UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES S.A. and
DR. REDDY'S LABORATORIES, INC.,
Petitioner,

v.

EYE THERAPIES, LLC,
Patent Owner.

Case IPR2024-00467
Patent 11,833,245

PATENT OWNER'S FIFTH 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 2276 - 2278 are being filed today.

EXHIBIT	DESCRIPTION
2001	Prosecution History for U.S. Patent No. 11,596,600
2002	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Preliminary Injunction Science Day Final Transcript, Jan. 23, 2024
2003	Derick, R., "Adrenergic Agonist Medications: Basic Mechanisms," J. Glaucoma, Vol. 4, Supp. 1 (1995)
2004	Raviola, G., "Conjunctival and Episcleral Blood Vessels are Permeable to Blood-borne Horseradish Peroxidase," Investigative Ophthalmology & Visual Science, June 1983
2005	Scruggs, J. T., et al. "The Teardrop Sign: A Rare Dermatological Reaction to Brimonidine," *British Journal of Ophthalmology*, vol. 84, no. 6, 2000, pp. 671–672
2006	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Preliminary Injunction Volume 3 Final Transcript, Jan. 26, 2024
2007	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Preliminary Injunction Volume 4 Final Transcript, Jan. 30, 2024
2008	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Transcript of the Deposition of Reza Dana, MD, MSC, MPH, Jan. 12, 2024
2009	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Preliminary Injunction Volume 1 Final Transcript, Jan. 24, 2024
2010	Jonescu-Cuypers, C., et al., "Effect of Brimonidine Tartrate on Ocular Hemodynamics in Healthy Volunteers", Journal of Ocular Pharmacology and Therapeutics, Vol. 7, No. 3, 2001
2011	U.S. Patent No. 6,982,079

EXHIBIT	DESCRIPTION
2012	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Declaration of John Ferris in Support of Plaintiffs' Motion for a Preliminary Injunction
2013	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Expert Declaration of John C. Galanis, MD, FACS in Support of Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction
2014	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Preliminary Injunction Volume 5 Final Transcript, Jan. 31, 2024
2015	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Declaration of Eric D. Donnenfeld, M.D. in Support of Plaintiffs' Motion for a Preliminary Injunction, Jan. 17, 2024
2016	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Preliminary Injunction Volume 2 Final Transcript, Jan. 25, 2024
2017	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Video Remote Deposition of John C. Galanis, M.D., F.A.C.S., Jan. 14, 2024
2018	*Slayback Pharma, LLC v. Eye Therapies, LLC*, IPR2022-00142, Patent No. 8,293,742, Transcription of the Deposition of Neal A. Sher, M.D., FACS, Jan. 27, 2023
2019	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Transcription of the Deposition of W. Daniel Stamer, Ph.D., Jan. 3, 2024
2020	*Slayback Pharma, LLC v. Eye Therapies, LLC*, IPR2022-00142, Patent No. 8,293,742, Transcription of the Deposition of Neal A. Sher, M.D., FACS, Aug. 10, 2022
2021	*Slayback Pharma, LLC v. Eye Therapies, LLC*, IPR2022-00142, Patent No. 8,293,742, Petition for *Inter Partes* Review, Nov. 4, 2021
2022	*Slayback Pharma, LLC v. Eye Therapies, LLC*, IPR2022-00142, Patent No. 8,293,742, Declaration of Neal A. Sher, M.D., FACS, Nov. 4, 2021

EXHIBIT	DESCRIPTION
2023	*Slayback Pharma, LLC v. Eye Therapies, LLC*, IPR2022-00142, Patent No. 8,293,742, Declaration of Paul A. Laskar, Ph.D., Nov. 4, 2021
2024	Robin A., "Short-term Effects of Unilateral 1% Apraclonidine Therapy," Arch. Ophthalmol. – Vol. 106, July 1988
2025	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Declaration of Dr. Daniel W. Gil, Ph.D. in Support of Plaintiffs' Motion for a Preliminary Injunction, Dec. 12, 2023
2026	Ruffolo, A., "α-Adrenoceptors", Monogr. Neural Sci., Vol. 10, pp 224-253, 1984
2027	Center for Drug Evaluation and Research, Application No. 208144Orig1s000, Summary Review, NDA 208144 Brimonidine Tartrate Ophthalmic Solution FDA Approval (2017)
2028	Fudemberg, S., et al., "Efficacy, safety, and current applications of brimonidine," Expert Opin., Drug Saf. (2008)**7**(6)
2029	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Order Denying Motion to Stay, Feb. 10, 2023. (ECF No. 75)
2030 (Revised)	*In Re Lumify*, C.A. 3:21-16766 (D.N.J.), Opinion Regarding Plaintiffs' Motion for a Preliminary Injunction, May 10, 2024 (ECF No. 326) (Public Version)
2031	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Excerpt of Defendants Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories S.A., Slayback Pharma LLC, and Slayback India LLP's Invalidity Contentions Regarding U.S. Patent No. 11,833,245.
2032	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Preliminary Injunction Transcription of the Deposition of Paul A. Laskar, Ph.D., Jan. 15, 2024

