

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 MARCH 6, 2018**

Pursuant to 37 C.F.R. § 42.63(e), Petitioner ARGENTUM PHARMACEUTICALS LLC presents a complete list of Petitioner's exhibits, including Exhibits 1057-1168, served on March 6, 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
1016	Kusters, S., <i>et al.</i> , "Effects of Antihistamines on Leukotriene and Cytokine Release from Dispersed Nasal Polyp Cells." ARZNEIM-	X

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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
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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
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1107	Vaidyanathan, Gayathri, "Failings Exposed at India's Drug Regulator," Nature News, May 18, 2012, <a href="https://www.nature.com/news/failings-exposed-at-india-s-drug-regulator-1.10668">https://www.nature.com/news/failings-exposed-at-india-s-drug-regulator-1.10668</a> (Accessed February 13, 2018).	X
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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
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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
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1126	Ayalew, Kassa, "FDA Perspective on International Clinical Trials," U.S. Federal Food and Drug Administration.	X
1127	Weigmann, Katrin, "The Ethics of Global Clinical Trials," EMBO Reports, 16(5): pp. 566-570, 2015.	X
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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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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 ( <b>filed under seal</b> )	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,” 19 <sup>th</sup> ed., 1995, pages 1495-1523	X
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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 91-114	X
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

Dated: March 6, 2018

By: s/*Michael R. Houston*/

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of the foregoing  
**PETITIONER'S EXHIBIT LIST AS OF MARCH 6, 2018** and **Exhibits 1057-1168** were served on March 6, 2018 on Counsel for Patent Owner via electronic mail to the following:

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