 2021, corresponding to counterpart Brazilian Application No. BR112019002538-3; 5 pages.	

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EXAMINER SIGNATURE

Examiner Signature	/REI TSANG SHIAO/	Date Considered	02/18/2022

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jeffrey S. Steen, Reg. #32063/	Date (YYYY-MM-DD)	2021-07-30
Name/Print	Jeffrey S. Steen	Registration Number	32,063

This collection of information is required by 37 CFR 1.97 and 1.98. 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 1 hour 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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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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Application Number	17024127
Filing Date	2020-09-17
First Named Inventor	Matthew During
Art Unit	1629
Examiner Name	Not Yet Assigned
Attorney Docket Number	2262-29-CON B CON III

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	1	2006118897	WO	A1	2006-11-09	Merck & Co., Inc		

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

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	Examiner Name	Not Yet Assigned R T Shiao
	Attorney Docket Number	2262-29-CON B CON III

	1	Indian Examination report dated December 7, 2020, corresponding to counterpart Indian Application No. 201917005079; 5 pages.

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EXAMINER SIGNATURE

Examiner Signature	/REI TSANG SHIAO/	Date Considered	02/18/2022

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Signature	/Jeffrey S. Steen, Reg. #32063/	Date (YYYY-MM-DD)	2021-01-07
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U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	8618087	B2	2013-12-31	Shaw et al.	
	2	9339495		2016-05-17	During	
	3	9351968		2016-05-31	During	
	4	9399034		2016-07-26	During et al.	
	5	9446028		2016-09-20	During	
	6	9629853		2017-04-25	Jones et al.	
	7	9682069		2017-06-20	During	
	8	9717716		2017-08-01	During et al.	

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	9	10071083		2018-09-11	During	
	10	10363246		2019-07-30	During	
	11	10603308		2020-03-31	During	
	12	10799485		2020-10-13	During	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20070032553	A1	2007-02-08	McKernan et al.	
	2	20070112017	A1	2007-05-17	Barlow et al.	
	3	20070141161	A1	2007-06-21	Shaw et al.	
	4	20070259912	A1	2007-11-08	Cooper	
	5	20110034562	A1	2011-02-10	REGAN	

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	6	20110046090	A1	2011-02-24	Barlow et al.	
	7	20130309306	A1	2013-11-21	Rogawski et al.	
	8	20150313913	A1	2015-11-05	CATTERALL et al.	
	9	20150352085	A1	2015-12-10	During	
	10	20160038469	A1	2016-02-11	DURING	
	11	20160228418	A1	2016-08-11	DURING	
	12	20160228454	A1	2016-08-11	Zhang et al.	
	13	20170014392	A1	2017-01-19	During	
	14	20170014393	A1	2017-01-19	DURING	
	15	20170065572	A1	2017-03-09	DURING	
	16	20170348232	A1	2017-12-07	DURING	

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	17	20180042903	A1	2018-02-15	DURING	
	18	20180235942	A1	2018-08-23	DURING et al.	
	19	20180344708	A1	2018-12-06	During	

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	1	2016127170	WO	A1	2016-08-11	Marinus Pharmaceuticals, Inc		

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	1	Archer et al., J. of Medical Genetics, 2006, 43(9):729-734.	
	2	James K. Walsh, Ph.D., "Enhancement of Slow Wave Sleep: Implications for Insomnia," Journal of Clinical Sleep Medicine, (2009), Supplement to vol. 5, No. 2; pp. 827-832.	
	3	Glykys et al., "The Main Source of Ambient GABA Responsible for Tonic Inhibition in the Mouse Hippocampus," J Physiol, (2007), vol. 582, No. 3; pp. 1163-1178.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17024127
	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

	4	Iber et al., "The AASM Manual for the Scoring of Sleep and Associated Events," American Academy of Sleep Medicine (2007); pp. 3-59 (57 pages).	
	5	Jennum et al., "Sleep Disorders in Neurodegenerative Disorders and Stroke," European Handbook of Neurological Management, (2011), vol. 1, 2nd Edition, Chapter 39, Section 6--Sleep Disorders, (Ed. Gilhus et al.) Blackwell Publishing Ltd. 2011; pp.529-543.	
	6	Jonas et al., "Neural Inhibition,", Scholarpedia - http://www.scholarpedia.org/article/Neural_inhibition - (2014); 10 pages.	
	7	Egawa et al., "Pathophysiological power of improper tonic GABA(A) conductances in mature and immature models." Frontiers in Neural Circuits, Oct. 24, 2013, vol. 7, Article 170; pp. 1-15.	
	8	Lennox-gastaut syndrome; Wikipedia article. dated Jul. 10, 2016; 11 pages.	
	9	Natural Patterns of Sleep - Healthy Sleep - (2007) http://healthysleep.med.harvard.edu/healthy/science/what/sleep-patterns-rem-nrem (2007); 3 pages.	
	10	Tropea et al., "Partial Reversal of Rett Syndrome-like Symptoms in MeCP2 Mutant Mice," PNAS, Feb. 10, 2009, vol. 106, No. 6; pp. 2029-2034.	
	11	Vardya et al., "Positive Modulation of .delta.-Subunit Containing GABAA Receptors in Mouse neurons," Neuropharmacology, (2012), vol. 63; pp. 469-479.	
	12	International Search Report and Written Opinion of the International Searching Authority, dated Sep. 27, 2016, corresponding to International Application No. PCT/US16/42238; 8 total pages.	
	13	International Search Report and Written Opinion, dated Oct. 4, 2016, corresponding to International Application No. PCT/US16/50702; 9 total pages.	
	14	International Search Report and Written Opinion of the International Searching Authority, dated Jul. 18, 2017, corresponding to International Application No. PCT/US17/34443; 5 total pages.	