EXHIBIT	DESCRIPTION
2033	"Drug Application Process for Nonprescription Drugs," FDA, *available at* https://www.fda.gov/drugs/types-applications/drug-application-process-nonprescription-drugs
2034	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
2035	Drugs@FDA: FDA-Approved Drugs, Alphagan P 0.15%, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021262
2036	Alphagan P (brimonidine tartrate ophthalmic solution) 0.1%, Approval Letter (Aug. 19, 2005)
2037	Debbasch, C., et al., "Evaluation of the Toxicity of Benzalkonium Chloride on the Ocular Surface," *J. Toxicol—Cut. & Ocular Toxicol.* 19(2&3):105-115 (2000)
2038	Pisella, P.J., et al., "Prevalence of ocular symptoms and signs with preserved and preservative free glaucoma medication," *Br J Ophthalmol* 86:418-423 (2002)
2039	Madhu, C., et al., "Effect of Benzalkonium Chloride/EDTA on the Ocular Bioavailability of Ketorolac Tromethamine following Ocular Instillation to Normal and De-epithelialized Corneas of Rabbits," *Journal of Pharmaceutical Sciences* 85(4):415-418 (1996)
2040	*Dr. Reddy's Laboratories S.A. et al. v. Eye Therapies, LLC*, IPR2024-00467, U.S. Patent No. 11,833,245, Transcription of the Deposition of Paul A. Laskar, Ph.D., Oct. 29, 2024
2041	*Allergan, Inc. v. Sandoz Inc. et al.*, Case No. 2014-1275 (Fed. Cir. 2015)
2042	Noecker, R. "Effects of Common Ophthalmic Preservatives on Ocular Health," *Advances in Therapy* 18(5):205-215 (2001)

EXHIBIT	DESCRIPTION
2043	Drugs@FDA Drug Details, Alphagan P 0.15%
2044	Drugs@FDA Drug Details, Acular Preservative Free
2045	"FDA Approves Preservative-Free Drug to Treat Glaucoma"
2046	CONFIDENTIAL NDA 208144, Section 2.3.P.1.1 Finished Product Composition (excerpt) **(Under Seal and Public versions)**
2047	Alphagan P (Brimonidine Tartrate) Ophthalmic Solution 0.15%, Center for Drug Evaluation and Research, Application No. 21-764, Chemistry Review(s)
2048	Alphagan P (Brimonidine Tartrate) Ophthalmic Solution 0.1%, Center for Drug Evaluation and Research, Application No. 21-770, Chemistry Review(s)
2049	Code of Federal Regulations, 21 CFR Part 330, "Over-the-Counter (OTC) Human Drugs Which Are Generally Recognized as Safe and Effective and Not Misbranded"
2050	Prescribing Information Label for Lumify® (Lumify ® label)
2051	Prescribing Information Label for Qoliana® (2006)
2052	https://www.glamour.com/gallery/best-beauty-innovators-of-2022
2053	https://intothegloss.com/2021/12/top-25-2021-cheap-thrills-beauty-under-35-dollars/
2054	https://www.newyou.com/beauty-awards/new-beauty-awards-2018/
2055	https://www.prnewswire.com/news-releases/nielsens-bases-names-lumify-eye-drops-to-2020-us-bases-top-25-breakthrough-innovations-list-301143761.html
2056	https://www.thezoereport.com/beauty-awards

