

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MARINUS PHARMACEUTICALS, INC.,
Petitioner

v.

OVID THERAPEUTICS, INC.,
Patent Owner

Case PGR2023-00020
Patent 11,395,817

PETITIONER'S UPDATED LIST OF EXHIBITS

LIST OF EXHIBITS

Exhibit Number	Exhibit Description
1001	U.S. Patent No. 11,395,817 to Ovid Therapeutics, Inc. “the ’817” or “the ’817 patent”
1002	Excerpts from the File History of the ’817 Patent
1003	Declaration and Curriculum Vitae of Dr. Michael A. Rogawski (“the Rogawski Declaration” or “First Rogawski Declaration”)
1004	Reddy and Kuruba, “Experimental Models of Status Epilepticus and Neuronal Injury for Evaluation of Therapeutic Interventions,” <i>Int. J. Mol. Sci.</i> 14:18284-318 (2013) (“Reddy” or “Reddy & Kuruba”)
1005	Seinfeld et al., “Status Epilepticus,” in Additional Perspectives on Epilepsy: The Biology of a Spectrum Disorder (Cold Spring Harbor Laboratory Press, 2016, ed. Gregory L. Holmes and Jeffrey L Noebels) (“Seinfeld”)
1006	Imtiyaz et al., “The Evolution of the Pilocarpine Animal Model of Status Epilepticus,” <i>Heliyon</i> 6:e04557 (2020) (“Imtiyaz”)
1007	Turski, et al., “Review: Cholinergic Mechanisms and Epileptogenesis. The Seizures Induced by Pilocarpine: A Novel Experimental Model of Intractable Epilepsy,” <i>Synapse</i> 3:154-71 (1989) (“Turski”)
1008	Kokate et al., “Neuroactive Steroids Protect Against Pilocarpine- and Kainic Acid-induced Limbic Seizures and Status Epilepticus in Mice,” <i>Neuropharmacology</i> , 35(8):1049-56 (1996) (“Kokate”)
1009	WIPO Publication No. WO 2016/127170 (“Zhang”)
1010	WIPO Publication No. WO 2007/062266 (“Shaw”)

1011	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 (“April 15, 2016, Press Release” or “Marinus’s Orphan Drug Press Release”)
1012	American Academy of Neurology (“AAN”) 2016 Annual Meeting Scientific Abstract Listing and Meeting Information, AAN 2016 Annual Meeting, Vancouver, BC, Canada, April 15-21, 2016, Available at: https://issuu.com/americanacademyofneurology/docs/16am_abstractlistingdigi_v1424 (“AAN Meeting Brochure”)
1013	Saporito et al., “Ganaxolone Administered Intravenously Prevents Behavioral Seizures and Promotes Survival in the Rat Lithium-Pilocarpine Model of Status Epilepticus,” Poster, presented April 17, 2016, at the 2016 AAN Annual Meeting (“Saporito P1” or “Saporito Poster 1” or “2016 AAN Poster 1” or “2016 AAN Saporito Poster 1”)
1014	Saporito et al., “Intravenous Administration of Ganaxolone Attenuates Electroencephalographic Seizures in a Diazepam Resistant Model of Status Epilepticus,” Poster, presented April 19 and April 20, 2016, at the 2016 AAN Annual Meeting (“Saporito P2” or “Saporito Poster 2” or “2016 AAN Poster 2” or “2016 AAN Saporito Poster 2”)
1015	Declaration of Michael Saporito
1016	Saporito, “Ganaxolone Administered IV Blocks Experimental Status Epilepticus,” “Data Blitz” Presentation, April 20, 2016, at the 2016 AAN Annual Meeting (“Saporito Data Blitz Slides”)
1017	Wylie et al., Status Epilepticus. [Updated 2022 May 15]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK430686/ (“Wylie”)

1018	Trinka et al., “A definition and classification of status epilepticus—Report of the ILAE Task Force on Classification of Status Epilepticus.” <i>Epilepsia</i> , 56(10):1515-1523 (2015) (“Trinka”)
1019	2016 AAN Annual Report
1020	Tsai et al., “Phase I Study to Determine the Pharmacokinetics, Pharmacodynamics, and Safety of IV Ganaxolone in Healthy Adults,” Abstract of Poster Presented at the 6 th London-Innsbruck Colloquium on Status Epilepticus and Acute Seizures April 6-8, 2017, Salzburg, Austria (“Tsai”)
1021	Drug Development and Review Definitions, August 20, 2015, Available at: https://www.fda.gov/drugs/investigational-new-drug-ind-application/drug-development-and-review-definitions
1022	Press Release: “Marinus Pharmaceuticals Doses First Subject in Phase I 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 (“June 22, 2016, Press Release” or “Marinus’s Phase I Press Release”)
1023	U.S. Patent No. 10,799,485
1024	U.S. Patent No. 10,603,308
1025	U.S. Patent No. 10,363,246
1026	Excerpts from the File History of US Patent No. 10,603,308
1027	Excerpts from the File History of US Patent No. 10,799,485
1028	Carter et al., “Characterization of the Anticonvulsant Properties of Ganaxolone (CCD 1042: 3 α -Hydroxy-3 β -methyl-5 α -pregnan-20-one), a Selective, High-Affinity, Steroid Modulator of the γ -Aminobutyric Acid _A Receptor,” <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 280(3):1284-95 (1997)

