

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ARGENTUM PHARMACEUTICALS LLC  
Petitioner

v.

CIPLA LTD.  
Patent Owner

Patent No. 8,168,620  
Issue Date: May 1, 2012  
Title: COMBINATION OF AZELASTINE AND STEROIDS

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*Inter Partes* Review No. IPR2017-00807

**PETITIONER'S EXHIBIT LIST AS OF APRIL 10, 2018**

Pursuant to 37 C.F.R. § 42.63(e), Petitioner ARGENTUM PHARMACEUTICALS LLC presents a complete list of Petitioner’s exhibits, along with Exhibits 1172 and 1173 filed by Petitioner on April 10, 2018, and Exhibit 1171 filed by Patent Owner on April 10, 2018.

**TABLE OF EXHIBITS**

<b>Ex #</b>	<b><u>Exhibit</u></b>	<b>Filed</b>
1001	U.S. Patent No. 8,168,620 (“620 patent”)	X
1002	Prosecution History of U.S. Patent No. 8,168,620	X
1003	Declaration of Dr. Robert Schleimer	X
1004	Declaration of Dr. Maureen Donovan	X
1005	<i>Meda Pharms. Inc. v. Apotex Inc.</i> , 14-cv-1453 (D. Del. May 12, 2016) (Claim Construction Memorandum and Order)	X
1006	UK Patent Application GB 0213739.6	X
1007	U.S. Patent No. 5,164,194 (“Hettche”)	X
1008	Physician’s Desk Reference, Astelin® Label, rev.1/99, pp.3147-3148 (54 <sup>th</sup> ed. 2000) (“Astelin® Label”)	X
1009	U.S. Patent No. 4,335,121 (“Phillipps”)	X
1010	Flonase® Label (1998)	X
1011	European Patent Application No. 0780127 (“Cramer”)	X
1012	PCT Publication No. WO 98/48839 to Segal (“Segal”)	X
1013	British Pharmaceutical Codex (1973)	X
1014	U.S. Patent Publication No. 20040136918 (“Garrett”)	X
1015	Falser, N., <i>et al.</i> , “Comparative efficacy and safety of azelastine and levocabastine nasal sprays in patients with seasonal allergic rhinitis.” ARZNEIMITTELFORSCHUNG, 51(5):387-93 (2001)	X

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1017	Stellato, C., et al., An in vitro Comparison of Commonly Used Topical Glucocorticoid Preparations, J. ALLERGY CLIN. IMMUNOL., Vol. 104, No. 3, Part 1, 623-629 (Sept. 1999)	X
1018	Johnson, M., Development of fluticasone propionate and comparison with other inhaled corticosteroids, J. Allergy Clin. Immunol., Vol. 101, No. 4, Part 2, S434-S439 (1998)	X
1019	Dykewicz, Mark S., et al., "Diagnosis and management of rhinitis: complete guidelines of the joint task force on practice parameters in allergy, asthma and immunology," ANNALS OF ALLERGY, ASTHMA & IMMUNOLOGY, Vol. 81, 478-518 (1998)	X
1020	Stoloff, R., et al., "Combination Therapy with Inhaled Long-Acting $\beta$ 2-Agonists and Inhaled Corticosteroids: A Paradigm Shift in Asthma Management," PHARMACOTHERAPY, Vol. 22, No. 2, 212-226 (Feb. 2002)	X
1021	Berger, W. E. et al., "Double-blind trials of azelastine nasal spray monotherapy versus combination therapy with loratadine tablets and beclomethasone nasal spray in patients with seasonal allergic rhinitis," ANNALS OF ALLERGY, ASTHMA & IMMUNOLOGY, Vol. 82, 535-541 (1999)	X
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1045	Ratner, Paul H., et al., “Combination therapy with azelastine hydrochloride nasal spray and fluticasone propionate nasal spray in the treatment of patients with seasonal allergic rhinitis,” ANNALS OF ALLERGY, ASTHMA & IMMUNOLOGY, VOL. 100, 74-81 (2008)	X
1046	IMITREX Prescribing Information (2013)	X
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1050	Ratner, Paul H., et al., “A double-blind, controlled trial to assess the safety and efficacy of azelastine nasal spray in seasonal allergic rhinitis,” Journal of Allergy and Clinical Immunology, Vol. 94, No. 5, 818-825 (1994)	X
1051	Curriculum Vitae of Dr. Robert Schleimer	X
1052	Curriculum Vitae of Dr. Maureen Donovan	X
1053	Patent Certification for U.S. Patent No. 5,164,194 - Astelin® Nasal Spray (2000)	X
1054	“Avicel® RC-591 Microcrystalline Cellulose and Carboxymethylcellulose Sodium, NF, BP,” FMC Corporation (1994)	X
1055	Dr. Accetta Patient Record (1998)	X
1056	U.S Patent No. 6,417,206, Antitussive Antihistaminic Decongestant Compositions July 9, 2002	X

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1109	Food and Drug Administration, "Claritin-D Drug Approval".	X
1110	Food and Drug Administration, "Nasalide Drug Approval".	X
1111	Food and Drug Administration Orange Book, "Traimcinolone".	X
1112	NDC Director - Ticanase.xlsx	X
1113	Food and Drug Administration Orange Book, "Fluticasone Propionate".	X
1114	Food and Drug Administration Orange Book, "Olopatadine".	X
1115	Food and Drug Administration Orange Book, "Budesonide".	X
1116	Food and Drug Administration Orange Book, "Mometasone".	X
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1122	Drug Topics, "2010 Top 200 Branded Drugs by Total Prescriptions," June 2011.	X

1123	Food and Drug Administration Orange Book, "Patent Listing: Beconase AQ".	X
1124	McDuff, R. DeForest, "Thinking Economically About Commercial Success," Landslide; 2017.	X
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1126	Ayalew, Kassa, "FDA Perspective on International Clinical Trials," U.S. Federal Food and Drug Administration.	X
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1130	Federal Trade Commission, "Authorized Generic Drugs: Short-Term Effects and Long-Term Impact," Federal Trade Commission, August 2011.	X
1131	Apotex Corp, "Apotex," Pharmacy Times, <a href="http://www.pharmacytimes.com/publications/supplement/2016/generic-supplement-2016/apotex-advancing-generics">http://www.pharmacytimes.com/publications/supplement/2016/generic-supplement-2016/apotex-advancing-generics</a> (Access February 22, 2018).	X
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1134	Bhadoria, Vikas, Ankur Bhajanka, Kaustubh Chakraborty, Palash Mitra, "Helping Indian Pharma Reach its Full Potential," in "Unlocking Pharma Growth, Navigating the Intricacies of Emerging Markets, McKinsey & Company, Pharmaceutical and Medical Products Practice, 2012, pp. 92-103.	X

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1136	Salunke, Sangita, Gauri Pathak, "Assessing Optimum Pricing in the Indian Market," EphMRA, 2011 Pharmaceutical Market Research Conference, Parallel Session 7,, 2011.	X
1137	Gilbert, Tina, Arda Ural, Myriam Lopez, "Five Branded Generics Strategies to Master for Global Pharmaceuticals in Emerging Markets," Accenture Life Sciences, 2012	X
1138	Lanjouw, "Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry," Center for Global Development, Working Paper Number 61, June 2005.	X
1139	Curriculum Vitae of John C. Staines, Jr.	X
1140	Declaration of John C. Staines, Jr.	X
1141	Deposition Transcript of Dr. Alexander Dominic D’Addio, February 21, 2018	X
1142	Deposition Transcript of Dr. Warner W. Carr, February 7, 2018	X
1143	Deposition Transcript of Dr. Hugh David Charles Smyth, January 31, 2018	X
1144	Second Declaration of Dr. Robert Schleimer	X
1145	Second Declaration of Dr. Maureen Donovan (filed under seal)	X
1146	Dell and Colliopoulos, “Avicel® RC/CL, Microcrystalline Cellulose and Carboxymethylcellulose Sodium, NF, BP,” (2001) pp. 1-27	X
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1149	Nairn J.G., “Solutions, Emulsions, Suspensions and Extracts,” Chapter 86 in “Remington: The Science and Practice of Pharmacy,”	X

	19th ed., 1995, pages 1495-1523	
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1151	Schmidt et al., “The New Topical Steroid Ciclesonide is Effective in the Treatment of Allergic Rhinitis,” J Clin Pharmacol 1999; 39: 1062-1069	X
1152	U.S. Patent No. 3,636,200 (“Zentner”)	X
1153	U.S. Patent No. 5,196,436 (“Smith”)	X
1154	U.S. Patent No. 5,658,919 (“Ratnaraj”)	X
1155	U.S. Patent No. 6,565,832 (“Haslwanter”)	X
1156	PCT Publication No. WO01/28563 (“Nagano”)	X
1157	Patent Assignment by and between VIATRIS and MedPointe, executed August 16, 2002	X
1158	E-mail correspondence between Adam LaRock and Michael R. Houston, February 20, 2018 to March 5, 2018	X
1159	Berger et al., “Efficacy of azelastine nasal spray in patients with an unsatisfactory response to loratadine,” Annals of Allergy, Asthma & Immunology, Vol. 91, August 2003, pages 205- 211	X
1160	Corren et al., “Effectiveness of Azelastine Nasal Spray Compared with Oral Cetirizine in Patients with Seasonal Allergic Rhinitis,” Clinical Therapeutics, Vol. 27, No. 5, May 2005, pages 543-553	X
1161	LaForce et al., “Efficacy of azelastine nasal spray in seasonal allergic rhinitis patients who remain symptomatic after treatment with fexofenadine,” Annals of Allergy, Asthma & Immunology, Vol. 93, August 2004, pages 154-159	X
1162	Berger et al., “Impact of azelastine nasal spray on symptoms and quality of life compared with cetirizine oral tablets in patients with seasonal allergic rhinitis,” Annals of Allergy, Asthma & Immunology, Vol., 97, September 2006, pages 375-381	X
1163	Updated Curriculum Vitae of Dr. Robert Schleimer	X
1164	McNeely et al., “Intranasal Azelastine - A Review of its Efficacy in the Management of Allergic Rhinitis,” Drugs 1998 Jul; 56 (1): pages	X

	91-114	
1165	Second Declaration of Dr. Maureen Donovan (redacted version)	X
1166	U.S. Patent No. 8,933,060 (“Lulla”)	X
1167	U.S. Patent No. 8,304,405 (“Lulla”)	X
1168	Kublik et al, “Nasal delivery systems and their effect on deposition and absorption,” Advanced Drug Delivery Reviews 29 (1998) pages 157–177	X
1169	Supplemental Declaration of John C. Staines, Jr.	
1170	Supplemental Declaration of Dr. Robert Schleimer	
1171	Errata to Staines Declaration of March 6, 2018 (Exhibit 1140)	X
1172	Email correspondence from Michael Houston to Adam LaRock dated December 27, 2017	X
1173	Email correspondence from Adam LaRock to Michael Houston dated January 4, 2018	X

Dated: April 10, 2018

By: /Michael R. Houston/

Michael R. Houston  
Reg. No. 58,486  
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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of the foregoing  
**PETITIONER'S EXHIBIT LIST AS OF APRIL 10, 2018** and **Exhibits 1172-1173** were served on April 10, 2018 on Counsel for Patent Owner via electronic mail to the following:

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