EXHIBIT	DESCRIPTION
2057	"LUMIFY™ Redness Reliever Eye Drops Honored By The National Association of Chain Drug Stores As Product Showcase Winner", PRNewswire (September 10, 2018)
2058	Evans and Choi, "The Best of beauty 2019", Brides (April/May 2019)
2059	"NewBeauty 2019 Award Winners: Best Innovations", NewBeauty (March 8, 2019)
2060	"Beauty Awards, The Best Even More, Never Knew We Needed", New Beauty (2022)
2061	"NewBeauty 2023 Beauty Awards", NewBeauty (2023)
2062	"Amazon Prime Day: Beauty", Campbell Hunt Puckett, Instagram (Oct. 2024)
2063	CONFIDENTIAL "Lumify Drops: Quarterly Business Review", Bausch + Lomb (Sept. 2024) (**Under Seal and Public versions)**
2064	"IQVIA: Claim Substantiation Validation Statement", IQVIA (Jul. 17, 2023)
2065	https://www.lumifyeyes.com/products/redness-reliever-eye-drops/
2066	https://www.lumifyeyes.com/products/redness-reliever-eye-drops/science/
2067	https://ecp.lumifyeyes.com/drops/lumify-difference/
2068	"Healthcare", Ispos, https://www.ipsos.com/en-hk/healthcare
2069	CONFIDENTIAL "Lumify ECP A&U Report", 27 March 2020 (**Under Seal and Public versions)**
2070	CONFIDENTIAL "Lumify ECP Tracker Study Wave 2," Jan. 5, 2024 (**Under Seal and Public versions)**
2071	"Bausch Health 3Q 2024 Earnings," October 30, 3034

EXHIBIT	DESCRIPTION
2072	CONFIDENTIAL Bausch + Lomb Profits and Losses Statement, Sept. 30, 2024 (**Under Seal and Public versions)**
2073	"Bausch + Lomb 4Q23 & FY23 Financial Results", (2024)
2074	CONFIDENTIAL Lumify Incremental to Eye Care and Red Relievers Category (Nov. 3, 2024) (**Under Seal and Public versions)**
2075	CONFIDENTIAL Lumify Incrementality (Sept. 8, 2024) (**Under Seal and Public versions)**
2076	"Circana's Heritage: Uniting IRI & NPD's Market Expertise," Circana
2077	CONFIDENTIAL Circana Panel Data (**Under Seal and Public versions)**
2078	CONFIDENTIAL Circana Point-of-Sale Data (**Under Seal and Public versions)**
2079	RESERVED
2080	RESERVED
2081	Huang, P., et al., "Comparison of postoperative redness of eyes after sub-Tenon's block and topical anesthesia following phacoemulsification cataract surgery," *British Journal of America* 112(2)381-382 (2014)
2082	Doshi, R., et al., "Subconjunctival Hemorrhage," StatPearls [Internet] (2023), *available at* https://www.ncbi.nlm.nih.gov/books/NBK551666/?report.printable
2083	Picture of an Eye

EXHIBIT	DESCRIPTION
2084	Middleton, J., "Meet the newest antidepressant: dextromethorphan/buproprion (Auvelity)" *American Family Physician* Community Blog (2022), https://www.aafp.org/pubs/afp/afp-community-blog/entry/meet-the-newest-antidepressant-dextromethorphan_buproprion-Auvelity.html
2085	*Dr. Reddy's Laboratories S.A. et al. v. Eye Therapies, LLC*, IPR2024-00467, U.S. Patent No. 11,833,245, Transcription of the Deposition of John C. Galanis, M.D., FACS, Oct. 19, 2024
2086	Yassen, A., et al., "Pharmacokinetic–Pharmacodynamic Modeling of the Effectiveness and Safety of Buprenorphine and Fentanyl in Rats," *Pharmaceutical Research* 25(1):183-193 (2007)
2087	Nita K. Pandit, PhD, *Introduction to the Pharmaceutical Sciences* (1st ed. 2007)
2088	Malcom Rowland, Ph.D. & Thomas N. Tozer, Ph.D., *Clinical Pharmacokinetics Concepts and Applications* (3d ed. 1995)
2089	Lee, D., et al., "Patient considerations in ocular hypertension: role of bimatoprost ophthalmic solution," *Clinical Ophthalmology* 11:1273-1280 (2017)
2090	Rahman, M.Q., et al. "Brimonidine for glaucoma," *Expert Opinion Drug Safety* 9(3): 483-491 (2010)
2091	Acheampong, A., et al., "Distribution of Brimonidine Into Anterior and Posterior Tissues of Monkey, Rabbit, and Rat Eyes," *Drug Metabolism & Disposition* 30(4):421-428 (2002)
2092	RESERVED
2093	*In re Lumify*, C.A. 3:21-16766 (D.N.J.), Preliminary Injunction Transcription of the Deposition of Dr. Daniel Gil, Dec. 31, 2023
2094	Belmonte, C., et al., "Nerves and Sensations from the Eye Surface," *The Ocular Surface* 2(4):248-253 (2004)

