

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. |

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| 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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