PTO/SB/08a (01-22)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18782666
Filing Date	2024-07-24
First Named Inventor	Steve CARTT
Art Unit	
Examiner Name	Not Yet Assigned
Attorney Docket Number	148570-014311

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	1	IVATURI et al. "Bioavailability and Tolerability of Intranasal Diazepam in Healthy Adult Volunteers" April 2009, Epilepsy Research 84(2-3): 120-126	☐

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Examiner Signature		Date Considered	

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Please see 37 CFR 1.97(e) 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.

☒ A certification statement is not submitted herewith.

FEE

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

COPIES

☒ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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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	/N. Nicole Endejann/	Date (YYYY-MM-DD)	2024-08-30
Name/Print	N. Nicole Endejann	Registration Number	50,229

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	1	File History for EP 12801372.9, Based on WO2012/174158 and PCT/US2012/042311, filed 29 January 2019 as EX1040 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 3 - pp. 501-662.	☐
	2	File History for Non-Provisional Patent Application No. 12/413,439, filed 27 March 2009, 439 FH, filed as EX1007 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 1 - pp. 1- 400.	☐
	3	File History for Non-Provisional Patent Application No. 12/413,439, filed 27 March 2009, 439 FH, filed as EX1007 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 1 - pp. 401-800.	☐
	4	File History for Non-Provisional Patent Application No. 12/413,439, filed 27 March 2009, 439 FH, filed as EX1007 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 3 - pp. 801-1200.	☐
	5	File History for Non-Provisional Patent Application No. 12/413,439, filed 27 March 2009, 439 FH, filed as EX1007 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 4 - pp. 1201-1600.	☐
	6	File History for Non-Provisional Patent Application No. 12/413,439, filed 27 March 2009, 439 FH, filed as EX1007 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 5 - pp. 1601-2000.	☐
	7	File History for Non-Provisional Patent Application No. 12/413,439, filed 27 March 2009, 439 FH, filed as EX1007 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 6 - pp. 2001-2400.	☐
	8	File History for Non-Provisional Patent Application No. 12/413,439, filed 27 March 2009, 439 FH, filed as EX1007 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 7 - pp. 2401-2800.	☐
	9	File History for Non-Provisional Patent Application No. 12/413,439, filed 27 March 2009, 439 FH, filed as EX1007 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 8 - pp. 2801-3200.	☐
	10	File History for Non-Provisional Patent Application No. 12/413,439, filed 27 March 2009, 439 FH, filed as EX1007 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 9 - pp. 3201-3488.	☐
	11	File History for US 8,895,546, Application No. 13/495,942, 546 FH, filed 29 January 2019 as EX1004 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 1 - pp. 1-350.	☐

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	12	File History for US 8,895,546, Application No. 13/495,942, 546 FH, filed 29 January 2019 as EX1004 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 2 - pp. 351-700.	☐
	13	File History for US 8,895,546, Application No. 13/495,942, 546 FH, filed 29 January 2019 as EX1004 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 3 - pp. 701-1050.	☐
	14	File History for US 8,895,546, Application No. 13/495,942, 546 FH, filed 29 January 2019 as EX1004 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 4 - pp. 1051-1400.	☐
	15	File History for US 8,895,546, Application No. 13/495,942, 546 FH, filed 29 January 2019 as EX1004 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 5 - pp. 1401-1750.	☐
	16	File History for US 8,895,546, Application No. 13/495,942, 546 FH, filed 29 January 2019 as EX1004 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 6 - pp. 1751-2100.	☐
	17	File History for US 8,895,546, Application No. 13/495,942, 546 FH, filed 29 January 2019 as EX1004 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 7 - pp. 2101-2450.	☐
	18	File History for US 8,895,546, Application No. 13/495,942, 546 FH, filed 29 January 2019 as EX1004 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 8 - pp. 2451-2681.	☐
	19	File History for US 9,763,876, Application No. 14/527,613, 876 FH, filed 29 January 2019 as EX1002 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 1 - pp. 1-270.	☐
	20	File History for US 9,763,876, Application No. 14/527,613, 876 FH, filed 29 January 2019 as EX1002 in IPR2019-00451, IPR2019-00450, IPR2019-00449, Part 2 - pp. 271-530.	☐
	21	Final Office Action mailed 02 November 2018 for U.S. Application No. 15/470,498, 9 pages.	☐
	22	Final Office Action mailed 05 May 2020 for U.S. Application No. 15/470,498, 14 pages.	☐

