

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SLAYBACK PHARMA LLC,

Petitioner,

v.

EYE THERAPIES, LLC,

Patent Owner.

Case IPR2022-00142
U.S. Patent No. 8,293,742

PATENT OWNER'S SECOND UPDATED EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Patent Owner Eye Therapies, LLC hereby submits a current listing of Patent Owner Exhibits. Exhibits 2212–2214, are being filed today.

EXHIBIT	DESCRIPTION
2001	<i>Bausch & Lomb, Inc., et al. v. Slayback Pharma LLC, et al.</i> , C.A. 21-16766 (D.N.J.), Joint Discovery Plan submitted Feb. 3, 2022
2002	<i>Bausch & Lomb, Inc., et al. v. Slayback Pharma LLC, et al.</i> , C.A. 21-16766 (D.N.J.), Defendants’ First Set of Requests for Production to Plaintiffs Nos. 1-2 served on Dec. 29, 2021
2003	<i>Bausch & Lomb, Inc., et al. v. Slayback Pharma LLC, et al.</i> , C.A. 21-16766 (D.N.J.), ECF No. 15, Scheduling Order signed by the Honorable Douglas E. Arpert, U.S.M.J. on Feb. 15, 2022
2004	<i>Bausch & Lomb, Inc., et al. v. Slayback Pharma LLC, et al.</i> , C.A. 21-16766 (D.N.J.), ECF No. 11, Order Setting the Initial Scheduling Conference dated Dec. 15, 2021
2005	Notice of Paragraph IV Certification Re: Slayback Pharma LLC’s Brimonidine Tartrate Ophthalmic Solution, 0.025%, U.S. Patent Nos. 8,293,742 and 9,259,425 dated Aug. 13, 2021
2006	<i>Bausch & Lomb, Inc., et al. v. Slayback Pharma LLC, et al.</i> , C.A. 21-16766 (D.N.J.), ECF No. 1, Complaint for Patent Infringement filed Sept. 10, 2021
2007	Louis B. Cantor, “Brimonidine in the treatment of glaucoma and ocular hypertension,” <i>Therapeutics & Clinical Risk Mgmt.</i> , 2(4): 337-346 (2006)
2008	U.S. Patent No. 6,982,079 B2, Compositions For Treating Hyperemia
2009	Ji Hoon Lee, et al., “Efficacy of brimonidine tartrate 0.2% ophthalmic solution in reducing halos after laser in situ keratomileusis,” <i>J. of Cataract & Refractive Surgery</i> , 34:963-967 (2008)

EXHIBIT	DESCRIPTION
2010	U.S. Patent No. 5,021,416, Method for Using (2-Imidazolin-2-Ylamino) Quinoxalines to Reduce or Maintain Intraocular Pressure
2011	Press Release, “New Survey From Bausch + Lomb and Glaucoma Research Foundation Reveals Emotional and Social Impact of Hyperemia on Glaucoma Patients” (Jan. 4, 2022), https://www.bausch.com/our-company/recent-news/artmid/11336/articleid/683
2012	Alphagan® (brimonidine tartrate ophthalmic solution) 0.5% and 0.2%, Alphagan® P (brimonidine tartrate ophthalmic solution) 0.15%, Highlights of Prescribing Information (Dec. 20, 2001)
2013	Visine-A Label (June 14, 2002)
2014	Alphagan® P (brimonidine tartrate ophthalmic solution) 0.1% and 0.15%, Highlights of Prescribing Information (Aug. 19, 2005)
2015	Alphagan™ (brimonidine tartrate ophthalmic solution) 0.2% Sterile, Approval Letter (Sept. 6, 1996)
2016	Drugs@ FDA Approved Drug Information, Alphagan 0.5%, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020490
2017	Drugs@ FDA Approved Drug Information, Alphagan 0.15%, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021262
2018	Press Release, “Allergan to focus on Alphagan-P, discontinue Alphagan (July 8, 2002), https://www.healio.com/news/ophthalmology/20120331/allergan-to-focus-on-alphagan-p-discontinue-alphagan
2019	Alphagan P (brimonidine tartrate ophthalmic solution) 0.1%, Approval Letter (Aug. 19, 2005)
2020	CONFIDENTIAL Declaration of Robert J. Noecker, MD, MBA (Under Seal and Public versions)

