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111163-0102Patent Trial and Appeal Board
US Patent and Trademark Office
PO Box 1450
Alexandria, Virginia 22313-1450
(electronically filed)**INTER PARTES REVIEW OF U.S. PAT. NO. 8,791,154**
Exhibit Cover Letter Per 37 C.F.R. § 42.6(e)(4)(ii)

Dear Patent Trial and Appeal Board,

This letter incorporates by reference the certificate of service attached to the end of the Petition for *Inter Partes* Review filed herewith, to Exhibits 1001-1063, as listed below:

Ex. #	Exhibit
1001	U.S. Patent No. 8,791,154 B2 (“154 Patent”)
1002	Declaration of Dr. Erning Xia
1003	Declaration of Dr. Leonard Bielory
1004	WO 2008/015695 A2 (“Bhowmick”)
1005	YANNI <i>et al.</i> , “The <i>In Vitro</i> and <i>In Vivo</i> Ocular Pharmacology of Olopatadine (AL-4943A), an Effective Anti-Allergic/Antihistaminic Agent,” <i>Journal of Ocular Pharmacology and Therapeutics</i> , Volume 12, Number 4, 1996, pp. 389-400 (“Yanni”)
1006	U.S. Pat. No. 6,995,186 B2 (“Castillo”)
1007	U.S. Pat. Pub. No. 2011/0082145 A1 (“Schneider”)

1008	U.S. Pat. No. 5,641,805 B2 (“Hayakawa”)
1009	Image File Wrapper for U.S. Patent No. 8,791,154 B2
1010	Image File Wrapper for U.S. Provisional Appl. No. 61/487,789
1011	Image File Wrapper for U.S. Provisional Appl. No. 61/548,957
1012	WO 1999/018963 (“Lisi”)
1013	WO 2002/024116 A1 (“Shahinian”)
1014	LOFTSSON <i>et al.</i> , “Cyclodextrins in eye drop formulations: enhanced topical delivery of corticosteroids to the eye,” <i>Acta Ophthalmologica Scandinavica</i> , 2002, pp. 144-150.
1015	NANDI <i>et al.</i> , “Synergistic Effect of PEG-400 and Cyclodextrin to Enhance Solubility of Progesterone,” <i>AAPS PharmSciTech</i> 2003; 4 (1), pp 1-5.
1016	WO 2011/138801 A1 (“Khopade”)
1017	JANSOOK <i>et al.</i> , “CDs as solubilizers: Effects of excipients and competing drugs,” <i>International Journal of Pharmaceutics</i> , 379, 2009, pp. 32-40.
1018	HARADA, A., “Preparation and structures of supramolecules between cyclodextrins and polymers,” <i>Coordination Chemistry Reviews</i> , 148, 1996, pp. 115-133.
1019	WO 2012/159064A1 (“Gamache”)
1020	EP 0 799 044 B1 (“Yanni III”)
1021	WO 2001/054687 A1 (“Yanni II”)
1022	WO 2009/003199 A1 (“Pipkin”)
1023	WO 2000/78396 A2 (“Graff”)
1024	Curriculum Vitae for Dr. Erning Xia
1025	Curriculum Vitae for Dr. Leonard Bielory
1026	U.S. Pat. No. 7,687,646 B2 (“Bader”)
1027	U.S. Pat. No. 4,871,865 (“Lever”)

