UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

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

Ex #	<u>Exhibit</u>	Filed
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	Meda Pharms. Inc. v. Apotex Inc., 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 th 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



Cytokine Release from Dispersed Nasal Polyp Cells." ARZNEIM-FORSCH/DRUG RES., 52(2): 97-102 (Feb. 2002) 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) 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) 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) 1020 Stoloff, R., et al., "Combination Therapy with Inhaled Long-Acting ß2-Agonists and Inhaled Corticosteroids: A Paradigm Shift in Asthma Management," PHARMACOTHERAPY, Vol. 22, No. 2, 212-226 (Feb. 2002) 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) 1022 Cauwenberge, P. et al., "Consensus statement on the treatment of allergic rhinitis," ALLERGY, Vol. 55: 116-134 (2000) Spector, S., "Ideal Pharmacology for Allergic Rhinitis," J. ALLERGY CLIN. IMMUNOL., Vol. 103, No. 3, Part 2, S386-87 (1999) 1024 Bousquet et al., Management of Allergic Rhinitis and Its Impact on Asthma, Journal of Allergy and Clinical Immunology, Vol. 108, No. 5 (2001)			
Topical Glucocorticoid Preparations, J. ALLERGY CLIN. IMMUNOL., Vol. 104, No. 3, Part 1,623-629 (Sept. 1999) 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) 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) 1020 Stoloff, R., et al., "Combination Therapy with Inhaled Long-Acting B2-Agonists and Inhaled Corticosteroids: A Paradigm Shift in Asthma Management," PHARMACOTHERAPY, Vol. 22, No. 2, 212-226 (Feb. 2002) 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) 1022 Cauwenberge, P. et al., "Consensus statement on the treatment of allergic rhinitis," ALLERGY, Vol. 55: 116-134 (2000) 1023 Spector, S., "Ideal Pharmacology for Allergic Rhinitis," J. ALLERGY CLIN. IMMUNOL., Vol. 103, No. 3, Part 2, S386-87 (1999) 1024 Bousquet et al., Management of Allergic Rhinitis and Its Impact on Asthma, Journal of Allergy And Clinical Immunology, Vol. 108, No. 5 (2001) Markham, A., et al., "Inhaled Salmeterol-Fluticasone Propionate Combination, A Review of its Use in Persistent Asthma," Drugs 60(5) 1207-1233 (Nov. 2000)	1016	Cytokine Release from Dispersed Nasal Polyp Cells." ARZNEIM-	X
with other inhaled corticosteroids, J. Allergy Clin. Immunol., Vol. 101, No. 4, Part 2, S434-S439 (1998) 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) 1020 Stoloff, R., et al., "Combination Therapy with Inhaled Long-Acting B2-Agonists and Inhaled Corticosteroids: A Paradigm Shift in Asthma Management," PHARMACOTHERAPY, Vol. 22, No. 2, 212-226 (Feb. 2002) 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) 1022 Cauwenberge, P. et al., "Consensus statement on the treatment of allergic rhinitis," ALLERGY, Vol. 55: 116-134 (2000) 1023 Spector, S., "Ideal Pharmacology for Allergic Rhinitis," J. ALLERGY CLIN. IMMUNOL., Vol. 103, No. 3, Part 2, S386-87 (1999) 1024 Bousquet et al., Management of Allergic Rhinitis and Its Impact on Asthma, JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY, Vol. 108, No. 5 (2001) 1025 Markham, A., et al., "Inhaled Salmeterol-Fluticasone Propionate Combination, A Review of its Use in Persistent Asthma," DRUGS 60(5) 1207-1233 (Nov. 2000)	1017	Topical Glucocorticoid Preparations, J. ALLERGY CLIN. IMMUNOL.,	X