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	15	International Search Report and Written Opinion of the International Searching Authority, dated Aug. 26, 2015, corresponding to International Application No. PCT/US15/34018; 12 total pages.	
	16	Brown et al., "Pharmacological Characterization of a Novel Cell Line Expressing Human .alpha.4.beta.3.delta. GABAA Receptors," British Journal of Pharmacology, (2002), vol. 136, No. 7; pp. 965-974.	
	17	International Search Report and Written Opinion of the International Searching Authority, dated Aug. 14, 2015, corresponding to International Application No. PCT/US2015/029155; 19 total pages.	
	18	Cao et al., "Clustered burst firing in FMR1 premutation hippocampal neurons: amelioration with allopregnanolone," Human Molecular Genetics, 2012, vol. 21, No. 13, pp. 2923-2935.	
	19	Oakley et al., "Synergistic GABA-Enhancing Therapy against Seizures in a Mouse Model of Dravet Syndrome," The Journal of Pharmacology and Experimental Therapeutics, May 2013, vol. 345; pp. 215-224.	
	20	International Search Report and Written Opinion of the International Searching Authority, dated Oct. 31, 2017, corresponding to International Patent Application No. PCT/US17/46256; 10 total pages.	
	21	Loescher, W., "Development of Tolerance to the Anticonvulsant Effect of GABA-mimetic Drugs in Animal Models of Seizure States in Tolerance to Beneficial and Adverse Effects of Antiepileptic Drugs," Koella et al. (eds.), (1986); pp. 37-45. cited byapplicant.	
	22	Petersen et al., "THIP: A Single Blind Controlled Trial in Patients with Epilepsy," Acta Neurol. Scand. 67; pp. 114-117 (1983).	
	23	PCT Notice concerning Transmittal of International Preliminary Report on Patentability (Chapter I of the Patent Cooperation Treaty), International Preliminary Report on Patentability and Written Opinion of the International Searching Authority,datedFeb. 1, 2018, corresponding to International Application No. PCT/US2016/042238; 8 total pages.	
	24	Reagan-Shaw et al., "Dose translation from animal to human studies revisited", FASEB J, vol. 22, No. 3, Oct. 17, 2007; pp. 659-661.	
	25	International Search Report and Written Opinion of the International Searching Authority, dated Apr. 24, 2018, corresponding to International Application No. PCT/US18/16602; 15 total pages.	

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	Examiner Name	~~Not Yet Assigned~~ R T Shiao
	Attorney Docket Number	2262-29-CON B CON III

	26	Bahi-Buisson et al., "The three stages of epilepsy in patients with CDKL5 mutations", Epilepsia, (2008), vol. 49, No. 6; pp. 1027-1037.	
	27	Tenney et al., "The Current State of Absence Epilepsy: Can We Have Your Attention?", Epilepsy Currents, Current Review in Clinical Science, vol. 13, No. 3 (May/Jun. 2013); pp. 135-140.	
	28	Bahi-Buisson et al., "CDKL5-Related Disorders: From Clinical Description to Molecular Genetics," Molecular Syndromology, (2011), vol. 2; pp. 137-152.	
	29	Monaghan et al., "Initial Human Experience with Ganaxolone, A Neuroactive Steroid with Antiepileptic Activity," Epilepsia, (1997), vol. 38, No. 9; pp. 1026-1031.	
	30	European Search Report dated Nov. 18, 2019, corresponding to European Application No. 19190461.4; 11 pages.	
	31	Charles A. Handforth, "GABA Receptor May Present Target for New ET Drug Therapy," Essential Tremor, Jun. 4, 2013; 1 page.	

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Examiner Signature	/REI TSANG SHIAO/	Date Considered	02/18/2022

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jeffrey S. Steen, Reg. #32063/	Date (YYYY-MM-DD)	2021-01-06
Name/Print	Jeffrey S. Steen	Registration Number	32,063

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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 inspections or an issued patent.

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THIRD-PARTY SUBMISSION UNDER 37 CFR 1.290	Application Number	17024127

U.S. PATENTS				
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U.S. PATENT APPLICATION PUBLICATIONS				
Cite No	Publication Number	Kind Code[1]	Publication Date (YYYY-MM-DD)	First Named Inventor

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Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[1]	Publication Date (YYYY-MM-DD)	Applicant, Patentee or First Named Inventor	T[5]
1	2016127170	WO	A1	2016-08-11	Marinus Pharmaceuticals, Inc.	☐
2	2007062266	WO	A1	2007-05-31	Marinus Pharmaceuticals	☐

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THIRD-PARTY SUBMISSION UNDER 37 CFR 1.290	Application Number	17024127

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STATEMENTS

The party making the submission is not an individual who has a duty to disclose information with respect to the above-identified application under 37 CFR 1.56.

This submission complies with the requirements of 35 U.S.C. 122(e) and 37 CFR 1.290.

☒ The fee set forth in 37 CFR 1.290(f) has been submitted herewith.

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☐ This resubmission is being made responsive to a notification of non-compliance issued for an earlier filed third-party submission. The corrections in this resubmission are limited to addressing the non-compliance. As such, the party making this resubmission: (1) requests that the Office apply the previously-paid fee set forth in 37 CFR 1.290(f), or (2) states that no fee is required to accompany this resubmission as the undersigned is again making the fee exemption statement set forth in 37 CFR 1.290(g).

Signature	/Robert H. Underwood/		
Name/Print	Robert H. Underwood	Registration Number (if applicable)	45170

Examiner Signature	/REI TSANG SHIAO/	Date Considered	02/18/2022

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17024127
Filing Date	2020-09-17
First Named Inventor	Matthew During
Art Unit	1629
Examiner Name	R. T. Shiao
Attorney Docket Number	2262-29-CON B CON III

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	1	European Communication dated February 17, 2022 corresponding to counterpart European Application No. 19190461.4; 8 pages.	

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Signature	/Jeffrey S. Steen, Reg. #32063/	Date (YYYY-MM-DD)	2022-02-24
Name/Print	Jeffrey S. Steen	Registration Number	32,063

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	1	2015189744	WO	A1	2015-12-17	Pfizer Ltd		

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17024127
	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

	1	English translation of Japanese Office Action dated June 1, 2021, corresponding to Japanese Application No. 2019-507328;	
	2	Charles A. Handforth, "A Delta GABA Receptor as a Target for Essential Tremor Therapy," National Institutes of Health, June 10, 2015; 4 pages.	
	3	Paris-Robidas et al., "Defective dentate nucleus GABA receptors in essnetial tremor," Brain: A Journal of Neurology, 2012, Vol. 135; pages 105-116.	
	4	English tranlsation of Israeli Office Action dated April 12, 2021, corresponding to counterpart Israeli Application No. 264510; 4 pages.	