EXHIBIT	DESCRIPTION
2021	CONFIDENTIAL Declaration of Robert O. Williams, III, Ph.D. (Under Seal and Public versions)
2022	Declaration of Stephen G. Davies, D.Phil.
2023	CONFIDENTIAL Declaration of John Ferris (Under Seal and Public versions)
2024	CONFIDENTIAL Declaration of John C. Jarosz (Under Seal and Public versions)
2025	USP 32, General Notices and Requirements, “Applying to Standards, Tests, Assays, and Other Specifications of the United States Pharmacopeia”, Pp. 1 - 12
2026	65 Fed. Reg. 83,041 (December 29, 2000)
2027	Skwietczynski, “Chapter 2 - Analysis of Medicinals”, Remington Essentials of Pharmaceuticals, edited by Linda Felton, (Pharmaceutical Press 2012), Pp. 9 - 28.
2028	CONFIDENTIAL 3.2.P.5.6 Justification of Specifications (BAU-LUM00057392-57399) (Under Seal and Public versions)
2029	“Legal Recognition - Standards Categories”, The United States Pharmacopeia Convention, https://www.usp.org/about/legal-recognition/standard-categories
2030	Agarwal, Priyanka, et al. “Review: Formulation Considerations for the Management of Dry Eye Disease.” <i>Pharmaceutics</i> , vol. 13, no. 2, Feb. 2021, pp. 1-19 (Agarwal 2021)
2031	21 CFR § 330.10 (2002) (21 CFR § 330.10)
2032	67 Fed. Reg. 3,060 (January 23, 2002)
2033	Orange Approved Drug Products with Therapeutic Equivalence Evaluations, Patent and Exclusivity for N021770, (Brimonidine Tartrate (Alphagan P) Solution/Drops 0.1%), https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=021770&Appl_type=N
2034	Orange Approved Drug Products with Therapeutic Equivalence Evaluations, Patent and Exclusivity for N021262, (Brimonidine Tartrate (Alphagan P) Solution/Drops 0.15%),

EXHIBIT	DESCRIPTION
	https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=021262&Appl_type=N
2035	“Drug Application Process for Nonprescription Drugs”, https://www.fda.gov/drugs/types-applications/drug-application-process-nonprescription-drugs
2036	Zhu and Chauhan, “Effect of Viscosity on Tear Drainage and Ocular Residence Time”, <i>Optometry and Vision Science</i> , 85(8):E715-E725 (August 2008)
2037	Coffey et al., “Development of a non-settling gel formulation of 0.5% loteprednol etabonate for anti-inflammatory use as an ophthalmic drop”, <i>Clinical Ophthalmology</i> , 7:299-312 (2013)
2038	Alphagan P (Brimonidine Tartrate) Ophthalmic Solution 0.15%, Center for Drug Evaluation and Research, Application No. 21-764, Chemistry Review(s), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/21-262_Alphagan%20P%20Ophthalmic_chemr.pdf
2039	Alphagan P (Brimonidine Tartrate) Ophthalmic Solution 0.1%, Center for Drug Evaluation and Research, Application No. 21-770, Chemistry Review(s), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2005/021770s000_ChemR.pdf
2040	de Mendoza et al., “Molecular recognition of oxoanions based on guanidinium receptors,” <i>36 CHEM. SOC. REV.</i> 198, 198 (2007) (de Mendoza 2007)
2041	Bagwell, Kyle, “The Economic Analysis of Advertising,” Columbia University Department of Economics Discussion Paper Series, Discussion Paper No.: 0506-01, August 2005.
2042	Congressional Budget Office, “Promotional Spending for Prescription Drugs,” December 2, 2009.
2043	Ching, Andrew T. and Masakazu Ishihara, “Measuring the Information and Persuasive Roles of Detailing on Prescribing Decisions,” <i>Management Science</i> , July 2012, Vol. 58, No. 7, 1374-1387

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