

February 5, 2016

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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 1001-1049, 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 1001-1049, as listed below:

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
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

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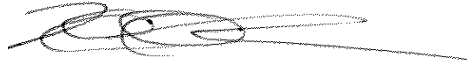
1006	U.S. Patent No. 5,202,333 (“Berger”)
1007	U.S. Provisional Application No. 60/444,351
1008	Applicant Initiated Interview Summary dated June 17, 2013, in Serial No. 13/901,830
1009	PCT Application No. PCT/EP2004/000888
1010	U.S. Patent No. 7,947,724
1011	U.S. Patent No. 7,947,725
1012	U.S. Patent No. 7,960,424
1013	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”)
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
1022	Non-Final Office Action dated November 22, 2013, in Serial No. 13/901,830
1023	Applicants’ Response dated February 21, 2014, in Serial No. 13/901,830
1024	Supplemental Response dated March 3, 2015 in Serial No. 13/901,830
1025	Originally Filed Claims dated May 23, 2013, in Serial No. 13/901,437 (8,598,219)
1026	U.S. Patent No. 8,729,094
1027	U.S. Patent No. 9,066,980
1028	Trial Tr. Candiotti (direct) 18-20, <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	<i>The American Heritage Dictionary of English Language</i> 61 (4th ed. 2000) (definition of “amount”)

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1032	Statutory Declaration of Daniele Bonadeo, M. Chem. Pharm. 37 C.F.R. §§ 131 and 132, filed Mar. 2, 2007
1033	Notice of Allowance dated August 25, 2015, in Serial No. 13/901,830)
1034	<i>The American Heritage Dictionary of English Language</i> 537 (4th ed. 2000) (definition of “dose”)
1035	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
1036	Memorandum Opinion, <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. (ANDA Litigation — CINV)
1037	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. (originally under seal, currently published) (505(b)(2) Litigation — chelating agent)
1038	Declaration of Dr. Christopher A. Fausel
1039	<i>Curriculum Vitae</i> of Dr. Christopher A. Fausel
1040	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)
1041	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) (Interim Op. ANDA Litigation)
1042	Supply and Purchase Agreement Between Helsinn Birex Pharmaceuticals Ltd. and MGI Pharma, Inc., dated April 6, 2001
1043	License Agreement between Helsinn Healthcare SA and MGI Pharma, Inc. for Palonosetron, dated April 6, 2001
1044	EDGAR filing documents for MGI Pharma, Inc., filed April 25, 2001, SEC Accession No. 0001045969-01-500128
1045	Trial Tr. Calderari (direct) 105-225 <i>Helsinn v. Dr. Reddy’s</i> , Civil Action No. 11-3962, June 2, 2015 (“On-sale”)
1046	Trial Tr. O’Malley (opening), 90, <i>Helsinn v. Dr. Reddy’s</i> , Civil Action No. 11-3962, June 2, 2015
1047	“MGI Pharma Signs Exclusive License Agreement with Helsinn Healthcare SA, For Palonosetron, a Phase 3 Anti-Emetic,” <i>Helsinn News</i> , April 10, 2001.
1048	Trial Tr. O’Malley (opening) 89:9-15, <i>Helsinn v. Dr. Reddy’s</i> , Civil Action No. 11-3962, June 2, 2015
1049	Mark Gibson (ed.), <i>Pharmaceutical Preformulation and Formulation, A Practical Guide from Candidate Drug Selection to Commercial Dosage Form</i> , p. 202 (2001)

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