If you wish to add additional non-patent literature document citation information please click the Add button [Add]

EXAMINER SIGNATURE

Examiner Signature	/REI TSANG SHIAO/	Date Considered	02/18/2022

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17024127
	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	2262-29-CON B CON III

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jeffrey S. Steen, Reg. #32063/	Date (YYYY-MM-DD)	2021-07-01
Name/Print	Jeffrey S. Steen	Registration Number	32,063

This collection of information is required by 37 CFR 1.97 and 1.98. 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 1 hour 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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S/

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 the Freedom of Information Act requires disclosure of these record s.

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 inspections 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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S/

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Electronic Acknowledgement Receipt	
EFS ID:	45502316
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/Elyssa Berger
Filer Authorized By:	Jeffrey S. Steen
Attorney Docket Number:	2262-29 CON B CON III
Receipt Date:	19-APR-2022
Filing Date:	17-SEP-2020
Time Stamp:	07:58:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		responsefiled.pdf	154870 de89b15f01b4a0a028c64af9f874248a0e113956	yes	6

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Request for Reconsideration-After Non-Final Rejection	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	6
Warnings:			
Information:			
	Total Files Size (in bytes):	154870	

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.

Electronic Acknowledgement Receipt	
EFS ID:	45495749
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/Elyssa Berger
Filer Authorized By:	Jeffrey S. Steen
Attorney Docket Number:	2262-29 CON B CON III
Receipt Date:	19-APR-2022
Filing Date:	17-SEP-2020
Time Stamp:	07:55:42
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$170
RAM confirmation Number	E20224I855350772
Deposit Account	502140
Authorized User	Elyssa Berger
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

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	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	41249 428c26cceda6a5546f52f2f59e9e7007dc5905f4	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	37826 5b33c27bae01b898452f2e3b97905548f0c7d456	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	79075		

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

New Applications Under 35 U.S.C. 111

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

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

Docket 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

RESPONSE

In response to a non-Final Office Action dated April 4, 2022, setting a shortened period for reply expiring on July 4, 2022, please enter the following:

A **Listing of Claims** begins on page 2; and

Remarks begin on page 5.

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**.

No amendments are made to the claims herein, and the following Listing of Claims is being provided solely for the benefit and convenience of the Examiner.

Listing of the Claims:

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.

REMARKS

The present application has been reviewed in light of the non-Final Office Action dated April 4, 2022. No amendments to the claims are made by the present response. In view of the following remarks, Applicant respectfully requests allowance of this application.

Double Patenting

Claims 1-20 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable independently over Claim 1 of U.S. Patent No. 10,799,485 ("the '485 patent"), and over Claims 1-13 of U.S. Patent No. 10,603,308 ("the '308 patent"), respectively.

The '485 patent, and the '308 patent are each parent patents of the present application and shares common ownership with the present application. An appropriate e-Terminal Disclaimer is being electronically filed herewith, thereby overcoming this double patenting rejection. Since claims 1-20 were not otherwise objected to, or rejected over any prior art, Applicant respectfully requests allowance of claims 1-20.

The e-Terminal Disclaimer is being provided to expedite prosecution and not as an admission that the claims are not patentably distinct.

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 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: April 19, 2022

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

Jeffrey S. Steen
Registration No. 32,063
Attorney for Applicant

CARTER, DELUCA & FARRELL, LLP
576 Broad Hollow Road
Melville, New York 11747
(631) 501-5700

Doc Code: DISQ.E.FILE
Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 17024127

Filing Date: 17-Sep-2020

Applicant/Patent under Reexamination: DURING

Electronic Terminal Disclaimer filed on April 19, 2022

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Doc Code: DIST.E.FILE **Document Description: Electronic Terminal Disclaimer - Filed**	PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT**
Application Number	17024127
Filing Date	17-Sep-2020
First Named Inventor	Matthew DURING
Attorney Docket Number	2262-29 CON B CON III
Title of Invention	METHODS AND COMPOSITIONS FOR TREATMENT OF EPILEPTIC DISORDERS

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
Ovid Therapeutics Inc.	100%

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

10799485

10603308

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

◉ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request. ○ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.	
Applicant claims the following fee status: ○ Small Entity ○ Micro Entity ◉ Regular Undiscounted I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.	
THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES I certify, in accordance with 37 CFR 1.4(d)(4) that I am: ◉ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application Registration Number 32063 ○ A sole inventor ○ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application ○ A joint inventor; all of whom are signing this request	
Signature	/Jeffrey S. Steen, Reg. #32063/
Name	Jeffrey S. Steen

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

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)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$550
RAM confirmation Number	E20225AB17184636
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		

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

New Applications Under 35 U.S.C. 111

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

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

Docket 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**.

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/

Jeffrey S. Steen
Registration No. 32,063
Attorney for Applicant

CARTER, DELUCA & FARRELL, LLP
576 Broad Hollow Road
Melville, New York 11747
(631) 501-5700

Electronic Acknowledgement Receipt

EFS ID:	45741202
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:	18-MAY-2022
Filing Date:	17-SEP-2020
Time Stamp:	11:27:12
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	EP_Communication_dated_512.pdf	186440 3dea6169a055f2119ee53ad0d35258485faf8363	no	5

Warnings:

Information:					
2	Non Patent Literature	AU_OA_dated_513.pdf	174219 7d8e6fa1c98737c26a1bb69e9f63a0b9273d6850	no	3
Warnings:					
Information:					
3	Transmittal Letter	Supp_IDS_Transmittal.pdf	125588 0a5b0908caa87ff245ecb3746c2674a6eb26b587	no	3
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	sb08IDS.pdf	1263344 944565e22e562d40f113fd59b31c9b192b3c9beb	no	4
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
Total Files Size (in bytes):			1749591		

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

New Applications Under 35 U.S.C. 111

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

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

Docket 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 | Confirmation No.: 4361

Filed: September 17, 2020 | Art Unit: 1629

For: METHODS AND COMPOSITIONS FOR TREATMENT OF EPILEPTIC DISORDERS | Examiner: R. T. Shiao

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)

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

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98, the attention of the United States Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of the above-identified application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed more than three months after the filing date of this application, OR more than three months after the date of entry of the national stage in the international application, AND after the mailing date of a first Office Action on the merits, but before the mailing date of any of a Final Action under 37 C.F.R. § 1.113, a Notice of Allowance under 37 C.F.R. § 1.311 or an action that otherwise closes prosecution in this application (37 C.F.R. § 1.97(c)).

