UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AZURITY PHARMACEUTICALS, INC.,
Petitioner,

v.

HELSINN HEALTHCARE S.A.,
Patent Owner.

Case IPR2025-00946
Patent US 9,186,357 B2

AZURITY PHARMACEUTICALS' EXHIBIT LIST

I. EXHIBIT LIST - §42.63(e)

Exhibit	Description
1001	F. Trento et al., *Compositions and methods for treating centrally mediated nausea and vomiting*, U.S. Patent 8,623,826 B2, issued 17 January 2014
1002	F. Trento et al., *Compositions and methods for treating centrally mediated nausea and vomiting*, U.S. Patent 9,186,357 B2, issued 17 November 2015
1003	F. Trento et al., *Compositions and methods for treating centrally mediated nausea and vomiting*, U.S. Patent 9,943,515 B2, issued 17 April 2018
1004	F. Trento et al., *Compositions and methods for treating centrally mediated nausea and vomiting*, U.S. Patent 10,828,297 B2, issued 10 November 2020
1005	Prosecution history for U.S. Appl. 13/077,462, filed 31 March 2011
1006	Prosecution history for U.S. Appl. 14/069,927, filed 01 November 2013
1007	Prosecution history for U.S. Appl. 15/003,327, filed 19 May 2016
1008	Prosecution history for U.S. Appl. 15/923,050, filed 16 March 2018
1009	Declaration of Stephen J. Peroutka, M.D., Ph.D.
1010	J. Herrstedt & P. Dombernowsky, *Anti-Emetic Therapy in Cancer Chemotherapy: Current Status*, 101 Basic & Clinical Pharmacology & Toxicology 143-150 (2007)
1011	T. Hoffmann et al., *Design and synthesis of a novel, achiral class of highly potent and selective, orally active neurokinin-1 receptor*

Exhibit	Description
	antagonists, 16 Bioorganic & Medicinal Chemistry Letters 1362-1365 (2006)
1012	R. Hargreaves, *Imaging Substance P Receptors (NK_1) in the Living Human Brain Using Positron Emission Tomography*, 63(11) J. Clinical Psychiatry 18-24 (2002)
1013	The Antiemetic Subcommittee of the Multinational Association of Supportive Care in Cancer (MASCC), *Prevention of chemotherapy- and radiotherapy-induced emesis: results of the 2004 Perugia International Antiemetic Consensus Conference*, 17 Annals of Oncology 20-28 (2006)
1014	M. Bös et al., *4-phenyl-pyridine derivatives*, U.S. Patent 6,297,375 B1 (issued 2 Oct. 2001)
1015	Eisai, Inc., ALOXI (palonosetron HCl) Capsules, package insert (Aug. 2008)
1016	J.D. Herrington et al., *Randomized, Placebo-controlled, Pilot Study Evaluating Aprepitant Single Dose Plus Palonosetron and Dexamethasone for the Prevention of Acute and Delayed Chemotherapy-induced Nausea and Vomiting*, 112 Cancer 2080 (2008).
1017	D. Bonadeo et al., *Soft Capsules Comprising Palonosetron Hydrochloride Having Improved Stability and Bioavailability*, PCT Publication WO 2008/049552 (published 2 May 2008)
1018	R.J. Gralla et al., *Recommendations for the use of antiemetics: evidence-based, clinical practice guidelines*, 17 Journal of Clinical Oncology 2971 (1999).
1019	K. Jordan et al., *Guidelines for Antiemetic Treatment of Chemotherapy-Induced Nausea and Vomiting: Past, Present, and Future Recommendations*, 12 The Oncologist 1143-1150 (September 2007)

Exhibit	Description
1020	Curriculum Vitae of Dr. Stephen J. Peroutka
1021	G.K. Reddy et al., *Novel Neurokinin-1 Antagonists as Antiemetics for the Treatment of Chemotherapy-Induced Emesis*, 3 Support Cancer Therapy 140-42 (2006).
1022	M.S. Aapro et al., *A phase III, double-blind, randomized trial of palonosetron compared with ondansetron in preventing chemotherapy-induced nausea and vomiting following highly emetogenic chemotherapy*, 17 Annals of Oncology 1441-49 (2006)
1023	D. Campos et al., *Prevention of cisplatin-induced emesis by the oral neurokinin-1 antagonist, MK-869, in combination with granisetron and dexamethasone or with dexamethasone alone*, 19(6) Journal of Clinical Oncology, 1759 (2001)
1024	A.E. Chang et al., eds., Oncology: An Evidence-Based Approach (2006)
1025	S.P. Chawla et al., *Establishing the Dose of the Oral NK_1 Antagonist Aprepitant for the Prevention of Chemotherapy-Induced Nausea and Vomiting*, 97 Cancer 2290 (2003).
1026	S.P. Chawla et al., *Establishing the Dose of the Oral NK_1 Antagonist Aprepitant for the Prevention of Chemotherapy-Induced Nausea and Vomiting*, 37th Annual Meeting of the American Society of Clinical Oncology, in 20 Proceedings of ASCO 383a (2001)
1027	A. De Leon, *Palonosetron (Aloxi): a second-generation 5-HT3 receptor antagonist for chemotherapy-induced nausea and vomiting*, in 19(4) Baylor University Medical Center Proceedings 413 (2006)

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1028	R.A. Duffy, *Potential therapeutic targets for neurokinin-1 receptor antagonists*, 9(1) Expert opinion on emerging drugs, 9 (2004)
1029	Press Release, Eisai Co., FDA Approves ALOXI® (Palonosetron HCl) Capsules for Prevention of Acute Chemotherapy-induced Nausea and Vomiting (Aug. 24, 2008)
1030	Merck & Co., EMEND, package insert (2008)
1031	DailyMed, EMEND (aprepitant) Capsule, https://web.archive.org/web/20090202144735/http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=7355 (archived Feb. 2, 2009)
1032	U.S. Food and Drug Administration, General Considerations for the Clinical Evaluation of Drugs (1978)
1033	U.S. Food and Drug Administration, Q3A Impurities in New Drug Substances (2008)
1034	D.G. Warr et al., *Efficacy and tolerability of aprepitant for the prevention of chemotherapy-induced nausea and vomiting in patients with breast cancer after moderately emetogenic chemotherapy*, 23(12) Journal of Clinical Oncology 2822 (2005)
1035	S.M. Grunberg et al., *Effectiveness of a single-day three-drug regimen of dexamethasone, palonosetron, and aprepitant for the prevention of acute and delayed nausea and vomiting caused by moderately emetogenic chemotherapy*, 17 Supportive Care in Cancer 589 (2009)
1036	Press Release, GSK provides update on regulatory filings for Zunrisa/Rezonic (Sep. 27, 2009), downloaded from https://www.gsk.com/en-gb/media/press-releases/gsk-provides-update-

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1037	P.J. Hesketh et al., *The Oral Neurokinin-1 Antagonist Aprepitant for the Prevention of Chemotherapy-Induced Nausea and Vomiting: A Multinational, Randomized, Double-Blind, Placebo-Controlled Trial in Patients Receiving High-Dose Cisplatin—The Aprepitant Protocol 052 Study Group*, 21(22) Journal of Clinical Oncology 4112 (2003)
1038	G.S. Paulekuhn et al., *Trends in active pharmaceutical ingredient salt selection based on analysis of the orange book database*, 50(26) Journal of Medicinal Chemistry 6665 (2007)
1039	S. Poli-Bigelli et al., *Addition of the neurokinin 1 receptor antagonist aprepitant to standard antiemetic therapy improves control of chemotherapy-induced nausea and vomiting: Results from a randomized, double-blind, placebo-controlled trial in Latin America*, 97(12) Cancer 3090 (2003)
1040	T. Qiu et al., *Antiemetic regimen with aprepitant in the prevention of chemotherapy-induced nausea and vomiting*, 99(33) Medicine e21559 (2020)
1041	C. Rojas, *The antiemetic 5-HT3 receptor antagonist Palonosetron inhibits substance P-mediated responses in vitro and in vivo*, 335(2) The Journal of Pharmacology and Experimental Therapeutics 362 (2010)
1042	C. Ruhlmann & J. Herrstedt, *Casopitant: a novel NK1-receptor antagonist in the prevention of chemotherapy-induced nausea and vomiting*, 5 Therapeutics and Clinical Risk Management 375 (2009)
1043	R. Saito et al., *Roles of substance P and NK1 receptor in the brainstem in the development of emesis*, 91(2) Journal of Pharmacological Sciences 87 (2003)