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) 1020 Stoloff, R., et al., "Combination Therapy with Inhaled Long-Acting β2-Agonists and Inhaled Corticosteroids: A Paradigm Shift in Asthma Management," Pharmacotherapy, Vol. 22, No. 2, 212-226 (Feb. 2002) 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) 1022 Cauwenberge, P. et al., "Consensus statement on the treatment of allergic rhinitis," Allergy, Vol. 55: 116-134 (2000) 1023 Spector, S., "Ideal Pharmacology for Allergic Rhinitis," J. Allergy Clin. Immunol., Vol. 103, No. 3, Part 2, S386-87 (1999) 1024 Bousquet et al., Management of Allergic Rhinitis and Its Impact on Asthma, Journal of Allergy and Clinical Immunology, Vol. 108, No. 5 (2001) 1025 Markham, A., et al., "Inhaled Salmeterol-Fluticasone Propionate Combination, A Review of its Use in Persistent Asthma," DRugs 60(5) 1207-1233 (Nov. 2000)	1018	with other inhaled corticosteroids, J. Allergy Clin. Immunol., Vol.	X
B2-Agonists and Inhaled Corticosteroids: A Paradigm Shift in Asthma Management," Pharmacotherapy, Vol. 22, No. 2, 212-226 (Feb. 2002) 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) 1022 Cauwenberge, P. et al., "Consensus statement on the treatment of allergic rhinitis," ALLERGY, Vol. 55: 116-134 (2000) 1023 Spector, S., "Ideal Pharmacology for Allergic Rhinitis," J. ALLERGY CLIN. IMMUNOL., Vol. 103, No. 3, Part 2, S386-87 (1999) 1024 Bousquet et al., Management of Allergic Rhinitis and Its Impact on Asthma, Journal of Allergy AND Clinical Immunology, Vol. 108, No. 5 (2001) 1025 Markham, A., et al., "Inhaled Salmeterol-Fluticasone Propionate Combination, A Review of its Use in Persistent Asthma," DRUGS 60(5) 1207-1233 (Nov. 2000)	1019	complete guidelines of the joint task force on practice parameters in allergy, asthma and immunology," ANNALS OF ALLERGY, ASTHMA &	X
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) 1022 Cauwenberge, P. et al., "Consensus statement on the treatment of allergic rhinitis," ALLERGY, Vol. 55: 116-134 (2000) 1023 Spector, S., "Ideal Pharmacology for Allergic Rhinitis," J. ALLERGY CLIN. IMMUNOL., Vol. 103, No. 3, Part 2, S386-87 (1999) 1024 Bousquet et al., Management of Allergic Rhinitis and Its Impact on Asthma, JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY, Vol. 108, No. 5 (2001) 1025 Markham, A., et al., "Inhaled Salmeterol-Fluticasone Propionate Combination, A Review of its Use in Persistent Asthma," DRUGS 60(5) 1207-1233 (Nov. 2000)	1020	ß2-Agonists and Inhaled Corticosteroids: A Paradigm Shift in Asthma Management," PHARMACOTHERAPY, Vol. 22, No. 2, 212-226	X
allergic rhinitis," ALLERGY, Vol. 55: 116-134 (2000) Spector, S., "Ideal Pharmacology for Allergic Rhinitis," J. ALLERGY CLIN. IMMUNOL., Vol. 103, No. 3, Part 2, S386-87 (1999) Bousquet et al., Management of Allergic Rhinitis and Its Impact on Asthma, JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY, Vol. 108, No. 5 (2001) Markham, A., et al., "Inhaled Salmeterol-Fluticasone Propionate Combination, A Review of its Use in Persistent Asthma," DRUGS 60(5) 1207-1233 (Nov. 2000)	1021	monotherapy versus combination therapy with loratadine tablets and beclomethasone nasal spray in patients with seasonal allergic rhinitis," Annals of Allergy, Asthma & Immunology, Vol. 82,	X
CLIN. IMMUNOL., Vol. 103, No. 3, Part 2, S386-87 (1999) Bousquet et al., Management of Allergic Rhinitis and Its Impact on Asthma, JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY, Vol. 108, No. 5 (2001) Markham, A., et al., "Inhaled Salmeterol-Fluticasone Propionate Combination, A Review of its Use in Persistent Asthma," DRUGS 60(5) 1207-1233 (Nov. 2000)	1022		X
Asthma, JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY, Vol. 108, No. 5 (2001) Markham, A., et al., "Inhaled Salmeterol-Fluticasone Propionate Combination, A Review of its Use in Persistent Asthma," DRUGS 60(5) 1207-1233 (Nov. 2000)	1023		X
Combination, A Review of its Use in Persistent Asthma," DRUGS 60(5) 1207-1233 (Nov. 2000)	1024	Asthma, JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY, Vol.	X
1026	1025	Combination, A Review of its Use in Persistent Asthma," DRUGS	X
· ·	1026		
1027 Ansel, et al., Pharmaceutical Dosage Forms and Drug Delivery Systems, ch. 7 (6th ed. 1995)	1027		X