I hereby certify, pursuant to 37 C.F.R. § 1.97(e)(1), that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

I hereby certify, pursuant to 37 C.F.R. 1.704(d)(1), that each item of information contained in the information disclosure statement:

> (i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement; or
> (ii) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), copies of U.S. patents and U.S. patent application publications are not submitted. Submitted herewith are copies of foreign patents and non-patent literature in accordance with 37 C.F.R. § 1.98(a)(2).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made. In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in this Information Disclosure Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98, and the Examiner is respectfully requested to consider the listed references.

Applicant believes no fee is due with this submission. However, if a fee is due, please charge our Deposit Account No. 50-2140, under Order No. 2262-29-CON B CON III from which the undersigned is authorized to draw.

Dated: May 18, 2022

Respectfully submitted,

/Jeffrey S. Steen, Reg. #32063/

Jeffrey S. Steen
Registration No.: 32,063
CARTER, DELUCA & FARRELL LLP
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Attorney for Applicant(s)

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17024127
Filing Date	2020-09-17
First Named Inventor	Matthew During
Art Unit	1629
Examiner Name	R. T. Shiao
Attorney Docket Number	2262-29-CON B CON III

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17024127
	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	R. T. Shiao
	Attorney Docket Number	2262-29-CON B CON III

	1	European Communication dated May 12, 2022, relating to counterpart European Application No. 17840261.6; 5 pages.	
	2	Australian Examination Report dated May 13, 2022, relating to counterpart Australian Application No. 2017311412; 3 pages.	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17024127
	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	R. T. Shiao
	Attorney Docket Number	2262-29-CON B CON III

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jeffrey S. Steen, Reg. #32063/	Date (YYYY-MM-DD)	2022-05-18
Name/Print	Jeffrey S. Steen	Registration Number	32,063

This collection of information is required by 37 CFR 1.97 and 1.98. 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 1 hour 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.**

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 the Freedom of Information Act requires disclosure of these record s.

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 inspections 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.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

31554 7590 06/13/2022

CARTER, DELUCA & FARRELL LLP
576 BROAD HOLLOW ROAD
MELVILLE, NY 11747

EXAMINER
SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
1629	

DATE MAILED: 06/13/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/024,127	09/17/2020	Matthew DURING	2262-29 CON B CON III	4361

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	$1200	$0.00	$0.00	$1200	09/13/2022

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. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

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

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

PART B - FEE(S) TRANSMITTAL

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

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

By fax, send to: (571)-273-2885

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

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

31554 7590 06/13/2022
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.
17/024,127	09/17/2020	Matthew DURING	2262-29 CON B CON III	4361

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	$1200	$0.00	$0.00	$1200	09/13/2022

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/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

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

1_____
2_____
3_____

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

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

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

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

4a. Fees submitted: ❑Issue Fee ❑Publication Fee (if required) ❑Advance Order - # of Copies _____

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

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

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

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

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/024,127	09/17/2020	Matthew DURING	2262-29 CON B CON III	4361

31554 7590 06/13/2022

CARTER, DELUCA & FARRELL LLP
576 BROAD HOLLOW ROAD
MELVILLE, NY 11747

EXAMINER	
SHIAO, REI TSANG	
ART UNIT	**PAPER NUMBER**
1629	

DATE MAILED: 06/13/2022

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. 17/024,127	Applicant(s) DURING, Matthew	
	Examiner REI TSANG SHIAO	Art Unit 1629	AIA (FITF) Status Yes

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

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

1. ☑ This communication is responsive to amendment filed on 5/11/2022.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-31 . 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)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 5/18/22.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/REI TSANG SHIAO/
Primary Examiner, Art Unit 1629

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 16/789,709 02/13/2020 PAT 10799485, which is a CON of 16/447,300 06/20/2019 PAT 10603308, which is a CON of 16/356,517 03/18/2019 PAT 10363246, which is a CON of 16/013,500 06/20/2018 ABN, which is a CON of 15/673,737 08/10/2017 ABN, which claims benefit of 62/490,293 04/26/2017, and claims benefit of 62/373,589 08/11/2016.

2. Amendment including addition of claims 21-31 in the amendment filed on 5/11/2022 is acknowledged. A terminal disclaimer filed on 4/19/2022 is also acknowledged. Claims 1-31 are pending in the application. No new matter has been found. Since the newly added claims 21-31 are commensurate within the scope of invention, claims 1-31 are prosecuted in the case.

Reasons for Allowance

3. Since the terminal disclaimer against During's '485 and '308 has been filed and approved in the Office. Therefore the rejection of claims 1-20 under the obviousness-type double patenting over During's '485 and '308 has been overcome in the amendment filed on 5/11/2022.

4. Claims 1-31 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 1-31 are allowed.

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

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REI TSANG SHIAO whose telephone number is (571)272-0707. The examiner can normally be reached on 8:30 am-5:00 pm.

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

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/REI TSANG SHIAO/

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

June 06, 2022

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	**Art Unit**
	REI TSANG SHIAO	1629

CPC						
Symbol					**Type**	**Version**
A61K	/	31	/	437	F	2013-01-01
A61K	/	31	/	57	I	2013-01-01
A61K	/	31	/	5513	I	2013-01-01
A61K	/	31	/	325	I	2013-01-01
A61K	/	31	/	44	I	2013-01-01
A61K	/	31	/	433	I	2013-01-01
A61K	/	31	/	55	I	2013-01-01
A61K	/	31	/	4015	I	2013-01-01
A61K	/	31	/	195	I	2013-01-01
A61K	/	31	/	165	I	2013-01-01
A61K	/	31	/	53	I	2013-01-01
A61K	/	31	/	444	I	2013-01-01
A61K	/	31	/	515	I	2013-01-01
A61K	/	31	/	4166	I	2013-01-01
A61K	/	31	/	197	I	2013-01-01
A61K	/	9	/	0019	I	2013-01-01
A61K	/	45	/	06	I	2013-01-01
A61K	/	31	/	19	I	2013-01-01
A61K	/	31	/	27	I	2013-01-01
A61K	/	31	/	36	I	2013-01-01
A61K	/	31	/	4192	I	2013-01-01
A61K	/	31	/	423	I	2013-01-01
A61K	/	31	/	4535	I	2013-01-01
A61K	/	31	/	513	I	2013-01-01
A61K	/	31	/	5517	I	2013-01-01
A61K	/	31	/	7048	I	2013-01-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
A61K	/	31	/	437	I	1	1	2013-01-01