EXHIBIT	DESCRIPTION
2095	Bausch Press Release, "New Survey from Bausch + Lomb and Glaucoma Research Foundation Reveals Emotional and Social Impact of Hyperemia on Glaucoma Patients" (Jan. 4, 2022)
2096	U.S. Patent No. 3,890,319
2097	U.S. Patent No. 11,596,600
2098	"OTC Drug Review Process | OTC Drug Monographs," FDA, https://www.fda.gov/drugs/otc-drug-review-process-otc-drug-monographs
2099	Drugs@FDA: FDA-Approved Drugs, Alphagan 0.5%, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020490
2100	*Dr. Reddy's Laboratories S.A. et al. v. Eye Therapies, LLC*, IPR2024-00467, U.S. Patent No. 11,833,245, Transcription of the Deposition of Reza Dana, M.D., MSc, MPH, Nov. 1, 2024
2101	Uretmen, O., et al., Letters to the Editor "Prophylactic Brimonidine Before LASIK" (2003)
2102	Zhan, GL, et al., "Effects of Apraclonidine and Brimonidine on Rabbit Ocular Blood Flow," *Invest Ophthalmol Vis Sci* 38(4):S783 (1997)
2103	CONFIDENTIAL 10-100-0008 Clinical Study Report (Excerpted) **(Under Seal and Public versions)**
2104	CONFIDENTIAL 11-100-0015 Clinical Study Report (Excerpted) **(Under Seal and Public versions)**
2105	CONFIDENTIAL 13-100-0005 Clinical Study Report (Excerpted) **(Under Seal and Public versions)**
2106	Enhancing the Management of Red Eye, https://www.lumifydrops.com/siteassets/ecp/pdfs/Lumify-news.pdf

EXHIBIT	DESCRIPTION
2107	Alphagan 0.2% Package Leaflet, https://www.medicines.org.uk/emc/files/pil.856.pdf
2108	Alphagan (0.2%), Product Monograph and Patient Medication Information
2109	"Lumify Lovers of the Month - Meet Dillon Pena", https://www.lumifydrops.com/lovers/march-2021-dillon-pena (Lumify Lovers)
2110	Schuman, J.S., et al. "A 1-Year Study of Brimonidine Twice Daily In Glaucoma and Ocular Hypertension." *Archives of Ophthalmology* 115(7):847-852 (1997)
2111	Alphagan (Brimonidine Tartrate) Ophthalmic Solutions 0.5%, 0.2%, 0.15%, Center for Drug Evaluation and Research, Application Nos. 20-490, 20-613, 21-262, Medical Review
2112	RESERVED
2113	Kusari, J., et al., "Effect of Brimonidine on Retinal and Choroidal Neovascularization in a Mouse Model of Retinopathy of Prematurity and Laser-Treated Rats," *Invest. Ophthalmol. Vis. Sci.* 52(8):5424-5431 (2011)
2114	WoldeMussie, E., et al., "Neuroprotection of Retinal Ganglion Cells by Brimonidine In Rats With Laser-Induced Chronic Ocular Hypertension," *Invest. Ophthalmol. Vis. Sci.* 42(12):2849-2855 (2001)
2115	Lambert, W.S., et al., "Brimonidine Prevents Axonal and Somatic Degeneration of Retinal Ganglion Cell Neurons," *Molecular Neurodegeneration* 6(4) (2011)
2116	Lai, R.K., et al., "Effect of Topical Brimonidine Formulations on Retinal Ganglion Cell Survival in a Rat Acute Retinal Ischemia/Reperfusion Model," *Invest. Ophthalmol. Vis. Sci.* 47(13):500 (2006)

EXHIBIT	DESCRIPTION
2117	Gil, D.W., et al., "Alpha-1-Adrenergic Receptor Agonist Activity of Clinical Alpha-Adrenergic Receptor Agonists Interferes With Alpha-2-Mediated Analgesia," *Anesthesiology* 110(2):401-407 (2009)
2118	Australian Patent Application No. AU 2002254265
2119	Alphagan P (0.15%), Product Monograph and Patient Medication Information
2120	Flammer, J., et al., "The Impact of Ocular Blood Flow in Glaucoma," *Progress in Retinal and Eye Research* 21:359-393 (2002)
2121	Bagwell, Kyle, "The Economic Analysis of Advertising," Columbia University Department of Economics Discussion Paper Series, Discussion Paper No.: 0506-01, August 2005.
2122	Congressional Budget Office, "Promotional Spending for Prescription Drugs," December 2, 2009.
2123	Ching, Andrew T. and Masakazu Ishihara, "Measuring the Information and Persuasive Roles of Detailing on Prescribing Decisions," *Management Science*, July 2012, Vol. 58, No. 7, 1374-1387
2124	Gonzalez, Agustin L., et al., "A survey of optometrists' ophthalmic medication prescribing," *Clinical Optometry*, March 5, 2014, Vol. 6, 11-15.
2125	IRI, "New Product Pacesetters: Innovation Before the 'New Normal,'" May 2020.
2126	Carlton, Dennis W. and Jeffery M. Perloff, *Modern Industrial Organization*, 4th Ed., Pearson Education Limited 2015.
2127	Samuelson, Paul A. and William D. Nordhaus, *Economics*, 19th Ed., McGraw-Hill 2010.