1028	U.S. Pat. No. 5,116,863 (“Oshima”)
1029	EP 0214779 B1 (“Lever”)
1030	Alcon Research, Ltd. v. Apotex Inc., 687 F.3d 1362 (Fed. Cir. 2012)
1031	Alcon Research, Ltd. v. Apotex Inc., 790 F. Supp. 2d 868 (S.D. Ind. 2011)
1032	EP 0 235 796 B2 (“Oshima”)
1033	ABELSON <i>et al.</i> , “Combined Analysis of Two Studies Using the Conjunctival Allergen Challenge Model to Evaluate Olopatadine Hydrochloride, a New Ophthalmic Antiallergic Agent With Dual Activity,” <i>American Journal of Ophthalmology</i> , Volume 126, No. 6, pp. 797-804.
1034	WO 2004/024126 A1 (“Thompson”)
1035	CHAUDHARI <i>et al.</i> , “Solubility enhancement of hydrophobic drugs using synergistically interacting cyclodextrins and cosolvent,” <i>Current Science</i> , 1586 Vol. 92, No. 11, 10 June 2007; pp. 1586-1591.
1036	ANSEL, Howard C., <i>Pharmaceutical Calculations</i> , 13 th Ed., Wolters Kluwer, 2010, pp. 82-83
1037	PATANOL® Label
1038	PATADAY® Label
1039	PATANASE® Label
1040	GENNARO, Alfonso R., <i>Remington: The Science and Practice of Pharmacy</i> , Philadelphia College of Pharmacy and Science, 1995, Vol. 1., pp. 613-627
1041	GENNARO, Alfonso R., <i>Remington: The Science and Practice of Pharmacy</i> , Philadelphia College of Pharmacy and Science, 1995, Vol. 2., pp. 1563-1576
1042	LIDE, David R., <i>CRC Handbook of Chemistry and Physics</i> , CRC Press, 2006, pp. 6-4 – 6-5.
1043	ABELSON and ANDERSON, “Demystifying Dumulcents,” <i>Review of Ophthalmology</i> , November 2006, pp. 122-125.

1044	LOFTSSON, <i>et al.</i> , “The effect of water-soluble polymers on the aqueous solubility and complexing abilities of β -cyclodextrin,” <i>International Journal of Pharmaceutics</i> , 1998, Vol. 163, pp. 15-21
1045	U.S. Patent Publication US 2009/0156568 A1 (“Hughes”)
1046	U.S. Pat. No. 5,985,310 (“Castillo III”)
1047	U.S. Pat. No. 7,977,376 B2 (“Singh I”)
1048	U.S. Pat. No. 8,399,508 B2 (“Singh II”)
1049	U.S. Pat. No. 7,402,609 B2 (“Castillo II”)
1050	WADE, <i>et al.</i> , “Ophthalmic antihistamines and H1–H4 receptors,” <i>Current Opinion in Allergy and Clinical Immunology</i> , 2012, Vol. 12, No. 5, pp. 510–516
1051	CHOI, <i>et al.</i> , “Late-phase reaction in ocular allergy,” <i>Current Opinion in Allergy and Clinical Immunology</i> , 2008, Vol 8, pp. 438–444.
1052	U.S. Pat. Pub. 2004/0198828 (“Abelson 2004”)
1053	LEONARDI, <i>et al.</i> , “Double-masked, randomized, placebo-controlled clinical study of the mast cell-stabilizing effects of treatment with olopatadine in the conjunctival allergen challenge model in humans,” <i>Clin Ther</i> 2003; 25, pp. 2539–2552.
1054	PROUD, <i>et al.</i> , “Inflammatory mediator release on conjunctival provocation of allergic subjects with allergent provocation of allergic subjects with allergen,” <i>Mediator generation in ocular allergy</i> , 1989, Vol. 85. No. 5, pp. 896-905
1055	SHARIF, <i>et al.</i> , “Characterization of the Ocular Antiallergic and Antihistaminic Effects of Olopatadine (AL-4943A), a Novel Drug for Treating Ocular Allergic Diseases,” <i>The Journal OF Pharmacology and Experimental Therapeutics</i> , 1996, Vol. 278, No. 3, pp. 1252-1261
1056	LOFTSSON, <i>et al.</i> , “Pharmaceutical Applications of Cyclodextrins. 1. Drug Solubilization and Stabilization,” <i>Journal of Pharmaceutical Sciences</i> , October 1996, Vol. 85, No. 10, pp. 1017-1025
1057	21 C.F.R. §349.12
1058	Polyvinylpyrrolidone K 30,

	http://www4.mpbio.com/ecom/docs/proddata.nsf/(webtds2)/102787
1059	SWEI, <i>et al.</i> , "Viscosity Correlation for Aqueous Polyvinylpyrrolidone (PVP) Solutions," <i>Journal of Applied Polymer Science</i> , 2003, Vol. 90, pp. 1153-1155
1060	68 Fed. Reg. 106, 32981-32983
1061	U.S. Pat. No. 6,316,483 B1 ("Haslwanter")
1062	U.S. Pat. Pub. No. 2010/0010082 A1 ("Chong")
1063	U.S. Pat. Pub. No. 2009/0136598 ("Chapin")

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this Application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

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