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	23	Final Office Action mailed 09 April 2021 for U.S. Application No. 16/594,897, 23 Pages.	☐
	24	Final Office Action mailed 10 April 2013 for U.S. Application No. 13/371,274, 16 Pages.	☐
	25	Final Office Action mailed 10 April 2019 for U.S. Application No. 14/948,081, 22 pages.	☐
	26	Final Office Action mailed 10 July 2012 for U.S. Application No. 12/266,529, 16 Pages.	☐
	27	Final Office Action mailed 13 March 2015 for U.S. Application No. 12/413,439, 6 pages.	☐
	28	Final Office Action mailed 14 July 2016 for U.S. Application No. 12/413,439, 9 Pages.	☐
	29	Final Office Action mailed 15 November 2011 for U.S. Application No. 12/116,842, 15 Pages.	☐
	30	Final Office Action mailed 17 December 2013 for U.S. Application No. 12/116,842, 26 Pages.	☐
	31	Final Office Action mailed 19 October 2017 for U.S. Application No. 12/413,439, 10 pages.	☐
	32	Final Office Action mailed 20 June 2017 for U.S. Application No. 14/948,041, 42 Pages.	☐
	33	Final Office Action mailed 20 June 2017 for U.S. Application No. 14/948,081, 19 pages.	☐

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	34	Final Office Action mailed 20 March 2020 for U.S. Application No. 15/955,397, 10 Pages.	☐
	35	Final Office Action mailed 21 April 2017 for U.S. Application No. 14/527,613, 7 pages.	☐
	36	Final Office Action mailed 21 November 2011 for U.S. Application No. 12/413,439, 9 pages.	☐
	37	Final Office Action mailed 25 August 2015 for U.S. Application No. 14/152,686, 16 Pages.	☐
	38	FIX "Oral Controlled Release Technology for Peptides: Status and Future prospects" December 1996, Pharmaceutical Research 13(12):1760-1764.	☐
	39	Florida Regional Common EMS Protocols Field Guide, Jones and Barlett Publishers, MA, 2005, [filed as EX1069 in IPR2019-00451], 134 Pages.	☐
	40	FOOD AND DRUG ADMINISTRATION "Applications Covered by Section 505(b)(2)" 1999, Guidance For Industry retrieved from the internet: https://www.fda.gov/media/72419/download 15 Pages, [filed as EX1148 in IPR2019-00451].	☐
	41	FOOD AND DRUG ADMINISTRATION "Determining Whether to Submit an ANDA or a 505(b)(2) Application" Published May 2019, Guidance for Industry FINAL 17 Pages, Retrieved from URL: https://www.fda.gov/media/123567/download [filed as EX1146 in IPR2019-00451].	☐
	42	FOOD AND DRUG ADMINISTRATION "Grant Fast Track, IND 112621; NRL-1 (Diazepam Intranasal Solution)" December 27, 2016, 3 Pages, [filed as EX2002 in IPR2019-00451, IPR2019-00450, IPR2019-00449].	☐
	43	FRENCH et al. "Initial Management of Epilepsy" July 10, 2008, The New England J. of Medicine 359:166-176, filed as EX2019 in IPR2019-00451.	☐
	44	FRENCH et al. "Pharmacopeial Standards and Specifications for Bulk Drugs and Solid Oral Dosage Forms" December 1967, J. Pharmaceutical Sciences 56(12):1622-1641, [filed as EX1033 in IPR2019-00451, IPR2019-00450, IPR2019-00449].	☐