EXHIBIT	DESCRIPTION
2128	Spiegel, A.J. and C. F. Gerber, "The compatibility of tetrahydrozoline hydrochloride solutions," *Journal of the American Pharmaceutical Association*, July 1959, Vol. 20, No. 7, 404-405.
2129	Thomas, Natalie A. "Secondary Considerations in Nonobviousness Analysis: The Use of Objective Indicia Following KSR v. Teleflex," *New York University Law Review*, December 2011, Vol. 86, No. 6, 2070-2112.
2130	Thomas, Randall and Ron Melton, "2016 Clinical Guide to Ophthalmic Drugs," *Review of Optometry*, May 15, 2016, 1-51.
2131	BAU-LUM00063901
2132	LUM.0205.USA.21 **(Under Seal and Public versions)**
2133	LUM.1827.USA.21
2134	Lumify_v9 - PRC APRVD
2135	CONFIDENTIAL IRI Panel Data **(Under Seal and Public versions)**
2136	CONFIDENTIAL IRI Point-of-Sale Data **(Under Seal and Public versions)**
2137	Visine Supplemental Approval, October 17, 2018
2138	Lumify Supplemental Approval, April 30, 2019
2139	https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/208144Orig1s015ltr.pdfLumify Supplemental Approval, February 21, 2019
2140	Lumify Supplemental Approval, March 5, 2020
2141	Lumify Supplemental Approval, November 29, 2021
2142	Lumify Supplemental Approval, September 23, 2020

EXHIBIT	DESCRIPTION
2143	Lumify NDA Approval, December 22, 2017
2144	Lumify NDA Summary Overview, November 29, 2017
2145	Bausch + Lomb Corporation SEC Form 10-Q for the quarterly period ended March 31, 2022
2146	Bausch + Lomb Corporation Q1 2022 Financial Results
2147	Bausch + Lomb Corporation SEC Form S-1, January 13, 2022
2148	Valeant Pharmaceuticals International, Inc. 2017 Annual Report
2149	Bausch Health Companies Inc. 2018 Annual Report
2150	Bausch Health Companies Inc. Q1 2019 Financial Results
2151	Bausch Health Companies Inc. Q4 and FY 2021 Financial Results
2152	Johnson & Johnson SEC Form 10-K for the fiscal year ended December 31, 2006
2153	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020065
2154	https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=020226#41039
2155	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020485
2156	https://www.amazon.com/Lumify-Redness-Reliever-Drops-7-5mL/dp/B07BVYZL88/ref=sr_1_4?keywords=lumify+drops&qid=1656719062&sr=8-4
2157	https://www.bausch.com/about-bausch-lomb/locations/
2158	https://www.bausch.com/news/messages-from-ceo/article/1/

EXHIBIT	DESCRIPTION
2159	https://www.bausch.com/products/otc-eye-care-supplements/redness-relief/
2160	https://www.businesswire.com/news/home/20220729005454/en/Dr.-Reddys-Laboratories-enters-into-a-licensing-agreement-with-Slayback-Pharma-to-%E2%80%A61/3
2161	https://www.cleareyes.com/eye-drops/redness-relief
2162	https://www.cleareyes.com/eye-drops/sensitive-eyes-relief/clear-eyes-complete-sensitive-eyes#ingredients
2163	https://www.cleareyes.com/eye-drops/redness-relief/clear-eyes-cooling-comfort-itchy-eye-relief#ingredients
2164	https://www.cleareyes.com/eye-drops/redness-relief/clear-eyes-maximum-redness-relief-eye-drops#ingredients
2165	https://www.cleareyes.com/eye-drops/redness-relief/clear-eyes-redness-relief-eye-drops#directions
2166	https://www.cleareyes.com/eye-drops/redness-relief/clear-eyes-redness-relief-eye-drops#ingredients
2167	https://www.cvs.com/shop/personal-care/eye-care/drops-lubricants/q/CVS_Health/Eye_Drops/brpt
2168	https://www.cvs.com/shop/lumify-redness-reliever-eye-drops-prodid-1910106
2169	https://dailymed.nlm.nih.gov/dailymed/druglnfo.cfm?setid=69166dec-fb86-4c 76-9efe-88c3bb 12a8f0
2170	https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e3c41a58-fc93-4e6c-99be-0529edfb54a4
2171	https://eyewire.news/news/dr-reddys-laboratories-enters-into-a-licensing-agreement-to-obtain-rights-for-the-private-label-version-of-lumify-in-the-us?c4src=article:infinite-scroll