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	31	
/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629	25 May 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20220525

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	**Art Unit**
	REI TSANG SHIAO	1629

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
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A61K	/	31	/	57	I	2	1	2013-01-01
A61K	/	2300	/	00	I	2	2	2013-01-01
A61K	/	31	/	5517	I	3	1	2013-01-01
A61K	/	2300	/	00	I	3	2	2013-01-01
A61K	/	31	/	5513	I	4	1	2013-01-01
A61K	/	2300	/	00	I	4	2	2013-01-01
A61K	/	31	/	44	I	5	1	2013-01-01
A61K	/	2300	/	00	I	5	2	2013-01-01
A61K	/	31	/	27	I	6	1	2013-01-01
A61K	/	2300	/	00	I	6	2	2013-01-01
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A61K	/	31	/	4192	I	16	1	2013-01-01
A61K	/	2300	/	00	I	16	2	2013-01-01

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	31	
/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629	25 May 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	**Art Unit**
	REI TSANG SHIAO	1629

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
A61K	/	31	/	19	I	17	1	2013-01-01
A61K	/	2300	/	00	I	17	2	2013-01-01
A61K	/	31	/	513	I	18	1	2013-01-01
A61K	/	2300	/	00	I	18	2	2013-01-01
A61K	/	31	/	36	I	19	1	2013-01-01
A61K	/	2300	/	00	I	19	2	2013-01-01
A61K	/	31	/	4535	I	20	1	2013-01-01
A61K	/	2300	/	00	I	20	2	2013-01-01
A61K	/	31	/	7048	I	21	1	2013-01-01
A61K	/	2300	/	00	I	21	2	2013-01-01
A61K	/	31	/	197	I	22	1	2013-01-01
A61K	/	2300	/	00	I	22	2	2013-01-01
A61K	/	31	/	423	I	23	1	2013-01-01
A61K	/	2300	/	00	I	23	2	2013-01-01
A61K	/	31	/	136	I	24	1	2013-01-01
A61K	/	2300	/	00	I	24	2	2013-01-01

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	31	
/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629	25 May 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20220525

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	**Art Unit**
	REI TSANG SHIAO	1629

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61K	/	31	/	437	

NON-CLAIMED					
	/		/		

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 31	
/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629 (Primary Examiner)	25 May 2022 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20220525

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	**Art Unit**
	REI TSANG SHIAO	1629

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	10	10	19	19	28	28								
2	2	11	11	20	20	29	29								
3	3	12	12	21	21	30	30								
4	4	13	13	22	22	31	31								
5	5	14	14	23	23										
6	6	15	15	24	24										
7	7	16	16	25	25										
8	8	17	17	26	26										
9	9	18	18	27	27										

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	31	
/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629	25 May 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20220525

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	Art Unit
	REI TSANG SHIAO	1629

CPC - Searched*		
Symbol	Date	Examiner
A61K 31/437	05/25/2022	RS

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
STN, structure, inventors, text	12/29/2021	RS
EAST group/subgroup	05/25/2022	RS
PALM inventors	02/18/2022	RS

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
A61K	31/437	05/25/2022	RS

/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629	

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L43	8606860	A61K 31/437	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/05/25 11:24 AM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N9	760121	A61K 31/437	(US-PGPUB; USPAT)	OR	ON	ON	2022/05/25 11:24 AM

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17024127
Filing Date	2020-09-17
First Named Inventor	Matthew During
Art Unit	1629
Examiner Name	R. T. Shiao
Attorney Docket Number	2262-29-CON B CON III

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17024127
	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	R. T. Shiao
	Attorney Docket Number	2262-29-CON B CON III

	1	European Communication dated May 12, 2022, relating to counterpart European Application No. 17840261.6; 5 pages.	
	2	Australian Examination Report dated May 13, 2022, relating to counterpart Australian Application No. 2017311412; 3 pages.	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/REI TSANG SHIAO/	Date Considered	05/25/2022

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17024127
	Filing Date	2020-09-17
	First Named Inventor	Matthew During
	Art Unit	1629
	Examiner Name	R. T. Shiao
	Attorney Docket Number	2262-29-CON B CON III

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jeffrey S. Steen, Reg. #32063/	Date (YYYY-MM-DD)	2022-05-18
Name/Print	Jeffrey S. Steen	Registration Number	32,063

This collection of information is required by 37 CFR 1.97 and 1.98. 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 1 hour 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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S/

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 the Freedom of Information Act requires disclosure of these record s.

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 inspections 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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S/

Electronic Acknowledgement Receipt	
EFS ID:	45950582
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/Donna Spinillo
Filer Authorized By:	Jeffrey S. Steen
Attorney Docket Number:	2262-29 CON B CON III
Receipt Date:	14-JUN-2022
Filing Date:	17-SEP-2020
Time Stamp:	16:06:34
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$600
RAM confirmation Number	E20226DG06314849
Deposit Account	
Authorized User	
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	Issue Fee Payment (PTO-85B)	Web85b.pdf	64278 28c5ea8d95fca86d1ee7c7284f7d1fb149f3db1e	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	40126 752acb18bbd30df8eeaa513729e8d8e6bf9909a0	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	104404		

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

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Issue Fee Transmittal Form

Application Number	Filing Date	First Named Inventor	Atty. Docket No.	Confirmation No.
17024127	17-Sep-2020	Matthew DURING	2262-29 CON B CON III	4361

TITLE OF INVENTION :

METHODS AND COMPOSITIONS FOR TREATMENT OF EPILEPTIC DISORDERS

Entity Status	Application Type	Art Unit	Class - Subclass	EXAMINER
~~Regular Undiscounted~~ Small	Utility under 35 USC 111(a)	1629	171000	

Issue Fee Due	Publication Due	Total Fee(s) Due	Date Due	Prev. Paid Fee
~~$1200~~ $600	$0	~~$1200~~ $600	13-Sep-2022	$0