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	45	FRICKER G., et al., "Permeation Enhancement of Octreotide by Specific Bile Salts in Rats and Human Subjects: In Vitro, in Vivo Correlations," British Journal of Pharmacology, January 1996, Vol. 117, No. 1, pp. 217-223.	☐
	46	GIZURARSON et al. "Intranasal Administration of Diazepam Aiming at the Treatment of Acute Seizures: Clinical Trials in Healthy Volunteers" April 1999, Biological and Pharmaceutical Bulletin 22(4):425-427 [filed as EX1030 in IPR2019-00451, IPR2019-00450, IPR2019-00449].	☐
	47	GORDON et al. "Nasal Absorption of Insulin: Enhancement by Hydrophobic Bile Salts" November 1985, Proceedings of the National Academy of Sciences of the United States of America 82:7419-7423.	☐
	48	GREENBLATT et al. "Pharmacokinetics and Pharmacodynamics of Single-Dose Triazolam: Electroencephalography Compared with the Digital-Symbol Substitution Test" 2005, British J. Clinical Pharmacology 60:244-248, [filed as EX1135 in IPR2019-00451].	☐
	49	GUDMUNDSDOTTIR et al. "Intranasal Administration of Midazolam in a Cyclodextrin Based Formulation: Bioavailability and Clinical Evaluation in Humans" 2001, Pharmazie 56(12):963-966,[filed as EX1127 in IPR2019-00451].	☐
	50	"Handbook of Pharmaceutical Excipients Fifth Ed." 2006, Pharmaceutical Press and American Pharmacists Association, Publishers 12 Pages, [filed as EX2029 in IPR2019-00451].	☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18782666
Filing Date	2024-07-24
First Named Inventor	Steve CARTT
Art Unit	
Examiner Name	Not Yet Assigned
Attorney Docket Number	148570-014311

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	25	Dr. Nicholas Peppas Deposition Transcript, October 24, 2019, 158 Pages, [filed as EX2011 in IPR2019-00451].	☐
	26	DREWE et al. "Enteral Absorption of Octreotide: Absorption Enhancement by Polyoxyethylene-24-cholesterol Ether" 1993, British J. Pharmacology 108(2):298-303.	☐
	27	Drug Prices from Internet, Accessed January 24, 2020, 6 Pages, [filed as EX1081 in IPR2019-00451].	☐
	28	DUQUESNOY et al. "Comparative Clinical Pharmacokinetics of Single Doses of Sumatriptan Following Subcutaneous, Oral, Rectal and Intranasal Administration" 1998, European J. Pharmaceutical Sciences 6(2):99-104.	☐
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	31	ELEY et al. "In Vitro Assessment of Alkylglycosides as Permeability Enhancers" 2001, AAPS PharmSciTech, 2(3):1-7.	☐
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	34	ERIKSSON et al. "Pharmacologic Management of Convulsive Status Epilepticus in Childhood" 2005, Expert Rev Neurotherapeutics 5(6):777-783, [Filed as EX1109 in IPR2019-00451].	☐
	35	European Communication Pursuant to Article 94(3) EPC for European Application No. 12801372.9, mailed 05 July 2016, 7 pages.	☐
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	37	European Office Action for European Application No. 18171484.1 mailed April 06, 2020, 8 Pages.	☒
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Name/Print	N. Nicole Endejann	Registration Number	50,229