EXHIBIT	DESCRIPTION
2172	https://fda.report/Company/Bausch-Lomb-Inc
2173	https://fda.report/Company/Prestige-Brands-Holdings-Inc
2174	RESERVED
2175	RESERVED
2176	https://ir.bauschhealth.com/news-releases/2018/05-07-2018-130249958
2177	https://ir.bauschhealth.com/news-releases/archive/2017/12-22-2017-200318686
2178	https://ir.bauschhealth.com/news-releases/2018/07-13-2018
2179	https://nielseniq.com/global/en/news-center/2020/capitalizing-on-innovation-trends-today-will-drive-business-growth-in-the-new-normal/
2180	https://www.lumifydrops.com/faqs
2181	https://www.lumifydrops.com/professional/clinical-information
2182	https://www.lumifydrops.com/lumify-science
2183	https://www.mckinsey.com/industries/life-sciences/our-insights/the-secret-of-successful-drug-launches
2184	https://www.ophthalmologyweb.com/1315-News/346489-FDA-Approves-LUMIFY-a-Brimonidine-OTC-for-Ocular-Redness/
2185	https://optometricmanagement.com/issues/2006/november/how-to-maximize-prescription-authority/
2186	https://www.optometrytimes.com/view/b-l-licenses-new-technology-treating-ocular-redness?qt-resource_topics_rightrail=1
2187	https://patents.bausch.com

EXHIBIT	DESCRIPTION
2188	https://www.bausch.com/contentassets/9589635e7955423d862887d43e76a09b/advance-eye-relief-redness-drug-facts.pdf/
2189	Advanced Eye Relief Max Drug Facts, available at https://pi.bausch.com/globalassets/pdf/downloads/consumer/vision-care/safety/advanced-eye-relief-maximum-redness-drug-facts.pdf
2190	https://pitchbook.com/profiles/company/492664-60#overview
2191	https://www.prestigebrands.com/products/eye-ear-nose-throat/clear-eyes
2192	https://www.prnewswire.com/news-releases/bausch--lomb-licenses-new-technology-with-potential-to-treat-millions-affected-by-ocular-redness-185856742.html
2193	https://www.prnewswire.com/news-releases/nielsens-bases-names-lumify-eye-drops-to-2020-us-bases-top-25-breakthrough-innovations-list-301143761.html
2194	https://www.reviewofoptometry.com/article/when-to-prescribe-an-otc-allergy-drop
2195	https://www.riteaid.com/shop/ra-rednss-relf-eye-drp-5z-0354534
2196	https://www.riteaid.com/shop/rite-aid-eye-care-sterile-eye-drops-0-5-fl-oz
2197	https://rohtoeyedrops.com/products/rohto-all-in-one-multi-symptom-eye-drops?srsltid=AfmBOoqvclRm97_Ej6HqbtuusekZaUordhyEDksEFyhsvpQuuozX74Uh
2198	https://rohtoeyedrops.com/products/rohto-cool-relief-cooling-eye-drops?srsltid=AfmBOoroYZZgemByouhpXiWphIML3kyD8Vl6qyd6CLHigjLXCyHPvdC8

EXHIBIT	DESCRIPTION
2199	https://rohtoeyedrops.com/products/rohto-max-strength-redness-relief-eye-drops?srsltid=AfmBOorWNNzYXhrjFPT4b4vjV5V2qcxql9iR-dEKvVAswZVQZCUxJQPu
2200	https://rohtoeyedrops.com/collections/redness-reliever/products/rohto-eye-drops-optic-glow
2201	https://rohtoeyedrops.com/collections/redness-reliever/products/rohto-digi-eye-digital-eye-strain-eye-drops
2202	https://rohtoeyedrops.com/collections/redness-reliever
2203	https://www.target.com/p/lumify-eye-drops/-/A-54293362
2204	RESERVED
2205	https://us.mentholatum.com/about-us/
2206	https://www.walgreens.com/store/c/productlist/walgreens-redness-relief/N=361377-118
2207	https://www.walmart.com/ip/LUMIFY-Redness-Reliever-Eye-Drops-Brimonidine-Tartrate-Ophthalmic-Solution-0-025-from-Bausch-Lomb-0-08-Fl-Oz-2-5-mL/193381081?athbdg=L1600
2208	https://walrus.com/questions/lumify-vs-visine-what-is-the-difference
2209	https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208144Orig1s006lbl.pdf
2210	https://www.drreddys.com/
2211	https://www.drreddys.com/who-we-are
2212	https://www.drreddys.com/contact-us
2213	Bausch Health 2023 10-K