1.Change of Correspondence Address and/or Indication Of Fee Address (37 CFR 1.33 & 1.363)

Current Correspondence Address:	Current Indicated Fee Address :
31554 CARTER, DELUCA & FARRELL LLP 576 BROAD HOLLOW ROAD MELVILLE NY 11747 UNITED STATES 6315015700 docket@carterdeluca.com	
☐ Change of correspondence address requested, system generated AIA/122-EFS form attached	☐ Fee Address indication requested, system generated SB/47-EFS form attached

2.Entity Status

Change in Entity Status

○ Applicant certifying micro entity status; system generated Micro Entity certification form attached. See 37 CFR 1.29.
Note: Absent a valid certification of micro entity status, issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. If this box is checked, you will be prompted to choose a micro entity status on the gross income basis (37 CFR 1.29(a)) or the institution of higher education basis (37 CFR 1.29(d)), and make the applicable certification online.

◉ Applicant asserting small entity status. See 37 CFR 1.27.
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.

○ Applicant changing to regular undiscounted fee status.
Note: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

Doc Code: IFEE PTOL/85B-EFS

Document Description: Issue Fee Payment (PTO-85B)

3.The Following Fee(s) Are Submitted:

☒ Issue Fee	☐ I authorize USPTO to apply my previously paid issue fee to the current fees due
☐ Publication Fee	☐ The Director is hereby authorized to apply my previously paid issue fee to the current fee due and to charge deficient fees to Deposit Account Number _____
☐ Advance Order - # of copies _____	☒ If **in addition to** the payment of the issue fee amount submitted with this form, there are any discrepancies in any amount(s) due, the Director is authorized to charge any deficiency, or credit any overpayment, to Deposit Account Number 502140 . The **issue fee must be submitted** with this form. **If payment of the issue fee does not accompany this form, checking this box and providing a deposit account number will NOT be effective to satisfy full payment of the fee(s) due.**

4.Firm and/or Attorney Names To Be Printed

NOTE: If no name is listed, no name will be printed
For printing on the patent front page, list to be displayed as entered

1. Carter, DeLuca & Farrell LLP
2.
3.

5.Assignee Name(s) and Residence Data To Be Printed

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

Name	City	State	Country	Category
Ovid Therapeutics Inc.	New York	NEW YORK	UNITED STATES	corporation

6.Signature

I certify, in accordance with 37 CFR 1.4(d)(4) that I am an attorney or agent registered to practice before the Patent and Trademark Office who has filed and has been granted power of attorney in this application. I also certify that this Fee(s) Transmittal form is being transmitted to the USPTO via EFS-WEB on the date indicated below.

Signature	/Jeffrey S. Steen/	**Date**	06-14-2022
Name	Jeffrey S. Steen	**Registration Number**	32063

WEB IFEE 1.0

Doc Code: IDS.3P
Document Description: Information Disclosure Statement Filed

PTO/SB/429 (06-15)
Approved for use through 09/30/2021. OMB 0651-0062
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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

THIRD-PARTY SUBMISSION UNDER 37 CFR 1.290

(Do **not** submit this form electronically via EFS-Web)

Application Number (required): 17/024,127

U.S. PATENTS AND U.S. PATENT APPLICATION PUBLICATIONS

Cite No.	Document Number Number-Kind Code[1]	Issue Date or Publication Date MM/DD/YYYY	First Named Inventor
	US-		
	US-		
	US-		
	US-		
	US-		
	US-		
	US-		
	US-		
	US-		

FOREIGN PATENTS AND PUBLISHED FOREIGN PATENT APPLICATIONS

Cite No.	Country or Patent Office and Document Number Country Code[2]-Number[3]-Kind Code[4]	Publication Date MM/DD/YYYY	Applicant, Patentee or First Named Inventor	Translation Attached
2	WO2016/127170	08/11/2016	Marinus Pharmaceuticals, Inc.	☐
3	WO007/062266	05/31/2007	Marinus Pharmaceuticals, Inc.	☐
				☐
				☐
				☐
				☐
				☐
				☐
				☐

1. If known, enter kind of document by the appropriate symbols indicated on the document under WIPO Standard ST.16. See MPEP 901.04(a). 2. Enter the country or patent office that issued the document by two-letter country code under WIPO Standard ST.3. See MPEP 1851. 3. For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 4. If known, enter kind of document by the appropriate symbols indicated on the document under WIPO Standard ST.16. See MPEP 901.04(a).

This collection of information is required by 35 U.S.C. 122(e) and 37 CFR 1.290. The information is required to obtain or retain a benefit by the public, which is to update (and by the USPTO to process) the file of a patent or reexamination proceeding. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 10 hours 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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S/

Doc Code: IDS.3P
Document Description: Information Disclosure Statement Filed

PTO/SB/429 (06-15)
Approved for use through 09/30/2021. OMB 0651-0062
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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THIRD-PARTY SUBMISSION UNDER 37 CFR 1.290

(Page 2 of 2)

Application Number (required): 17/024,127

NON-PATENT PUBLICATIONS (e.g., journal article, Office action)

Cite No.	Author (if any), title of the publication, page(s) being submitted, publication date, publisher (where available), and place of publication (where available)	Translation Attached	Evidence of Publication Attached
1	Carter et al., "Characterization of the Anticonvulsant Properties of Ganaxolone (CCD 1042; 3α-hydroxy-3β-methyl-5α-pregnan-20-one), a Selective, High-Affinity, Steroid Modulator of the γ-Aminobutyric Acid(A) Rec	☐	☑
4	Sayenko et al., "Maximizing Administration of Ganaxolone Alleviates Lesion-Induced Allodynia in a Rat Spinal Cord Injury Model of Status Epilepticus," Neurology, 94 (15 Supplement), published April 11,	☐	☑
5	Sayenko et al., "Ganaxolone Administered Intravenously Reverses Behavioral Deficits and Promotes Survival in the Rat Lithium-Pilocarpine Model of Status Epilepticus," Neurology, 88 (16 Supplement), published A	☐	☑
6	Marinus Pharmaceuticals, "Marinus Completes Rolling NDA Submission for Ganaxolone IV," Published on June 22, 2016, Available at: https://ir.marinuspharma.com/news/news-details/2016/Marinus	☐	☑
7	Press Release: "Marinus Pharmaceuticals Receives FDA Orphan Drug Designation for Ganaxolone IV to Treat Status Epilepticus," Published April 18, 2016, Available at: https://ir.marinuspharmaceuticals.com/	☐	☑
8	Chez, Ganaxolone Therapy Improves Interictal EEG and Seizure Control in Lennox Gastaut Syndrome in Patients with PCDH19 and CDKL5," Child Society for Neuroscience published October 26, 2016	☐	☑
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

STATEMENTS

The party making the submission is not an individual who has a duty to disclose information with respect to the above-identified application under 37 CFR 1.56.