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	1	OGISO et al. "Percutaneous Absorption of Elcatonin and Hypocalcemic Effect in Rat" February 1991, Chemical & Pharmaceutical Bulletin, The Pharmaceutical Society of Japan, Tokyo, Japan 39(2):449-453.	☐
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	5	OSBORNE et al. "Skin Penetration Enhancers Cited In The Technical Literature" November 1997, Pharmaceutical Technology, 35 Pages, (filed as EX1024 in IPR2019-00451, IPR2019-00450, IPR2019-00449).	☐
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	8	Patent Owner's Notice of Appeal filed 08 October 2020 in IPR2019-00451, 5 Pages.	☐
	9	Patent Owner's Preliminary Response, filed 06 May 2019 in IPR2019-00449, 30 Pages.	☐
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	12	Patent Owner's Request for Rehearing of U.S. Patent No. 9,763,876, filed 27 August 2019 in IPR2019-00451, 17 Pages.	☐
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	14	Patent Owner's Surreply to Patent Owner's Response, filed 10 March 2020 in IPR2019-00451, 34 Pages.	☐
	15	PAULSSON "Controlled Drug Release from Gels Using Surfactant Aggregates. II. Vesicles formed from Mixtures of Amphiphilic Drugs and Oppositely Charged Surfactants" November 2001, Pharmaceutical Research, 18 (11):1586-1592.	☐
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	17	Petition for Inter Partes Review for U.S. Patent No. 9,763,876 (IPR2019-00449) dated January 28, 2019, 103 Pages.	☐
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	19	Petition for Inter Partes Review for U.S. Patent No. 9,763,876 (IPR2019-00451) dated January 29, 2019, 107 Pages.	☐
	20	Petitioner's Reply to Patent Owner's Response to the Petition of U.S. Patent No. 9,763,876, filed 28 January 2020 in IPR2019-00451, 38 Pages.	☐
	21	Petitioner's Request for Rehearing Pursuant to 37 C.F.R. 42.71(d) of U.S. Patent No. 9,763,876, filed 03 September 2019 in IPR2019-00449, 19 Pages.	☐
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	23	PILLION et al. "Synthetic Long-chain Alkyl Maltosides and Alkyl Sucrose Esters as Enhancers of Nasal Insulin Absorption" June 2002, J. Pharmaceutical Sciences 91(6):1456-1462.	☐
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	28	RICHARDS "Inactivation of Resistant Pseudomonas Aeruginosa By Antibacterial Combinations" January 18, 1971, J. Pharmacy and Pharmacology 23:136S-140S.	☐
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	33	RUDY et al. "A Multiple-Dose Phase 1 Study of Intranasal Hydromorphone Hydrochloride in Healthy Volunteers" 2004, Anesthesia Analgesia 99:1379-1386, [filed as EX1122 in IPR2019-00451].	☐

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	34	Rule 36 Judgment entered 7 October 2021, U.S. Court of Appeals for the Federal Circuit, Neurelis, Inc., Appellant v. Aquestive Therapeutics, Inc., Appellee, Appeal No. 2021-1038, affirming decision in IPR2019-00451, 2 Pages, (U.S. Pat. No. 9,763,876).	☐
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	36	SALZMAN et al. "Intranasal Aerosolized Insulin" April 1985, The New England J. Medicine, 312(17):1078-1084.	☐
	37	SANDERS et al. "Pharmacokinetics of Ergotamine in Healthy Volunteers Following Oral and Rectal Dosing" 1989, European J. Clinical Pharmacology, 30(3):331-334.	☐
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	43	SMITH "Treatment of Status Epilepticus" May 2001, Neurologic Clinics 19(2):347-369, [filed as EX1108 in IPR2019-00451].	☐
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	45	STEVENS et al. "Use of Glucagon to Treat Neonatal Low-Output Congestive Heart Failure after Maternal Labetalol Therapy" July 1995, J. Pediatrics 127(1):151-153.	☐
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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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Application Number	18782666
Filing Date	2024-07-24
First Named Inventor	Steve CARTT
Art Unit	
Examiner Name	Not Yet Assigned
Attorney Docket Number	148570-014311

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	1	Transcript of Dr. Gizurarson's Deposition on January 14, 2020, [filed as EX1149 in IPR2019-00451], 162 Pages.	☐
	2	Transcript of Telephone Conference on February 11, 2020, [filed as EX2027 in IPR2019-00451], 25 Pages.	☐
	3	TSUCHIDO et al. "Lysis of Bacillus Subtilis Cells by Glycerol and Sucrose Esters of Fatty Acids," March 1987, Applied and Environmental Microbiology 53(3):505-508.	☐
	4	TURKER et al. "Nasal Route and Drug Delivery Systems" 2004, Pharmacy World and Science 26(3):137-142.	☐
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	6	"UCB announces NAYZILAM (Midazolam) Nasal Spray Now Approved By FDA To Treat Intermittent, Stereotypic Episodes Of Frequent Seizure Activity In People Living With Epilepsy In The U.S" May 20, 2019, UCB Press Release, 14 pages, [filed as EX2018 in IPR2019-00451].	☐
	7	U.S. Patent Application No. 14/990,645 filed January 7, 2016, 83 Pages.	☐
	8	U.S. Provisional Application No. 60/148,464 filed 12 August 1999, 93 Pages.	☐
	9	U.S. Provisional Application No. 60/632,038, filed 30 November 2004, 37 Pages, [filed as EX1065 in IPR2019-00451, IPR2019-00450].	☐
	10	U.S. Provisional Application No. 61/040,281, filed 28 March 2008, 25 Pages, [filed as EX1046 in IPR2019-00451, IPR2019-00450, IPR2019-00449].	☐
	11	U.S. Provisional Application No. 61/040,558, filed 28 March 2008, [filed as EX1008 in IPR2019-00451, IPR2019-00450, IPR2019-00449], 60 Pages.	☐

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	12	U.S. Provisional Application No. 61/497,017, filed 14 June 2011, [filed as EX1005 in IPR2019-00451, IPR2019-00450, IPR2019-00449], 105 Pages.	☐
	13	U.S. Provisional Application No. 61/570,110, filed 13 December 2011, [filed as EX1006 in IPR2019-00451, IPR2019-00450, IPR2019-00449], 104 Pages.	☐
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	17	VAN DER LUBBEN et al. "Chitosan and Its Derivatives in Mucosal Drug and Vaccine Delivery" 2001, European J. Pharmaceutical Sciences 14(3):201-207.	☐
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	20	WANG et al. "Factors Predictive of Outcome in Posttraumatic Seizures" 2008, The J. Trauma 64(4):883-888, [filed as EX1103 in IPR2019-00451].	☐
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	23	Webpage for Anatrace Products of Affymetrix, retrieved from the internet: http://www.affymetrix.com/estore/browse/level_three_category_and_products.jsp?category=35843&categoryIdClicked=35843&expand=true&parent=35900 Accessed online on (December 13, 2012) 2 Pages.	☐
	24	WERMELING et al. "A pharmacokinetic and pharmacodynamic study, in healthy volunteers, of a rapidly absorbed intranasal midazolam formulation," February 2009, Epilepsy Res. 83(2-3):124-132.	☐
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	26	WERMELING et al. "Pharmacokinetics and Pharmacodynamics of a New Intranasal Midazolam Formulation in Healthy Volunteers" 2006, Anesthesia & Analgesia 103(2):344-349, XP002585302.	☐
	27	WERMELING "Intranasal Delivery of Antiepileptic Medications for Treatment of Seizures" April 2009, Neurotherapeutics 6(2):352-358, [Filed as EX1151 in IPR2019-00451].	☐
	28	WIKIPEDIA "Benzodiazepine Overdose" September 23, 2019, entire document, especially page 2 paragraph 1, retrieved from the internet: https://en.wikipedia.org/w/index.php?title=Benzodiazepine_overdose&oldid=917464003 (March 10, 2022) 10 Pages.	☐
	29	WILSON et al. "Nasal/Buccal Midazolam Use in the Community" 2004, Archives of Disease in Childhood 59(1):50-51, [filed as EX1141 in IPR2019-00451].	☐
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Please see 37 CFR 1.97(e) to make the appropriate selection(s):

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

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Please see 37 CFR 1.97(e) 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.

☒ A certification statement is not submitted herewith.

FEE

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

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☒ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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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.

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Name/Print	N. Nicole Endejann	Registration Number	50,229

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☐ See attached certification statement.

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FEE

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

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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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18782666
Filing Date	2024-07-24
First Named Inventor	Steve CARTT
Art Unit	1612
Examiner Name	Michael P. COHEN
Attorney Docket Number	148570-014311

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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	20060222597	A1	2006-10-05	DUGGER, Harry	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	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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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	18782666
	Filing Date	2024-07-24
	First Named Inventor	Steve CARTT
	Art Unit	1612
	Examiner Name	Michael P. COHEN
	Attorney Docket Number	148570-014311

	1	LI et al. "Development of an ethyl laurate-based microemulsion for rapid-onset intranasal delivery of diazepam" 2002, Int J Pharmaceutics, 237:77-85.	☐

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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	Art Unit	1612
	Examiner Name	Michael P. COHEN
	Attorney Docket Number	148570-014311

CERTIFICATION STATEMENT

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

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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.

☐ A certification statement is not submitted herewith.

FEE

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

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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	/Marissa S. Kuzirian/	Date (YYYY-MM-DD)	2024-11-25
Name/Print	Marissa S. Kuzirian, Ph.D.	Registration Number	78,983

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Filing Date	2024-07-24
First Named Inventor	Steve CARTT
Art Unit	1612
Examiner Name	Michael P. COHEN
Attorney Docket Number	148570-014311

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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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	Art Unit	1612
	Examiner Name	Michael P. COHEN
	Attorney Docket Number	148570-014311

	1	Li et al. "Rapid-onset intranasal delivery of anticonvulsants: pharmacokinetic and pharmacodynamic evaluation in rabbits" 2000, Int J Pharmaceutics, 199:65-76.	☐

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☐ A certification statement is not submitted herewith.

FEE

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COPIES

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SIGNATURE

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Signature	/Marissa S. Kuzirian/	Date (YYYY-MM-DD)	2024-12-12
Name/Print	Marissa S. Kuzirian, Ph.D.	Registration Number	78,983

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Filing Date	2024-07-24
First Named Inventor	Steve CARTT
Art Unit	1612
Examiner Name	Michael P. COHEN
Attorney Docket Number	148570-014311

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Inventor of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
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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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	Art Unit	1612
	Examiner Name	Michael P. COHEN
	Attorney Docket Number	148570-014311

	1	Declaration of Dr. Maureen Donovan, Ph.D.	☐
	2	Petition for Inter Partes Review of U.S. Patent No. 11,241,414 filed January 17, 2025 in IPR2025-00465.	☐
	3	Petition for Inter Partes Review of U.S. Patent No. 11,793,786 filed January 17, 2025 in IPR2025-00466.	☐
	4	Petition for Inter Partes Review of U.S. Patent No. 8,895,546 filed January 17, 2025 in IPR2025-00464.	☐
	5	Preliminary Invalidity Contentions filed December 20, 2024, in Neurelis, Inc. v. Padagis LLC et al., Civil Action No. 24-562 (MN) (D. Delaware).	☐
	6	SHARMA et al. "Permeation enhancers in the transmucosal delivery of macromolecules" 2006, Pharmazie, 61 (6):495-504.	☐

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TIMING STATEMENT

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☒ See attached timing statement under 37 CFR 1.97(e).

☐ A timing statement under 37 CFR 1.97(e) is not submitted herewith.

TIMING FEE

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

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98(d)(1) is attached.

SIZE FEE ASSERTION

Please see 37 CFR 1.17(v) and the IDS Auto-Load Instructions for completing this form to make the appropriate selection of an assertion under 37 CFR 1.98. For the information disclosure statement (IDS) submitted herewith, the applicant or patent owner certifies the following with respect to the cumulative number of applicant-provided or patent-owner provided items of information submitted to date including those in the accompanying IDS (select only one):

☒ No IDS size fee is required under 37 CFR 1.17(v) at this time.

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(1).

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(2).

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(3).

SIGNATURE

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Signature	/Marissa S. Kuzirian/	Date (YYYY-MM-DD)	2025-02-03
Name/Print	Marissa S. Kuzirian, Ph.D.	Registration Number	78,983

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	Examiner Name	Michael P. COHEN
	Attorney Docket Number	148570-014311

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