1028		
1029		
1030	Advair Diskus Prescribing Information (2000)	X
1031	Juniper, E., "First-line Treatment of Seasonal (Ragweed) Rhinoconjunctivitis)," Canadian Medical Association Journal, Vol. 156, No. 8, April 1997, 1123-31.	X
1032		
1033	Wade & Weller, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS (1994)	X
1034	Ratner, P., et al., "A Comparison of the Efficacy of Fluticasone Propionate Aqueous Nasal Spray and Loratadine, Alone and in Combination, for the Treatment of Seasonal Allergic Rhinitis," JOURNAL OF FAMILY PRACTICE, Vol. 47, No. 2, 118-125 (Aug. 1998)	X
1035	Drouin, M., et al. "Adding Loratadine to Topical Nasal Steroid Therapy Improves Moderately Severe Seasonal Allergic Rhinoconjunctivitis." ADVANCES IN THERAPY, 12(6): 340-349; 1995.	X
1036	Simpson, R., Budesonide and terfenadine, separately and in combination, in the treatment of hay fever, ANNALS OF ALLERGY, Vol. 73 497-502 (Dec. 1994)	X
1037		
1038	Brooks, C. et al. "Spectrum of Seasonal Allergic Rhinitis Symptom Relief with Topical Corticoid and Oral Antihistamine Given Singly or in Combination." Am. J. RHINOL., Vol. 10, 193-196 (1996)	X
1039	Juniper, E F., et al., "Comparison of beclomethasone dipropionate aqueous nasal spray, astemizone, and the combination in the prophylactic treatment of ragweed pollen-induced rhinoconjunctivitis," JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY, Vol. 83, No. 3, Cover page, Publications page, 627-633 (Mar. 1989)	X
1040	Benincasa, C. & Lloyd, R.S., "Evaluation of Fluticasone Propionate Aqueous Nasal Spray Taken Alone and in Combination with Cetirizine in the Prophylactic Treatment of Seasonal Allergic Rhinitis," DRUG INVEST., Vol. 8, Issue 4, 225-233 (1994)	X
1041	Galant, S. and Wilkinson, R., "Clinical Prescribing of Allergic	X



	Rhinitis Medication in the Preschool and Young School-Age Child." BIODRUGS, 15(7): 453-463; 2001	
1042	Schleimer, R., "Glucocorticosteroids: Their Mechanisms of Action and Use in Allergic Diseases," ALLERGY PRINCIPLES & PRACTICE, pp.638-660 (1998)	X
1043		
1044		
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
1047	NASACORT AQ Prescribing Information (2013)	X
1048	Rabago, David, et al., "Efficacy of daily hypertonic saline nasal irrigation among patients with sinusitis: A randomized controlled trial," The Journal of Family Practice, Vol. 51, No. 12, 1049-1055 (2002)	X
1049	Budavari, S., et al. (Ed), "Edetate Disodium," The Merck Index, Eleventh Edition, 550 (1989)	X
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



DOCKET

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