EXHIBIT	DESCRIPTION
2214	https://www.drreddysusa.com/sites/g/files/nstucr196/files/2023-02/dr-3398_product_cat_update_020422.pdf
2215	https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/208144Orig1s015ltr.pdf
2216	Bausch + Lomb 3Q24 Financial Results
2217	Bausch + Lomb 2Q24 Financial Results
2218	Bausch + Lomb Corporation SEC Form 10-K for the fiscal year ending December 31, 2022
2219	Bausch + Lomb SEC Form 10-Q for quarter ending September 30, 2024
2220	https://www.lumifyeyes.com/siteassets/pdf/lumify-drug-facts.pdf
2221	https://www.cnet.com/health/personal-care/best-eye-drops/
2222	https://www.allaboutvision.com/treatments-and-surgery/remedies/lumify-eye-drops/
2223	CONFIDENTIAL Declaration of Robert J. Noecker, M.D., MBA **(Under Seal and Public versions)**
2224	Declaration of Eric D. Donnenfeld, M.D.
2225	Declaration of W. Daniel Stamer, Ph.D.
2226	CONFIDENTIAL Declaration of Robert O. Williams, III, Ph.D. **(Under Seal and Public versions)**
2227	Declaration of Daniel W. Gil, Ph.D.
2228	Declaration of Kurt R. Karst, Esq.
2229	CONFIDENTIAL Declaration of John Jarosz **(Under Seal and Public versions)**

EXHIBIT	DESCRIPTION
2230	CONFIDENTIAL Declaration of John Ferris **(Under Seal and Public versions)**
2231–2244	RESERVED
2245	Sertkaya, A., et al., Examination of Clinical Trial Costs and Barriers for Drug Development, 3-2 (Jul. 25, 2014), *available at* https://aspe.hhs.gov/system/files/pdf/77166/rpt_erg.pdf (Served But Not Filed)
2246	FDA, Antiseptic FDA Letters, *available at* https://www.fda.gov/drugs/information-drug-class/antiseptic-fda-letters (Served But Not Filed)
2247	FDA, Approval Letter, RID MOUSSE (NDA 021043) (Mar. 7, 2000) (Served But Not Filed)
2248	FDA, Approval Package NDA 208144 (LUMIFY), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208144Orig1s000TOC.cfm (Served But Not Filed)
2249	FDA, Citizen Petition Response, Legacy Docket Nos. 2001P-0323/CP1 & C5, 2002P-0447/CP1, and 2003P-0408/CP 1 (Oct. 14, 2003) (Served But Not Filed)
2250	FDA, CPG sec. 450.300, OTC Drugs—General Provisions and Administrative Procedures for Marketing Combination Products (Served But Not Filed)
2251	FDA, Draft Guidance for Industry, Applications Covered by Section 505(b)(2) (Oct. 1999), *available at* https://www.fda.gov/media/72419/download (Served But Not Filed)

EXHIBIT	DESCRIPTION
2252	FDA, FDA Overview of Issues for the Joint Nonprescription Drugs Advisory Committee and the Pulmonary-Allergy Drugs Advisory Committee (May 11, 2001), *available at* https://web.archive.org/web/20170711050457/http://www.fda.gov/ohrms/dockets/ac/01/briefing/3737b_02_overview.pdf (Served But Not Filed)
2253	FDA, Guidance Document Search ("OTC"), *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents (Served But Not Filed)
2254	FDA, Guidance for Industry, Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products — Content and Format (Jan. 2006), *available at* https://www.fda.gov/media/72139/download (Served But Not Filed)
2255	FDA, Guidance for Industry, ANDAs: Pharmaceutical Solid Polymorphism (July 2007), *available at* https://www.fda.gov/media/71375/download (Served But Not Filed)
2256	FDA, Guidance for Industry, Expedited Programs for Serious Conditions – Drugs and Biologics (May 2014), *available at* https://www.fda.gov/media/86377/download (Served But Not Filed)
2257	FDA, Draft Guidance for Industry, Innovative Approaches for Nonprescription Drug Products (July 2018), *available at* https://www.fda.gov/media/114328/download (Served But Not Filed)
2258	FDA Guidance for Industry, Label Comprehension Studies for Nonprescription Drug Products (Aug. 2010), *available at* https://www.fda.gov/media/75626/download?attachment (Served But Not Filed)
2259	FDA, Guidance for Industry, Self-Selection Studies for Nonprescription Drug Products (Apr. 2013), *available at* https://www.fda.gov/media/81141/download (Served But Not Filed)