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1044	Ronald D. Schoenwald, Pharmacokinetics in Drug Discovery and Development (2002)
1045	A.G. Thomas, *Netupitant and palonosetron trigger NK1 receptor internalization in NG108-15 cells*, 232 Experimental Brain Research 2637 (2014)
1046	K.E. Thummel, *Gut instincts: CYP3A4 and intestinal drug metabolism*, 117(11) Journal of Clinical Investigation 3173 (2007)
1047	D.S. Wang, *Effect of aprepitant for the prevention of chemotherapy-induced nausea and vomiting in women: a randomized clinical trial*, 4(4) JAMA Network Open e215250 (2021)
1048	W. Yeo et al., *A randomized study of aprepitant, ondansetron and dexamethasone for chemotherapy-induced nausea and vomiting in Chinese breast cancer patients receiving moderately emetogenic chemotherapy*, 113 Breast Cancer Research and Treatment 529 (2009)
1049	S.F. Zhou, *Drugs Behave as Substrates, Inhibitors and Inducers of Human Cytochrome P450 3A4*, 9(4) Current Drug Metabolism 310 (2008)
1050	*Parenteral*, Merriam-Webster, https://www.merriam-webster.com/dictionary/parenterally
1051	NK1 receptor antagonist by Roche, Advances in Drug Discovery (Feb. 23, 2006), https://web.archive.org/web/20080215091703/http://leaddiscovery.blogspot.com/2006/02/nk1-receptor-antagonist-by-roche.html (archived Feb. 15, 2008)

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1052	RxList, ALOXI (palonosetron HCl) Capsules, https://web.archive.org/web/20080924091503/http://www.rxlist.com:80/script/main/hp.asp (archived Oct. 24, 2008)
1053	DailyMed excerpts relating to ALOXI (palonosetron HCl) Capsules, downloaded from https://dailymed.nlm.nih.gov/dailymed/index.cfm, https://dailymed.nlm.nih.gov/dailymed/dailymed-announcements-details.cfm?date=2015-10-08, https://dailymed.nlm.nih.gov/dailymed/archives/index.cfm?query=palonosetron&date=10%2F30%2F2008, & https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=9092
1054	DailyMed excerpts relating to Aloxi (palonosetron HCl) Capsules, as archived at https://web.archive.org/web/20081112024512/http://dailymed.nlm.nih.gov/dailymed/about.cfm (archived Nov. 12, 2008), https://web.archive.org/web/20090117151926/http://dailymed.nlm.nih.gov/dailymed/drugList.cfm?startswith=P (archived Jan. 17, 2009), and https://web.archive.org/web/20090521131758/http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=8295 (archived May 21, 2009)
1055	PCT Publication WO 2011/061622, filed 18 November 2010
1056	Provisional Patent Appl. 61/382,709, filed 14 September 2010
1057	Provisional Patent Appl. 61/262,470, filed 18 November 2009
1058	Drugs@FDA: FDA-Approved Drugs, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022233

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1059	P. Li & L. Zhao, *Developing Early Formulations: Practice and Perspective*, 341 International Journal of Pharmaceutics 1 (2007)
1060	G. Sanso, *Double capsule for the administration of active principles in multiple therapies*, U.S. Patent 6,350,468 B1 (issued 26 Feb. 2002)
1061	B. Cromie, *Drug Combinations*, 1(2) Current Medical Research and Opinion 78 (1972)
1062	RESERVED
1063	RESERVED
1064	RESERVED
1065	RESERVED
1066	Page 64 of EX2088 with Dr. Roeland's markings from his deposition
1067	Deposition of Eric Roeland, M.D. (11 May 2026)
1068	Azurity Demonstrative Exhibits

II. CERTIFICATIONS

A. Rule 42.6(e)(4) Certificate of Service

I certify that today this paper was served electronically on Helsinn's counsel at PH-Azurity-Helsinn-IPR@paulhastings.com. See #4 (PO Mand. Not.).

B. Declaration

All statements in this certificate of service made of my own knowledge are true and all statements made on information and belief are believed to be true. I acknowledge that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of this proceeding.

Dated: September 11, 2026 / Yawen Wang /
Yawen Wang