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Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
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Post Grant Review of U.S. Patent No. 9,173,942  
Exhibit Cover Letter Per 37 C.F.R. § 42.6(e)(4)(ii)

Dear Patent Trial and Appeal Board:

This transmittal letter identifies Exhibits 1001-1061, being filed concurrently with the present Post Grant Review. Pursuant to 37 C.F.R. § 42.6(e)(4)(ii), the Certificate of Service attached to the end of the Petition for Post Grant Review filed herewith, incorporates Exhibits 1001-1061, as listed below:

<b>Exhibit #</b>	<b>Reference</b>
1001	U.S. Patent No. 9,173,942
1002	Prosecution history of Serial No. 13/901,830
1003	Complaint, <i>Helsinn Healthcare S.A. and Roche Palo Alto LLC v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.</i> , Civil Action No. 15-8662 (DNJ), filed 12/15/2015
1004	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> , Civil Action No. 14-4274 (DNJ) filed 7/7/2014 and amended on 9/2/2015

Exhibit #	Reference
1005	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. and Dr. Reddy's Laboratories, Inc.</i> , U.S.D.C.N.J. Civil Action No. 3:12-cv-02867-MLC-DEA filed 5/11/2012; and <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 9/30/2013 and amended on 12/27/2013
1006	U.S. Patent No. 5,202,333 ("Berger")
1007	Mark Gibson (ed.), <i>Pharmaceutical Preformulation and Formulation, A Practical Guide from Candidate Drug Selection to Commercial Dosage Form</i> (Ch.3 p.34; Ch.6 pp.175, 196-210; Ch.8 pp.309-11, 318; Ch.9 pp.332-36, 341-42) (2001)
1008	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 <i>Anesth. Analg.</i> , 462-7 (1998) ("Tang")
1009	ZOFTRAN (2001). In <i>Physician's Desk Reference</i> 1503-07 (55th ed.) Montvale, NJ: PDR Network
1010	KYTRIL (2001). In <i>Physician's Desk Reference</i> 3104-06 (55th ed.) Montvale, NJ: PDR Network
1011	ANZEMET (2001). In <i>Physician's Desk Reference</i> 680-83 (55th ed.) Montvale, NJ: PDR Network
1012	Declaration of Dr. Joanne Broadhead
1013	<i>Curriculum Vitae</i> of Dr. Joanne Broadhead
1014	U.S. Patent No. 8,598,219
1015	Application Data Sheet of Continuation-in-Part Serial No. 13/901,437 (8,598,219)
1016	Letter entitled "Identification of Continuation-in-Part Claim Support Required Under 37 C.F.R. § 1.78(d)(3) and Choice of Law" filed May 23, 2013, in Serial No. 13/901,437 (8,598,219)
1017	Office Communication dated July 12, 2013, in Serial No. 13/901,437 (8,598,219)
1018	Examiner Initiated Interview Summary dated July 16, 2013, in Serial No. 13/901,437 (8,598,219)
1019	Application Data Sheet filed May 24, 2013, in Serial No. 13/901,830
1020	Preliminary Amendment filed May 24, 2013, in Serial No. 13/901,830
1021	Office Communication dated September 16, 2013, in Serial No. 13/901,830

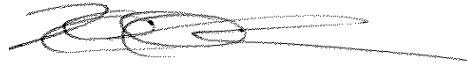
Exhibit #	Reference
1022	Trial Tr. of Dr. Amidon direct 156:15-165:9, June 15, 2015 (K.I.S.S. 5ml, Golden Rule, Ex.13 commercially viable)
1023	Avis <i>et al.</i> (eds.), 1 (Chs.2,4, 5) <i>Pharmaceutical Dosage Forms:Parenteral Medications</i> 115-16, 140-43, 146-48, 193-95 (2nd ed. rev. expanded Marcel Dekker, Inc. 1992)
1024	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)
1025	Eglen <i>et al.</i> , <i>Pharmacological characterization of RS 25259-197, a novel and selective 5-HT<sub>3</sub> receptor antagonist, in vivo</i> , 114 <i>British J. Pharmacol.</i> 860-66 (1995) (“Eglen”)
1026	Declaration of Dr. Christopher A. Fausel
1027	<i>Curriculum Vitae of Dr. Christopher A. Fausel</i>
1028	Trial Tr. Candiotti (direct) 18:19-20:7, <i>Helsinn v. Dr. Reddy’s</i> , Civil Action No. 11-3962, June 10, 2015 (“POSA”)
1029	Definition of “formula” (formulation),” <i>The American Heritage Dictionary of English Language</i> 691 (4th ed. 2000)
1030	Definition of “pharmaceutical,” <i>The American Heritage Dictionary of the English Language</i> 1316 (4th ed. 2000)
1031	Notice of Allowance mailed October 11, 2013, in Serial No. 13/901,437
1032	Leon Lachman, Ph.D. <i>et al.</i> , <i>The Theory and Practice of Industrial Pharmacy</i> 642-784 (3rd ed. Lea & Febiger 1986)
1033	James Swarbrick & James C. Boylan (editors), <i>Excipients: Their Role in Parenteral Dosage Forms</i> 137-72, 19 (Supp.2) <i>Encyclopedia of Pharmaceutical Technology</i> (2000) (“Swarbrick”)
1034	James I. Wells, <i>PHARMACEUTICAL PREFORMULATION:The Physicochemical Properties of Drug Substances</i> 152-91 (1988)
1035	Robert R. Strickley, <i>Parenteral Formulations of Small Molecule Therapeutics Marketed in the United States (1999)</i> — Parts I, II, III, 53(6) <i>PDA J. of Pharmaceutical Science &amp; Technology</i> (Nov./Dec. 1999).
1036	Arthur H. Kibbe (ed.), <i>Citric Acid Monohydrate</i> , <i>Handbook of Pharmaceutical Excipients</i> 140-42 (3d ed. 2000)
1037	Trial Tr. Amidon (cross-examination) 106:2-107:18, <i>Helsinn v. Dr. Reddy’s</i> , Civil Action No. 11-3962, June 16, 2015 (EDTA & citric acid)
1038	U.S. Food and Drug Administration, <i>Guidance for Industry and Reviewers 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)
1039	Chong Min Won <i>et al.</i> , <i>Photolytic and oxidative degradation of an antiemetic agent, RG 12915</i> , 121 <i>Int’l J. Pharmaceutics</i> 95-105 (July 6, 1995)
1040	Non-Final Office Action dated November 22, 2013, in Serial No. 13/901,830

