

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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AZURITY PHARMACEUTICALS, INC.,  
Petitioner,

v.

HELSINN HEALTHCARE S.A.,  
Patent Owner.

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Case IPR2025-00948  
Patent No. 9,943,515

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**PATENT OWNER'S CURRENT LIST OF EXHIBITS**

**LIST OF EXHIBITS**

<b>Exhibit No.</b>	<b>Description</b>	<b>Previously Submitted</b>
2001	Curran, P. et al., <i>Aprepitant A Review of its Use in the Prevention of Nausea and Vomiting</i> , <i>Drugs</i> 2009: 69 (13): 1853-1878	
2002	EMEND® (aprepitant) FDA Approval Letter, NDA 21-549, dated March 26, 2003, available at <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/21-549_Emend_Approv.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/21-549_Emend_Approv.pdf</a>	
2003	Ruhlmann, <i>Casopitant: a novel NK1-receptor antagonist in the prevention of chemotherapy-induced nausea and vomiting</i> , <i>Therapeutics and Clinical Risk Management</i> 2009:5 375-384	
2004	Emend IV (fosaprepitant) FDA Approval Letter, NDA 22-023, dated January 25, 2008, available at <a href="https://www.accessdata.fda.gov/drugsatfda_docs/NDA/2008/022023s000_Approv.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/NDA/2008/022023s000_Approv.pdf</a>	
2005	Akynzeo (netupitant/palonosetron) FDA Approval Letter, dated October 10, 2014, available at <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205718Orig1s000Approv.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205718Orig1s000Approv.pdf</a>	
2006	Global CINV Drugs Market \$4.3 Billion by 2031, <i>ihealthcareanalyst</i> , Feb. 3, 2025, available at <a href="https://www.ihealthcareanalyst.com/global-chemotherapy-induced-nausea-vomiting-drugs-market/">https://www.ihealthcareanalyst.com/global-chemotherapy-induced-nausea-vomiting-drugs-market/</a>	
2007	Heron Form 10-K, Feb. 27, 2025	
2008	Azurity (Aprepitant Injectable Emulsion) FDA Tentative Approval Letter, NDA 218754, dated July 25, 2024, available at <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/218754Orig1s000TAltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/218754Orig1s000TAltr.pdf</a>	
2009	U.S. Patent No. 12,097,197 to Dubewar et al.	
2010	IDS Statement, Application No. 18/069,204, dated June 29, 2023	

2011	Press Release – CutisPharma Announces Acquisition of Silvergate Pharmaceuticals, Name Change to Azurity Pharmaceuticals, June 12, 2019, 6:00 ET	
2012	Press Release – Silvergate Pharmaceuticals Release: FDA Approves XATMEP, The First and Only Ready-To-Use Methotrexate Oral Solution, April 26, 2017	
2013	GLIADEL® WAFER label	
2014	Press Release - Azurity Pharmaceuticals Acquires Slayback Pharma, Sept. 27, 2023, available at <a href="https://azurity.com/azurity-pharmaceuticals-acquires-slayback-pharma/">https://azurity.com/azurity-pharmaceuticals-acquires-slayback-pharma/</a>	
2015	U.S. Patent Application Publication No. 2024/0156829 A1	
2016	EMEND® label, March 2003	
2017	An Efficacy and Safety Study of Oral Netupitant and Palonosetron for the Prevention of Nausea and Vomiting, last updated Nov. 26, 2014, available at <a href="https://clinicaltrials.gov/study/NCT01339260">https://clinicaltrials.gov/study/NCT01339260</a>	
2018	A Safety Study of Oral Netupitant and Palonosetron for the Prevention of Nausea and Vomiting, last updated Nov. 17, 2014, available at <a href="https://clinicaltrials.gov/study/NCT01376297">https://clinicaltrials.gov/study/NCT01376297</a>	
2019	An Efficacy and Safety Study of Oral and Intravenous Palonosetron for the Prevention of Nausea and Vomiting, last updated Sept. 22, 2021, available at <a href="https://clinicaltrials.gov/study/NCT01363479">https://clinicaltrials.gov/study/NCT01363479</a>	
2020	FDA Approves Akynzeo for Injection, FDA Approves Intravenous Formulation of Akynzeo (fosnetupitant/palonosetron) for Chemotherapy-Induced Nausea and Vomiting, available at <a href="https://www.drugs.com/newdrugs/fda-approves-intravenous-formulation-akynzeo-fosnetupitant-palonosetron-chemotherapy-induced-nausea-4726.html">https://www.drugs.com/newdrugs/fda-approves-intravenous-formulation-akynzeo-fosnetupitant-palonosetron-chemotherapy-induced-nausea-4726.html</a>	
2021	Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, available at <a href="https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=002&amp;Appl_No=210493&amp;Appl_type=N">https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=002&amp;Appl_No=210493&amp;Appl_type=N</a>	