EXHIBIT	DESCRIPTION
2260	FDA, Guidance for Industry, Time and Extent Applications for Nonprescription Drug Products (Sept. 2011), *available at* https://www.fda.gov/media/72219/download (Served But Not Filed)
2261	FDA, Historical Status of OTC Rulemakings, Status of OTC Rulemakings Prior to the CARES Act, *available at* https://www.fda.gov/drugs/over-counter-otc-drugs/status-otc-rulemakings (Served But Not Filed)
2262	FDA, Labeling for CBER-Regulated Products, *available at* https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/labeling-cber-regulated-products (Served But Not Filed)
2263	FDA, MAPP 6020.5 Rev. 2, Good Review Practice: OND Review Management of INDs and Marketing Applications for Nonprescription Drug Products (June 2018), *available at* https://public4.pagefreezer.com/content/FDA/16-06-2022T13:39/https://www.fda.gov/media/72730/download (Served But Not Filed)
2264	RESERVED
2265	FDA, OTC Monograph M018: Ophthalmic Drug Products for Over-the-Counter Human Use (Posted April 4, 2022), Final Administrative Order OTC000023, *available at* https://dps-admin.fda.gov/omuf/sites/omuf/files/monograph-documents/2022-09/OTC%20Monograph_M018-Ophthalmic%20Drug%20Products%20for%20OTC%20Human%20Use%2004.04.22.pdf (Served But Not Filed)
2266	FDA, OTC Monographs@FDA, Rulemaking History for OTC Ophthalmic Drug Products, *available at* https://www.fda.gov/drugs/historical-status-otc-rulemakings/rulemaking-history-otc-ophthalmic-drug-products (Served But Not Filed)

EXHIBIT	DESCRIPTION
2267	FDA, Regulatory Procedures Manual, Chapter 4: Advisory Actions (July 2024), *available at* https://www.fda.gov/media/71878/download (Served But Not Filed)
2268	Pharmaceutical Research and Manufacturers of America ("PhRMA"), PhRMA, Research & Development Policy Framework, *available at* https://phrma.org/en/policy-issues/Research-and-Development-Policy-Framework (Served But Not Filed)
2269	U.S. Bureau of Labor Statistics, CPI Inflation Calculator, *available at* https://www.bls.gov/data/inflation_calculator.htm (Served But Not Filed)
2270	Declaration of Matthew J. Luneack in Support of Motion for Admission *Pro Hac Vice*
2271	RESERVED
2272	RESERVED
2273	RESERVED
2274	RESERVED
2275	RESERVED
2276	Email chain regarding IPR2024-00467, 00563 Depositions
2277	In Re Lumify, C.A. No. 21-16766, Docket Entry 430 Order Granting Motion to Stay
2278	Email chain regarding In Re Lumify, C.A. No. 21-16766 (RK) (RLS) – Cross Use Agreement

Respectfully submitted,

Dated: January 29, 2025

By: /Bryan C. Diner/
Bryan C. Diner
Reg. No. 32,409

Counsel for the Patent Owner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **Patent Owner's Fifth Updated Exhibit List** and **Exhibits 2276 - 2278** was served on January 29, 2025 via email directed to counsel of record for the Petitioners at the following:

Linnea P. Cipriano
Timothy J. Beavers
Goodwin Procter LLP
620 Eighth Avenue
New York, NY 10018
lcipriano@goodwinlaw.com
TBeavers@goodwinlaw.com

Elaine Herrmann Blais
Robert Frederickson III
Alexandra Lu
Anna Zhou
Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
EBlais@goodwinlaw.com
Rfrederickson@goodwinlaw.com
Alu@goodwinlaw.com
AZhou@goodwinlaw.com

Christopher Cassella
Goodwin Procter LLP
1900 N Street N.W.
Washington, DC 20036
CCassella@goodwinlaw.com
extDG-Brimonidine@goodwinlaw.com

Dated: January 29, 2025

By: /Geneva Eaddy/
Geneva Eaddy
Case Manager
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP