

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC

Petitioner

v.

CIPLA LIMITED

Patent Owner

Case No. IPR2017-00807

U.S. Patent No. 8,168,620

CIPLA LTD.'S EXHIBIT LIST

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Patent Trial and Appeal Board

U.S. Patent and Trademark Office

P.O. Box 1450

Alexandria, VA 22313-1450

<i>Cipla's Exhibit #</i>	<i>Description</i>
2001	Warner Carr, M.D. Declaration
2002	Warner Carr, M.D. <i>Curriculum Vitae</i>
2003	Alexander Dominic D'Addio, Ph.D. Declaration
2004	Alexander Dominic D'Addio, Ph.D. <i>Curriculum Vitae</i>
2005	John C. Jarosz Declaration
2006	John C. Jarosz <i>Curriculum Vitae</i>
2007	Hugh David Charles Smyth, Ph.D. Declaration
2008	Hugh David Charles Smyth, Ph.D. <i>Curriculum Vitae</i>
2009	Complaint for Patent Infringement, December 2, 2014, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-UNA (D. Del.)
2010	Complaint for Patent Infringement, September 9, 2016, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Perrigo UK Finko Limited Partnership, Perrigo Company and Perrigo Pharmaceuticals Co.</i> , Case No. 1:16-cv-00794-LPS (D. Del.)
2011	Expert Report of Robert P. Schleimer, Ph.D., August 19, 2016, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-LPS (D. Del.)
2012	Expert Rebuttal Report of Robert P. Schleimer, Ph.D., July 29, 2016, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-LPS (D. Del.)
2013	Expert Reply Report of Robert P. Schleimer, Ph.D., August 19, 2016, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-LPS (D. Del.)
2014	Dr. Maureen Donovan Deposition transcript, October 7, 2016, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-LPS (D. Del.)
2015	Expert Report of Maureen D. Donovan, Ph.D., June 30, 2016, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-LPS (D. Del.)

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2016	Expert Reply Report of Maureen D. Donovan, Ph.D., August 19, 2016, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-LPS (D. Del.)
2017	Publicly Filed Proposed Joint Pretrial Order, November 10, 2016, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-LPS (D.I.137) (Redactions in Original)
2018	Bench Trial Transcript, Volume A, December 13, 2016, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-LPS (D. Del.)
2019	Bench Trial Transcript, Volume B, December 14, 2016, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-LPS (D. Del.)
2020	Bench Trial Transcript, Volume C, December 15, 2016, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-LPS (D. Del.)
2021	Bench Trial Transcript, Volume D, December 16, 2016, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-LPS (D. Del.)
2022	Plaintiffs' Proposed Findings of Fact, January 10, 2017, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-LPS (D. Del.) (D.I. 155)
2023	Defendants' Proposed Finding of Facts, January 10, 2017, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-LPS (D. Del.) (D.I. 156)
2024	Defendants' Opening Post-Trial Brief, January 24, 2017, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-LPS (D. Del.) (D.I. 158)
2025	Dr. Robert Schleimer Deposition transcript, September 29, 2016, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-LPS (D. Del.)
2026	Gennaro, A. R. <i>Remington's Pharmaceutical Sciences</i> (17 th ed., 1985), Ch. 80: 1455-1477; Ch. 82: 1478-1491; Ch. 84:1492-1517

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2027	Accolate Approval Letter and Label, Application Number 20-547/S011, Zeneca Pharmaceuticals
2028	Avomeen Analytical Services Report, June 30, 2016 (PTX0129)
2029	Expert Report of Dr. Matthew J. Herpin and Corresponding Documents (PTX1663)
2030	Expert Report of Dr. Ramprakash Govindarajan and Corresponding Documents (PTX1664)
2031	Duonase Imitator Product Labels (PTX0026)
2032	Allegra-D Approval Letter, Application Number 20786, Approved December 24, 1997, (PTX0126)
2033	Intentionally Left Blank
2034	<i>Physicians' Desk Reference</i> , 54 th ed., pp. 1343-1344, 2404-2406, 2781-2783 (2000)
2035	Riordan, John. <i>An Introduction to Combinatorial Analysis</i> (1958), Ch. 1: 1-18
2036	Zyrtec-D FDA Label, Approved August 10, 2001
2037	Argentum Pharmaceuticals, "About," http://www.argentumpharmaceuticals.com/about/ (accessed May 17, 2017)
2038	Khan, M., and Reddy, I. <i>Pharmaceutical and Clinical Calculations</i> (2nd ed., 2000), pp. 149-167 (PTX0194)
2039	Flonase [®] Label 1998, Application Number 20-121/S009, November 1998 (PTX0059)
2040	British Pharmaceutical Codex (1973), "Hyromellose," pp. 232, 307-308 (PTX0193)
2041	Howarth, P. H. "A comparison of the anti-inflammatory properties of intranasal corticosteroids and antihistamines in allergic rhinitis," <i>Allergy</i> , 62: 6-11; 2000 (PTX0337)
2042	Nielsen, Lars P. "Review Article, Intranasal Corticosteroids for Allergic Rhinitis - Superior Relief?" <i>Am. J. Respir Med.</i> , 2(1): 55-65; 2001 (PTX0338)

<i>Cipla's Exhibit #</i>	<i>Description</i>
2043	Shenfield, G. M. "Fixed drug combinations: which ones can be recommended?" <i>Current Therapeutics</i> , 27(11): 15-29; 1986 (DTX-048)
2044	Michael, Y., <i>et al.</i> "Characterisation of the aggregation behavior in a salmeterol and fluticasone propionate inhalation aerosol system," <i>International Journal of Pharmaceutics</i> , 221: 165-174; 2001 (PTX0179)
2045	Hampel, F., <i>et al.</i> "Double-blind, Placebo-Controlled Study of Azelastine and Fluticasone in a Single Nasal Spray Delivery Device," <i>Annals of Allergy, Asthma, & Immunology</i> , 105: 168-173; 2010 (PTX0230)
2046	Weiler, J. M., <i>et al.</i> "Azelastine nasal spray as adjunctive therapy to azelastine tablets in the management of seasonal allergic rhinitis," <i>Ann. Allergy Asthma Immunol</i> , 79: 327-332; 1997 (PTX0329)
2047	Blaiss, M. "Efficacy, Safety, and Patient Preference of Inhaled Corticosteroids: A Review of Pertinent Published Data," <i>Allergy and Asthma Proc.</i> , 22(6): S5-S10; 2001 (PTX0058)
2048	DataMonitor – "Pipeline and Commercial Insight: Allergic Rhinitis," July 2010 (PTX0396)
2049	2006 Cipla-Meda License Agreement with Quality Agreement (PTX1016)
2050	2011 First Amendment to Cipla-Meda Agreement (PTX0282)
2051	<i>Physicians' Desk Reference</i> , 54 th ed., pp. 2783- 2786 (2000)
2052	Leung, D., <i>et al.</i> "The Editors' Choice: MP29-02: A Major Achievement in the treatment of allergic rhinitis," <i>J. Allergy Clin. Immunol.</i> , 129(5): 1216; 2012 (PTX0029)
2053	Allergic Rhinitis - Global Drug Forecast and Market Analysis to 2024, GlobalData, September 2015 (PTX0397)
2054	MedPointe Making Medicine Better: Astelin [®] Day Life CyclePlan, November 1, 2002 (PTX1005)

<i>Cipla's Exhibit #</i>	<i>Description</i>
2055	MedPointe Product & Process Development Program Priorities and Issues - September 9, 2002 (PTX0143)
2056	Astelin [®] Nasal Spray Life Cycle Management Projects (Preliminary Plan) (PTX1006)
2057	2006.02.06 Email from Paul Edick to Dennis Fuge re: Pfeiffer Bi Dose Nasal Spray System (PTX0149)
2058	2006.03.21 Email and attachment from Kalidas Kale to Alex D'Addio re: Astelin – Flonase Combination Product Feasibility Assessment Plan (PTX0151)
2059	Dang, Phuong Grace, <i>et al.</i> U.S. Patent No. 8,071,073 (Filed November 22, 2005; Issued December 6, 2011)
2060	Dang, Phuong Grace, <i>et al.</i> U.S. Patent No. 8,518,919 (Filed November 10, 2011; Issued August 27, 2013)
2061	MedPointe Laboratory Notebook No. 1044 - Excerpts (PTX0142)
2062	IMS data for U.S. allergic rhinitis products, 01.2012-04.2016 (PTX0929)
2063	Intentionally Left Blank
2064	2011.11.02 Email and attachment from Ashwini Dumaswala to Bryan Roecklein re: 2012 Dymista [®] Strategic Plan (PTX1118)
2065	"All Products - Apotex Products: United States," http://www.apotex.com/us/en/products/search.asp?qt=AII&qs=&t=AII%20Products (accessed June 22, 2016) (PTX0420)
2066	Dymista [®] Prescribing Information 2015 (PTX0024)
2067	Drug Approval Package: Dymista [®] , Application Number 202236, Meda Pharmaceuticals, Inc., Approved May 1, 2012 (PTX0392)
2068	Meda AB Interim Report, Jan.-Sept. 2012 (PTX0393)
2069	"At a Glance" Cipla, http://www.cipla.com/en/corporate-information/at-a-glance.html (accessed June 28, 2016) (PTX0379)
2070	Duonase Nasal Spray – Prescribing Information (PTX0134)

<i>Cipla's Exhibit #</i>	<i>Description</i>
2071	Cipla Website, "Respiratory," http://www.cipla.com/en/our-businesses/strategic-business-units/respiratory.html (accessed June 28, 2016) (PTX0380)
2072	IMS data for Duonase competitor products, 2005-2016 (PTX0816)
2073	Dymista [®] briefing document (PTX1654)
2074	2014.11.14 Email and attachment from Stuart Loeschto Betsy Orrison re: Dymista [®] US Marketing Plan 2015 (PTX0271)
2075	Dymista [®] Competitor Benchmarking Presentation 2012 (PTX0926)
2076	Meda – 2016 Dymista [®] Brand Plan (PTX0406)
2077	FDA.gov, "Prescription to Over-the-Counter (OTC) Switch List," http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm106378.htm (accessed June 28, 2016) (PTX0407)
2078	Johnson & Johnson Press Release, "RHINOCORT [®] Allergy Spray Now Available Over The Counter Nationally," February 8, 2016, http://www.jnj.com/news/all/RHINOCORT-Allergy-Spray-Now-Available-Over-The-Counter-Nationally (accessed June 30, 2016) (PTX0408)
2079	2011.11.02 Email and attachment from Ashwini Dumaswala to Bryan Roecklein re: 2012 Dymista [®] Strategy Plan (PTX0267)
2080	MEDA Presentation re: staffing, timelines for expansion, price comparisons (2001) (PTX0871)
2081	FDA.gov, "First-Time Generic Drug Approvals - March 2016," http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugsandBiologicApprovalReports/ANDAGenericDrugApproval (accessed June 28, 2016) (PTX0424)
2082	Renavatio Presentation & Meda Presentation - Dymista [®] Phase I Exploratory Research (PTX0426)

<i>Cipla's Exhibit #</i>	<i>Description</i>
2083	Transmittal of advertisements and promotional labeling to the U.S. Food and Drug Administration for Dymista [®] , June 17, 2015 (PTX0914)
2084	Transmittal of advertisements and promotional labeling to the U.S. Food and Drug Administration for Dymista [®] , June 16, 2015 (PTX0916)
2085	Transmittal of advertisements and promotional labeling to the U.S. Food and Drug Administration for Dymista [®] , November 26, 2012 (PTX0917)
2086	Transmittal of advertisements and promotional labeling to the U.S. Food and Drug Administration for Dymista [®] , June 29, 2015 (PTX0915)
2087	Cipla Duonase Marketing Presentation (PTX0315)
2088	Meda/Cipla Powerpoint – Complete Picture (PTX0412)
2089	"The Difference Between AR and Sinusitis," Drs. Miller & Alt, December 2, 2015, http://healthcare.utah.edu/the-scopelshows.php?shows=O_hf3tm0mc (accessed June 28, 2016) (PTX0429)
2090	Family Allergy & Asthma Care of Montana Website, "If one is good, 2 are better...A new nasal spray containing 2 medications!", March 11, 2013, http://www.familyallergyasthmacare.com/2013103/if-one-is-good-2-are-better-a-new-nasal-spray-containing-2-medications/ (accessed June 28, 2016) (PTX0430)
2091	Bousquet, Jean, <i>et al.</i> "Allergic Rhinitis," Dymista [®] : in a class of its own for treatment of AR - Key Opinion, http://keyopinions.info/downloads/dymista-class-treatment-allergic-rhinitis/ (accessed June 28, 2016) (PTX0431)
2092	Samuelson, Paul A., and Nordhaus, William D. (Eds.). <i>Economics</i> (19th ed., 2010), p. 49 (PTX0415)
2093	Dymista [®] Marketing Plan 2016 (PTX0438)
2094	Dymista [®] Formulary Coverage Powerpoint 2014 (PTX0892)

<i>Cipla's Exhibit #</i>	<i>Description</i>
2095	Meda Memorandum re: CVS Caremark Formulary Decisions 2015 (PTX0447)
2096	Bagwell, K. "The Economic Analysis of Advertising," <i>Handbook of Industrial Organization</i> (2007), eds. M. Armstrong and R. Porter, vol. 3, pp. 1703-1706 (PTX0432)
2097	Ching, A. and Ishihara, M. "Measuring the Informative and Persuasive Roles of Detailing on Prescribing Decisions," April 27, 2010, Working Paper (PTX0433)
2098	Berndt, Ernst R. "The U.S. Pharmaceutical Industry: Why Major Growth In Times of Cost Containment?" <i>Health Affairs</i> , 20(2): 110-111; 2001 (PTX0434)
2099	Bloomberg Website, "Pharmaceutical Company Overview of Mylan Specialty L.P.," http://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapld=3346320 (accessed May 19, 2017)
2100	Newsroom Website, "Mylan Completes Acquisition of Meda," http://newsroom.mylan.com/2016-08-05-Mylan-Completes-Acquisition-of-Meda (accessed May 19, 2017)
2101	Apotex Press Release, "Apotex Launches First Generic Version of Merck's Nasonex [®] ," March 24, 2016, http://www.apotex.com/global/about/press/20160324.asp (accessed June 28, 2016) (PTX0409)
2102	Intentionally Left Blank
2103	The United States Pharmacopeia: 24 National Formulary 19 (1999), pp. 2107-2130 (PTX0188)
2104	Lieberman, H. A., <i>et al.</i> (Eds.). <i>Pharmaceutical Dosage Forms</i> (2 nd ed., 1996), Ch. 4: 149-181 (PTX0177)
2105	Shin Etsu Pharmacoat USP Hypromellose Brochure (2005) (PTX0186)
2106	Intentionally Left Blank
2107	Gennaro, A. R., <i>et al.</i> (Eds.). <i>Remington: The Science and Practice of Pharmacy</i> (20 th ed., 2000), Ch. 22: 316-334 (PTX0184)

<i>Cipla's Exhibit #</i>	<i>Description</i>
2108	Intentionally Left Blank
2109	Intentionally Left Blank
2110	Kibbe, A. H. (Ed.). "Hydroxypropyl Methylcellulose," in <i>Handbook of Pharmaceutical Excipients</i> (3 rd ed., 2000), pp. 252-255 (PTX0198)
2111	Michael, Y., <i>et al.</i> "The physico-chemical properties of salmeterol and fluticasone propionate in different solvent environments," <i>International Journal of Pharmaceutics</i> , 200: 279-288; 2000 (PTX0180)
2112	Allen, Jr., L.V. (Ed.). <i>The Art, Science, and Technology of Pharmaceutical Compounding</i> (1998), Ch. 20: 219-238 (PTX0167)
2113	Lieberman, H. A., <i>et al.</i> (Eds.). <i>Pharmaceutical Dosage Forms</i> (2 nd ed., 1996), vol. 2, Ch. 5: 183-241 (PTX0192)
2114	Meda Highlights of Prescribing Information 2015 (PTX0154)
2115	Intentionally Left Blank
2116	Intentionally Left Blank
2117	Intentionally Left Blank
2118	Intentionally Left Blank
2119	Intentionally Left Blank
2120	MedPointe Product & Process Development, Program Priorities and Issues - November 18, 2002, "Commercial Product Technical Support" (PTX0144)
2121	2006.02.06 Email from Richard Spivey to Alex D'Addio re: Pfeiffer Bi Dose Nasal Spray System (PTX0150)
2122	2003.11.11 Email and attachment from Mary Lehr to Gul Balwani (PTX0255)
2123	IMS data for Indian allergic rhinitis nasal spray products, December 2010-December 2014 (PTX0823)
2124	IMS data for Indian allergic rhinitis nasal sprays products, March 2013 – March 2017

<i>Cipla's Exhibit #</i>	<i>Description</i>
2125	Intentionally Left Blank
2126	IMS data for Duonase competitor products, 2005-2017
2127	2017.03.21 Email from Mike Houston to Adam LaRock re IPR2017-00807
2128	Intentionally Left Blank
2129	FDA, Center for Drug Evaluation and Research, "Allergic Rhinitis: Clinical Development Programs for Drug Products," Guidance for Industry, 2000 (PTX0025)
2130	Hitti, Miranda. "FDA Oks Generic Version of Flonase," WebMD, http://www.webmd.com/allergies/news/20060222/fdaoksgenericversionofflonase (accessed May 26, 2017)
2131	"What is a Tiered Formulary and What Does it Mean for Me?," Medicare News and Updates, https://blog.medicaremadeclear.com/blog/bid/78229/WhatisaTieredFormularyandWhatDoesitMeanforMe (accessed May 26, 2017)
2132	IMS data for U.S. allergic rhinitis products, May 2011 - April 2017
2133	Bousquet, J., <i>et al.</i> "Management of Allergic Rhinitis and Its Impact on Asthma," <i>Journal of Allergy and Clinical Immunology</i> , 108(5); excerpt; 2001. (ARIA Contributors) (PTX0326)
2134	Memorandum Opinion, May 12, 2016, <i>Meda Pharmaceuticals Inc. and Cipla Ltd., v. Apotex Inc. and Apotex Corp.</i> , Case No. 1:14-cv-01453-LPS (D. Del.) (D.I. 114)
2135	Wade, A., and Weller, P. (Eds.). <i>Handbook of Pharmaceutical Excipients</i> (2nd ed., 1994), p. 154
2136	Talbot, Andrew, <i>et al.</i> "Mucociliary Clearance and Buffered Hyperonic Saline Solution," <i>Laryngoscope</i> , 107(4): 500-503; 1997
2137	Intentionally Left Blank
2138	DataMonitor – "Commercial and Stakeholder Perspectives: Allergic Rhinitis," September 2004 (PTX0098)

<i>Cipla's Exhibit #</i>	<i>Description</i>
2139	Affidavit in Support of Motion for <i>Pro Hac Vice</i> Admission of Uma N. Everett
2140	Declaration of Adam C. LaRock

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Date: May 30, 2017

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CERTIFICATE OF SERVICE (37 C.F.R. §§ 42.6(e))

The undersigned hereby certifies that the above-captioned "Cipla Ltd's Exhibit List," along with Exhibits 2001 – 2140, were served in their entirety on May 30, 2017, upon the following parties via electronic mail:

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