2022	Netupitant and Palonosetron Hydrochloride in Preventing Chemotherapy Induced Nausea and Vomiting in Patients With Cancer Undergoing BEAM Conditioning Regimen Before Stem Cell Transplant, last updated Jul 12, 2021, available at <a href="https://clinicaltrials.gov/study/NCT03097588">https://clinicaltrials.gov/study/NCT03097588</a>	
2023	PK/ PD Study of Netupitant and Palonosetron in Pediatric Patients for Prevention of Chemotherapy-induced Nausea and Vomiting (CINV), last updated Jun 25, 2024, available at <a href="https://clinicaltrials.gov/study/NCT03204279">https://clinicaltrials.gov/study/NCT03204279</a>	
2024	A Study to Assess the Safety and the Efficacy of IV Fosnetupitant/ Palonosetron (260 mg/ 0.25 mg) Combination Compared to Oral Netupitant/ Palonosetron (300 mg/ 0.5 mg) Combination for the Prevention of CINV in AC Chemotherapy in Women With Breast Cancer, last updated Jun 1, 2020, available at <a href="https://clinicaltrials.gov/study/NCT03403712">https://clinicaltrials.gov/study/NCT03403712</a>	
2025	Safety and Antiemetic Efficacy of Akynzeo Plus Dexamethasone During Radiotherapy and Concomitant Weekly Cisplatin, last updated Dec. 14, 2021, available at <a href="https://clinicaltrials.gov/study/NCT03668639">https://clinicaltrials.gov/study/NCT03668639</a>	
2026	Oral Akynzeo® Vs Standard of Care in Preventing CINV in High-risk MEC Patients (MyRisk) (CINV), last updated Dec. 4, 2024, available at <a href="https://clinicaltrials.gov/study/NCT04817189">https://clinicaltrials.gov/study/NCT04817189</a>	
2027	A Clinical Trial to Assess Safety and Pharmacokinetics of Fosnetupitant 235mg and Metabolites in Healthy Volunteers, last updated May 4, 2025, available at <a href="https://clinicaltrials.gov/study/NCT06840769">https://clinicaltrials.gov/study/NCT06840769</a>	
2028	Prevention of Breakthrough CINV in Patients Receiving Moderately or Highly Emetogenic Chemotherapy, last updated Oct. 10, 2023, available at <a href="https://clinicaltrials.gov/study/NCT06065722">https://clinicaltrials.gov/study/NCT06065722</a>	
2029	Study With IV NEPA (Fosnetupitant/ Palonosetron) for the Prevention of Chemotherapy-induced Nausea and Vomiting in Paediatric Cancer Patients Undergoing Highly Emetogenic Chemotherapy (HEC), last updated Jul 28, 2025, available at <a href="https://clinicaltrials.gov/study/NCT06904235">https://clinicaltrials.gov/study/NCT06904235</a>	

2030	An Efficacy and Safety Study of Intravenous Palonosetron Administered as an Infusion and as a Bolus for the Prevention of Nausea and Vomiting, last update Jun 20, 2018, available at <a href="https://clinicaltrials.gov/study/NCT02557035">https://clinicaltrials.gov/study/NCT02557035</a>	
2031	A Safety Study of Intravenous Pro-Netupitant and Palonosetron Combination for the Prevention of Nausea and Vomiting, last updated Jun 20, 2018, available at <a href="https://clinicaltrials.gov/study/NCT02517021">https://clinicaltrials.gov/study/NCT02517021</a>	
2032	U.S. Patent No. 5,202,333 to Berger et al.	
2033	Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, available at <a href="https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&amp;Appl_No=210493&amp;Appl_type=N">https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&amp;Appl_No=210493&amp;Appl_type=N</a>	
2034	Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, available at <a href="https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&amp;Appl_No=205718&amp;Appl_type=N">https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&amp;Appl_No=205718&amp;Appl_type=N</a>	
2035	AKYNZEO® label	

Dated: August 4, 2025

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that I caused to be served on the counsel identified below a true and correct copy of the foregoing Patent Owner's Current List of Exhibits by electronic means on August 4, 2025:

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