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INTELLECTUAL PROPERTY LAW

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(Electronically Filed)
Patent Trial and Appeal Board
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Inter Partes Review of U.S. Patent No. 8,729,094
Exhibit Cover Letter Per 37 C.F.R. § 42.6(e)(4)(ii)

Dear Patent Trial and Appeal Board:

This transmittal letter identifies Exhibits 1001-1055, being filed concurrently with the present Petition for *Inter Partes* Review. Pursuant to 37 C.F.R. § 42.6(e)(4)(ii), the Certificate of Service attached to the end of the Petition for *Inter Partes* Review filed herewith, incorporates Exhibits 1001-1055, as listed below:

Exhibit #	Reference
1001	U.S. Patent No. 8,729,094
1002	U.S. Patent No. 7,947,724
1003	U.S. Patent No. 7,947,725
1004	U.S. Patent No. 7,960,424
1005	U.S. Patent No. 8,598,219
1006	Complaint for Patent Infringement, <i>Helsinn Healthcare S.A. and Roche Palo Alto LLC v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.</i> , U.S.D.C.N.J. Civil Action No. 3:14-cv-04274-MLC-DEA

Exhibit #	Reference
1007	Complaints for Patent Infringement, <i>Helsinn Healthcare S.A. and Roche Palo Alto LLC v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc., et al.</i> U.S.D.C.N.J. Civil Action No. 3:11-cv-03962-MLC-TJB filed 7/8/2011; <i>Helsinn Healthcare S.A. and Roche Palo Alto LLC v. Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc., et al.</i> , U.S.D.C.N.J. Civil Action Nos. 3:11-cv-05579-MLC-DEA filed 9/23/2011; <i>Helsinn Healthcare S.A. and Roche Palo Alto LLC v. Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc., et al.</i> , 3:13-cv-05815-MLC-DEA filed 12/27/2013; and <i>Helsinn Healthcare S.A. and Roche Palo Alto LLC v. Dr. Reddy's Laboratories, Ltd. & Dr. Reddy's Laboratories, Inc.</i> , U.S.D.C.N.J. Civil Action No. 3:12-cv-02867-MLC-DEA filed 5/12/2012
1008	Serial No. 13/902,132 Final Rejection, Dec. 6, 2013
1009	Serial No. 13/902,132, Amendment After Final, Feb. 21, 2014
1010	U.S. Patent No. 5,202,333 ("Berger")
1011	Eglen <i>et al.</i> , <i>Pharmacological characterization of RS 25259-197, a novel and selective 5-HT₃ receptor antagonist, in vivo</i> , 114 British J. Pharmacol. 860-66 (1985) ("Eglen")
1012	Chelly <i>et al.</i> , <i>Oral RS-25259 Prevents Postoperative Nausea and Vomiting Following Laparoscopic Surgery</i> , Abstracts of Scientific Papers 1996 Annual Meeting, 85 Anesthesiology, No. 34, A21 (Sept. 1996) ("Chelly")
1013	Gralla <i>et al.</i> , <i>Recommendations for the Use of Antiemetics: Evidence-Based, Clinical Practice Guidelines</i> , 17 J. Clin. Oncology, No. 9, 2971-94 (Sept. 1999)
1014	Gibson, <i>Parenteral Dosage Forms</i> , Pharmaceutical Preformulation and Formulation, A Practical Guide from Candidate Drug Selection to Commercial Dosage Form 175-237, 295-354 (2001)
1015	ZOFRAN (2001). In <i>Physician's Desk Reference</i> 1503-07 (55th ed.) Montvale, NJ: PDR Network
1016	KYTRIL (2001). In <i>Physician's Desk Reference</i> 3104-06 (55th ed.) Montvale, NJ: PDR Network
1017	ANZEMET (2001). In <i>Physician's Desk Reference</i> 680-83 (55th ed.) Montvale, NJ: PDR Network
1018	Gaia Piraccini <i>et al.</i> , <i>An Interesting 5-HT₃ Receptor Antagonist Antiemetic for Patients Undergoing Chemotherapy-Based Conditioning Regimens</i> , Abstract 5169, 98(11) J. of the American Society of Hematology 350b (Nov. 16, 2001)
1019	Tang <i>et al.</i> , <i>The Efficacy of RS-25259, a Long-Acting Selective 5-HT₃ Receptor Antagonist, for Preventing Postoperative Nausea and Vomiting After Hysterectomy Procedures</i> , 87 Anesth. Analg., 462-7 (1998) ("Tang")

Exhibit #	Reference
1020	Lauri P. Cohen, <i>Many Medicines Are Potent Years Past Expiration Dates</i> , Wall St. J., March 28, 2000.
1021	Declaration of William McGuire, M.D.
1022	William McGuire, M.D. <i>curriculum vitae</i>
1023	Declaration of David G. Frame, Pharm.D.
1024	David G. Frame, Pharm.D. <i>curriculum vitae</i>
1025	Tr. transcript Dr. Kirsch 19:12-20:23, June 5, 2015 (what is a POSA)
1026	Tr. transcript Dr. Candiotti 18:19-20:4, June 10, 2015 (what is a POSA)
1027	Gandara <i>et al.</i> , <i>Consensus Proposal for 5-HT₃ Antagonists in the Prevention of Acute Emesis Related to Highly Emetogenic Chemotherapy</i> , Support Care Cancer (1998) 6:237-243 (“Gandara”)
1028	Tr. transcript Dr. Frame direct 109:2-110:15, 121:18-123:3, 124:20-128:4, June 8, 2015 (PONV to CINV)
1029	Tr. transcript Dr. Candiotti direct 82:12-83:15, June 10, 2015 (PONV to CINV)
1030	Tr. Transcript Dr. Frame direct 107:14-108:25, June 8, 2015 (oral to IV)
1031	U.S. Food and Drug Administration. <i>Estimating the safe starting dose in clinical trials for therapeutics in adult healthy volunteers</i> (Draft Guidance Document) Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research (Dec. 2002)
1032	Tr. transcript Dr. Candiotti direct 108:21-109:20, June 10, 2015 (5 ml volume)
1033	January 16, 2002 Helsinn Press Release
1034	October 3, 2001 Helsinn Press Release
1035	April 10, 2001 Helsinn Press Release
1036	Kibbe, <i>Handbook of Pharmaceutical Excipients</i> , Citric Acid 191-94 (3rd ed. 2000)
1037	U.S. Patent No. 9,066,980
1038	Serial No. 13/902,132 Official Action, Aug. 8, 2013
1039	Serial No. 13/902,182 Applicants’ Amendment and Response to Office Action, Oct. 9, 2013
1040	Declaration of Dr. Patrick P. DeLuca
1041	Dr. Patrick P. DeLuca <i>curriculum vitae</i>
1042	Patrick P. DeLuca and James C. Boylan, <i>5 Formulation of Small Volume Parenterals</i> , 1 Pharmaceutical Dosage Forms:Parenteral Medications, 173(2nd ed. rev. expanded Marcel Dekker, Inc. 1992)
1043	Tr. transcript Dr. Amidon direct 156:15-165:9, June 15, 2015 (K.I.S.S. 5ml, Golden Rule, Ex.13 commercially viable)

Exhibit #	Reference
1044	Brown <i>et al.</i> , <i>The Effectiveness of a Single Intravenous Dose of Ondansetron</i> , <i>Oncology</i> 1992;49:273-278
1045	<i>Helsinn Healthcare S.A. et al. v. Dr. Reddy's Laboratories, Ltd. et al.</i> , Civil Action No. 12-2867-MLC (D.N.J. Feb. 19, 2015) <i>Markman</i> Order (Dkt.91), Feb. 19, 2015
1046	Tr. transcript Dr. Amidon direct 106:2-107:18, June 16, 2015 (EDTA citric acid)
1047	Tr. transcript Dr. Candiotti cross-examination 141:15-143:25, June 10, 2015 (human dose based on animals)
1048	Prosecution History of U.S. Patent No. 7,947,724 (U.S. Ser. No. 11/186311), Amend. Resp., Apr. 6, 2009
1049	Mikawa <i>et al.</i> , <i>Optimal Dose of Granisetron for Prophylaxis Against Postoperative Emesis After Gynecological Surgery</i> , 85 <i>Anesth. Analg.</i> , 652-6 (1997)
1050	Avis <i>et al.</i> , <i>2 Parental Drug Administration: Routes, Precautions, Problems, Complications, and Drug Delivery Systems</i> , 1 <i>Pharmaceutical Dosage Forms: Parenteral Medications</i> 173(2nd ed. rev. expanded Marcel Dekker, Inc. 1992)
1051	Reproduction of Figure 5 of Eglen Exh.1011, at 863
1052	Reproduction of Figure 6a of Eglen Exh.1011, at 863
1053	Dose response curves for Chelly (Exh.1012) and Tang (Exh.1019)
1054	Approved KYTRIL Label, Aug. 16, 2002
1055	R.E. Leak and J.D. Woodford, <i>Pharmaceutical Development of Ondansetron Injection</i> , 25 (Suppl. 1) <i>Eur. J. Cancer Clin. Oncol.</i> 567-69 (1989)

Respectfully submitted,

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