This submission complies with the requirements of 35 U.S.C. 122(e) and 37 CFR 1.290.

☑ The following fee set forth in 37 CFR 1.290(f) is submitted herewith: ☒ regular undiscounted ☒ small entity*

☐ The fee set forth in 37 CFR 1.290(f) is not required because this submission lists three or fewer total items and, to the knowledge of the person signing the statement after making reasonable inquiry, this submission is the first and only submission under 35 U.S.C. 122(e) filed in the above-identified application by the party making the submission or by a party in privity with the party.

☐ This resubmission is being made responsive to a notification of non-compliance issued for an earlier filed third-party submission. The corrections in this resubmission are limited to addressing the non-compliance. As such, the party making this resubmission: (1) requests that the Office apply the previously-paid fee set forth in 37 CFR 1.290(f), or (2) states that no fee is required to accompany this resubmission as the undersigned is again making the fee exemption statement set forth in 37 CFR 1.290(g).

Signature	/Robert H. Underwood, Reg. No. 45,170/	Date February 8, 2021	
Name (Printed/Typed)	Robert H. Underwood	Reg. No., if applicable	45,170

Examiner Signature**	/REI TSANG SHIAO/	Date Considered	02/18/2022

*SUBMITTER: By selecting the "small entity" box and paying the applicable small entity fee, the party making the submission asserts that the party qualifies as a small entity. A third party is not eligible for the micro entity discount.

06/21/2022

**EXAMINER: Signature indicates all items listed have been considered, except for citations through which a line is drawn. Draw line through citation if not considered. Include a copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S/

Privacy Act Statement

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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).
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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.
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/024,127	09/17/2020	Matthew DURING	2262-29 CON B CON III	4361

31554 7590 06/24/2022

CARTER, DELUCA & FARRELL LLP
576 BROAD HOLLOW ROAD
MELVILLE, NY 11747

EXAMINER	
SHIAO, REI TSANG	

ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
06/24/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@carterdeluca.com

Notice of Allowability	Application No. 17/024,127	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 amendemnt filed on 4/19/2022.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-20 . 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)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/REI TSANG SHIAO/
Primary Examiner, Art Unit 1629

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 16/789,709 02/13/2020 PAT 10799485, which is a CON of 16/447,300 06/20/2019 PAT 10603308, which is a CON of 16/356,517 03/18/2019 PAT 10363246, which is a CON of 16/013,500 06/20/2018 ABN, which is a CON of 15/673,737 08/10/2017 ABN, which claims benefit of 62/490,293 04/26/2017, and claims benefit of 62/373,589 08/11/2016.

2. Amendment including a terminal disclaimer in the amendment filed on 4/19/2022 is acknowledged. Claims 1-20 are pending in the application.

Reasons for Allowance

3. Since the terminal disclaimer against During's '485 and '308 has been filed and approved in the Office, therefore the rejection of claims under the obviousness-type double patenting against During's '485 and '308has been overcome in the amendment filed on 4/19/2022.

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/REI TSANG SHIAO/

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

June 21, 2022

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	**Art Unit**
	REI TSANG SHIAO	1629

CPC						
Symbol					**Type**	**Version**
A61K	/	31	/	437	F	2013-01-01
A61K	/	31	/	57	I	2013-01-01
A61K	/	31	/	5513	I	2013-01-01
A61K	/	31	/	325	I	2013-01-01
A61K	/	31	/	44	I	2013-01-01
A61K	/	31	/	433	I	2013-01-01
A61K	/	31	/	55	I	2013-01-01
A61K	/	31	/	4015	I	2013-01-01
A61K	/	31	/	195	I	2013-01-01
A61K	/	31	/	165	I	2013-01-01
A61K	/	31	/	53	I	2013-01-01
A61K	/	31	/	444	I	2013-01-01
A61K	/	31	/	515	I	2013-01-01
A61K	/	31	/	4166	I	2013-01-01
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A61K	/	31	/	36	I	2013-01-01
A61K	/	31	/	4192	I	2013-01-01
A61K	/	31	/	423	I	2013-01-01
A61K	/	31	/	4535	I	2013-01-01
A61K	/	31	/	513	I	2013-01-01
A61K	/	31	/	5517	I	2013-01-01
A61K	/	31	/	7048	I	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
A61K	/	31	/	437	I	1	1	2013-01-01

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629	20 April 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20220420

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	**Art Unit**
	REI TSANG SHIAO	1629

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
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A61K	/	31	/	57	I	2	1	2013-01-01
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A61K	/	31	/	5517	I	3	1	2013-01-01
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A61K	/	31	/	4015	I	9	1	2013-01-01
A61K	/	2300	/	00	I	9	2	2013-01-01
A61K	/	31	/	195	I	10	1	2013-01-01
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A61K	/	31	/	4192	I	16	1	2013-01-01
A61K	/	2300	/	00	I	16	2	2013-01-01

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629	20 April 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20220420

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	**Art Unit**
	REI TSANG SHIAO	1629

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
A61K	/	31	/	19	I	17	1	2013-01-01
A61K	/	2300	/	00	I	17	2	2013-01-01
A61K	/	31	/	513	I	18	1	2013-01-01
A61K	/	2300	/	00	I	18	2	2013-01-01
A61K	/	31	/	36	I	19	1	2013-01-01
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A61K	/	2300	/	00	I	20	2	2013-01-01
A61K	/	31	/	7048	I	21	1	2013-01-01
A61K	/	2300	/	00	I	21	2	2013-01-01
A61K	/	31	/	197	I	22	1	2013-01-01
A61K	/	2300	/	00	I	22	2	2013-01-01
A61K	/	31	/	423	I	23	1	2013-01-01
A61K	/	2300	/	00	I	23	2	2013-01-01
A61K	/	31	/	136	I	24	1	2013-01-01
A61K	/	2300	/	00	I	24	2	2013-01-01

