

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC. and APOTEX CORP.

Petitioner

v.

ALCON RESEARCH, LTD

Patent Owner

Patent No. 8,791,154

Issue Date: July 29, 2014

Title: HIGH CONCENTRATION OLOPATADINE
OPHTHALMIC COMPOSITION

Inter Partes Review No. IPR2016-01640

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,791,154
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *ET SEQ.***

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TABLE OF EXHIBITS

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</i>

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