1029	Saporito et al., Intravenous Administration of Ganaxolone Attenuates Electroencephalographic Seizures in a Diazepam Resistant Model of Status Epilepticus, <i>Neurobiology</i> , 86 (16 supplement), Abstract, published April 4, 2016 (“Saporito A2”)
1030	Saporito et al., Ganaxolone Administered Intravenously Prevents Behavioral Seizures and Promotes Survival in the Rat Lithium-Pilocarpine Model of Status Epilepticus, <i>Neurology</i> 86 (16 Supplement), Abstract, published April 4, 2016 (“Saporito A1”)
1031	Chez, “Ganaxolone Therapy Improves Interictal EEG and Seizure Control in Lennox Gastaut Syndrome in Patients with PCDH19 and CDKL5,” <i>Annals of Neurol.</i> 80 (suppl 20), S326 published October 26, 2016.
1032	Declaration of Deanna Reichel in Support of Motion for pro hac vice Admission
1033	Supplemental Declaration of Michael Saporito
1034	Table of Contents, <i>Neurology</i> Issue 86 (16 Supplement), dated April 5, 2016; available at https://n.neurology.org/content/86/16_Supplement
1035	Saporito et al., Ganaxolone Administered Intravenously Prevents Behavioral Seizures and Promotes Survival in the Rat Lithium-Pilocarpine Model of Status Epilepticus (I11.003), <i>Neurology</i> 86 (16 Supplement), Abstract, published April 5, 2016, available at https://n.neurology.org/content/86/16_Supplement/I11.003
1036	Intentionally Left Blank
1037	Intentionally Left Blank
1038	Intentionally Left Blank
1039	Intentionally Left Blank
1040	Intentionally Left Blank
1041	Supplemental Declaration of Dr. Michael A. Rogawski (“Second Rogawski Declaration”)

1042	Transcript of Deposition of Dr. Raman Sankar, February 9, 2024 (“Sankar Deposition Transcript”)
1043	Beale and Ostrander, “Sizing up Dogs,” <i>Current Biology</i> 22(9):R315-6 (2012) (“Beale”)
1044	Intentionally Left Blank
1045	Clinicaltrials.gov record for NCT03350035
1046	Marinus PCT/US2020/044843 (WO 2021/026124))
1047	Excerpts from the File History of the ’817 Patent
1048	Ovid’s 2022 Annual Report
1049	Intentionally Left Blank
1050	Patterson, “Status Epilepticus and Cluster Seizures,” <i>Vet Clin Small Anim</i> 44:1103-1112 (2014) (“Patterson”)
1051	Charlambous et al., “ACVIM Consensus Statement on the Management of Status Epilepticus and Cluster Seizures in Dogs and Cats,” <i>J Vet Intern Med</i> 2023:1-22 (2023). DOI: 10.1111/jvbm.16928 (“Charlambous”)
1052	Rosetti and Lowenstein, “Management of Refractory Status Epilepticus in Adults,” <i>Lancet. Neurol.</i> 10(10):922-30 (2011) (“Rosetti”)
1053	Shorvon and Ferlisi, “The Treatment of Super-Refractory Status Epilepticus: a Critical Review of Available Therapies and a Clinical Treatment Protocol,” <i>Brain</i> 134:2802-18 (2011) (“Shorvon”)
1054	Nohria and Giller, “Ganaxolone,” <i>Neurotherapeutics</i> 4:102-105 (2007) (“Nohria”)
1055	Supplemental Information to Vaitkevicius et al., “Intravenous Ganaxolone for the Treatment of Refractory Status Epilepticus: Results from an Open-Label, Dose-Finding Phase 2 Trial,” <i>Epilepsia</i> 63:2381-91 (2022) (“ <i>Epilepsia</i> Supplemental Information” or “ <i>Epielpsia</i> SI”)
1056	Publication of Marinus’s U.S. Patent Application Serial No. 17/729,427 (US20220265680)

1057	Publication of Marinus's U.S. Patent Application Serial No. 17/186,569 (US20210186987)
1058	Declaration of Sharon Baughman, Ph.D.
1059	RESERVED
1060	Supplemental Declaration of Sharon Baughman, Ph.D.
1061	Gasior, et al., "Intravenous Ganaxolone: Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability in Healthy Adults," Clinical Pharmacology in Drug Development 2042
1062	September 15, 2023, Supplemental Evidence Served
1063	March 22, 2024, Supplemental Evidence Served
1064	Petitioner's Demonstratives

Respectfully submitted,

Dated: May 13, 2024

/Katie E. Hyma/
Katie Hyma, Reg. No. 75,037
Fish & Richardson P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
Tel: 858-678-5070
Fax: 877-769-7945

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4)(i) and 42.105(b), the undersigned certifies that on May 13, 2024 a complete and entire copy of this Petitioner's Updated Exhibit List and Demonstrative Exhibit were provided via email to the Patent Owner as follows:

Anthony C. Tridico, Reg. No. 45,958
Erin M. Sommers, Reg. No. 60,974
Ryan V. McDonnell, Reg. No. 76,982
Kaitlyn S. Pehrson
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
anthony.tridico@finnegan.com
erin.sommers@finnegan.com
ryan.mcdonnell@finnegan.com
kaitlyn.pehrson@finnegan.com

/Crena Pacheco/
Crena Pacheco
Fish & Richardson P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
pacheco@fr.com