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 20	
/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629 (Primary Examiner)	20 April 2022 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20220420

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	**Art Unit**
	REI TSANG SHIAO	1629

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61K	/	31	/	437

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 20	
/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629 (Primary Examiner)	20 April 2022 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20220420

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	**Art Unit**
	REI TSANG SHIAO	1629

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	10	10	19	19										
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7	7	16	16												
8	8	17	17												
9	9	18	18												

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 20	
/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629 (Primary Examiner)	20 April 2022 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

U.S. Patent and Trademark Office Part of Paper No.: 20220420

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	Art Unit
	REI TSANG SHIAO	1629

CPC - Searched*		
Symbol	Date	Examiner
A61K 31/437	04/20/2022	RS

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
STN, structure, inventors, text	12/29/2021	RS
EAST group/subgroup	04/20/2022	RS
PALM inventors	02/18/2022	RS

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
A61K	31/437	04/20/2022	RS

/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629	

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	180,358	A61K 31/437	USPAT	OR	OFF	2022/04/20 15:33

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	180,358	A61K 31/437	USPAT	OR	OFF	2022/04/20 15:33

4/20/2022 3:33:52 PM

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	**Art Unit**
	REI TSANG SHIAO	1629

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	10	10	19	19	28	28								
2	2	11	11	20	20	29	29								
3	3	12	12	21	21	30	30								
6 ~~4~~	4	13	13	22	22	31	31								
5	5	14	14	23	23										
4 ~~8~~	6	15	15	24	24										
7	7	16	16	25	25										
8	8	17	17	26	26										
9	9	18	18	27	27										

Change(s) applied
to document,
/C.H.J./
6/15/2022

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	31	
/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629	25 May 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20220525

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/024,127	09/17/2020	Matthew DURING	2262-29 CON B CON III	4361

31554 7590 06/29/2022

CARTER, DELUCA & FARRELL LLP
576 BROAD HOLLOW ROAD
MELVILLE, NY 11747

EXAMINER	
SHIAO, REI TSANG	

ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
06/29/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@carterdeluca.com

Notice of Allowability	**Application No.** 17/024,127	**Applicant(s)** DURING, Matthew	
	Examiner REI TSANG SHIAO	**Art Unit** 1629	**AIA (FITF) Status** Yes

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

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

1. ☑ This communication is responsive to amendment filed on 5/11/2022.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-31 . 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)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/REI TSANG SHIAO/
Primary Examiner, Art Unit 1629

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 16/789,709 02/13/2020 PAT 10799485, which is a CON of 16/447,300 06/20/2019 PAT 10603308, which is a CON of 16/356,517 03/18/2019 PAT 10363246, which is a CON of 16/013,500 06/20/2018 ABN, which is a CON of 15/673,737 08/10/2017 ABN, which claims benefit of 62/490,293 04/26/2017, and claims benefit of 62/373,589 08/11/2016.

2. Amendment including a terminal disclaimer in the amendment filed on 4/19/2022 is acknowledged. Claims 1-31 are pending in the application.

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/REI TSANG SHIAO/

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

June 24, 2022

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	**Art Unit**
	REI TSANG SHIAO	1629

CPC						
Symbol					**Type**	**Version**
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CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
A61K	/	31	/	437	I	1	1	2013-01-01

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	31	
/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629	24 June 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20220624

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	**Art Unit**
	REI TSANG SHIAO	1629

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
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A61K	/	2300	/	00	I	3	2	2013-01-01
A61K	/	31	/	5513	I	4	1	2013-01-01
A61K	/	2300	/	00	I	4	2	2013-01-01
A61K	/	31	/	44	I	5	1	2013-01-01
A61K	/	2300	/	00	I	5	2	2013-01-01
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A61K	/	2300	/	00	I	7	2	2013-01-01
A61K	/	31	/	55	I	8	1	2013-01-01
A61K	/	2300	/	00	I	8	2	2013-01-01
A61K	/	31	/	4015	I	9	1	2013-01-01
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A61K	/	2300	/	00	I	15	2	2013-01-01
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NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	31	
/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629	24 June 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

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Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	**Art Unit**
	REI TSANG SHIAO	1629

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
A61K	/	31	/	19	I	17	1	2013-01-01
A61K	/	2300	/	00	I	17	2	2013-01-01
A61K	/	31	/	513	I	18	1	2013-01-01
A61K	/	2300	/	00	I	18	2	2013-01-01
A61K	/	31	/	36	I	19	1	2013-01-01
A61K	/	2300	/	00	I	19	2	2013-01-01
A61K	/	31	/	4535	I	20	1	2013-01-01
A61K	/	2300	/	00	I	20	2	2013-01-01
A61K	/	31	/	7048	I	21	1	2013-01-01
A61K	/	2300	/	00	I	21	2	2013-01-01
A61K	/	31	/	197	I	22	1	2013-01-01
A61K	/	2300	/	00	I	22	2	2013-01-01
A61K	/	31	/	423	I	23	1	2013-01-01
A61K	/	2300	/	00	I	23	2	2013-01-01
A61K	/	31	/	136	I	24	1	2013-01-01
A61K	/	2300	/	00	I	24	2	2013-01-01

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	31	
/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629	24 June 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20220624

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	**Art Unit**
	REI TSANG SHIAO	1629

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61K	/	31	/	437

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 31	
/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629 (Primary Examiner)	24 June 2022 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/024,127	DURING, Matthew
	Examiner	**Art Unit**
	REI TSANG SHIAO	1629

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	10	10	19	19	28	28								
2	2	11	11	20	20	29	29								
3	3	12	12	21	21	30	30								
4	4	13	13	22	22	31	31								
5	5	14	14	23	23										
6	6	15	15	24	24										
7	7	16	16	25	25										
8	8	17	17	26	26										
9	9	18	18	27	27										

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	31	
/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629	24 June 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

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ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

The Patent Term Adjustment is 109 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

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 Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PAIR WEB site http://pair.uspto.gov for additional inventors):

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IR103 (Rev. 10/09)