Exhibit #	Reference
1042	Supplemental Response dated March 3, 2015 in Serial No. 13/901,830
1043	Notice of Allowance dated August 25, 2015, in Serial No. 13/901,830)
1044	Trial Tr. Candiotti, direct 108:4-109:23, <i>Helsinn v. Dr. Reddy's</i> , Civil Action No. 11-3962, June 10, 2015 (“5ml”)
1045	Stipulation and Order, <i>Helsinn Healthcare S.A. et al. v. Dr. Reddy's Laboratories, Ltd. et al.</i> , Civ. Action No. 11-3962 (D.N.J.), June 1, 2015, Mary L. Cooper, U.S.D.J. (“18-24 month stability (“18-24 month stability”)
1046	Gaia Piraccini <i>et al.</i> , <i>Clinical Care-Transplantation Regimen Toxicities and Engraftment</i> , 98(11) Part 2, J. Am. Society of Hematology, Abstract #5169 (43rd Annual meeting program and abstracts (Dec. 7-11, 2001))
1047	G. Piraccini <i>et al.</i> , <i>Pharmacokinetic Features of a Novel 5-HT<sub>3</sub> -Receptor-Antagonist: Palonosetron (RS-25259-197)</i> , Symptom Management 400, Am. Society of Clinical Oncology (ASCO) (May 12-15, 2001 San Francisco-USA)
1048	Order, <i>Helsinn Healthcare S.A. et al. v. Dr. Reddy's Laboratories, Ltd. et al.</i> , Civil Action No. 12-2867 (Dkt.91), Feb. 19, 2015, Mary L. Cooper, U.S.D.J. (505(b)(2) Litigation — chelating agent)
1049	Trial Tr. Kirsch (direct) 19:12-20:7, <i>Helsinn v. Dr. Reddy's</i> , Civil Action No. 11-3962, June 5, 2015 (DRL “POSA”)
1050	‘437 Application claims as originally filed
1051	U.S. Patent No. 8,729,094
1052	U.S. Patent No. 9,066,980
1053	Paul F. White, Ph.D., M.D. & Phillip Scuderi, M.D., <i>Prevention of Postoperative Nausea and Vomiting (PONV): A Dose-Ranging Study Involving Palonosetron, a Potent 5-HT<sub>3</sub> Receptor Antagonist</i> , <i>Anesthesiology</i> 2005; 103:A703
1054	Statutory Declaration of Daniele Bonadeo, M. Chem. Pharm. 37 C.F.R. §§ 131 and 132, filed Mar. 2, 2007
1055	<i>The American Heritage Dictionary of English Language</i> 61 (4th ed. 2000) (definition of “amount”)
1056	<i>The American Heritage Dictionary of English Language</i> 537 (4th ed. 2000) (definition of “dose”)
1057	Order Construing the Terms of U.S. Patent Nos. 7,947,724; 7,947,725; 7,960,424; 8,598,219 & 8,729,094, <i>Helsinn Healthcare S.A. et al. v. CIPLA Ltd. et al.</i> (D. Del. 13-688), filed Mar. 9, 2015
1058	Markman Order, <i>Helsinn Healthcare S.A. et al. v. Dr. Reddy's Laboratories, Ltd. et al.</i> , Civil Action No. 11-3962, filed Apr. 22, 2015, Mary L. Cooper, U.S.D.J. (originally under seal, currently published) (ANDA Litigation — CINV)
1059	reserved

Exhibit #	Reference
1060	Final Judgment, <i>Helsinn Healthcare S.A. et al. v. Dr. Reddy's Laboratories, Ltd. et al.</i> , Civ. Action No. 11-3962 (consolidated) D.N.J., Nov. 16, 2015, Mary L. Cooper, U.S.D.J. (ANDA Litigation)
1061	Memorandum Opinion, <i>Helsinn Healthcare S.A. et al. v. Dr. Reddy's Laboratories, Ltd. et al.</i> , Civ. Action No. 11-3962 (D.N.J.), Nov. 13, 2015, Mary L. Cooper, U.S.D.J. (originally under seal, currently published) (Partial Op. ANDA Litigation)

Respectfully submitted,

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