



US008304405B2

(12) **United States Patent**
Lulla et al.

(10) **Patent No.:** **US 8,304,405 B2**
(45) **Date of Patent:** ***Nov. 6, 2012**

- (54) **COMBINATION OF AZELASTINE AND CICLESONIDE FOR NASAL ADMINISTRATION**
- (75) Inventors: **Amar Lulla**, Mumbai (IN); **Geena Malhotra**, Mumbai (IN)
- (73) Assignee: **Cipla Limited**, Mumbai (IN)
- (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **12/508,393**

(22) Filed: **Jul. 23, 2009**

(65) **Prior Publication Data**

US 2009/0318397 A1 Dec. 24, 2009

Related U.S. Application Data

(62) Division of application No. 10/518,016, filed as application No. PCT/GB03/02557 on Jun. 13, 2003, now Pat. No. 8,168,620.

(30) **Foreign Application Priority Data**

Jun. 14, 2002 (GB) 0213739.6

(51) **Int. Cl.**
A01N 45/00 (2006.01)

(52) **U.S. Cl.** **514/171**

(58) **Field of Classification Search** None
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,837,464	A	6/1958	Nobile
3,067,197	A	12/1962	Agnello et al.
3,312,590	A	4/1967	Elks et al.
3,506,694	A	4/1970	Oxley
3,557,162	A	1/1971	Voorschoten et al.
3,639,434	A	2/1972	Oxley et al.
3,755,302	A	8/1973	Ercoli et al.
3,828,080	A	8/1974	May et al.
3,856,828	A	12/1974	Phillipps et al.
3,891,631	A	6/1975	Phillipps et al.
3,981,894	A	9/1976	Phillipps et al.
3,989,686	A	11/1976	Phillipps et al.
4,093,721	A	6/1978	Phillipps et al.
4,113,680	A	9/1978	Kamano et al.
4,187,301	A	2/1980	Edwards
4,188,385	A	2/1980	Edwards
4,198,403	A	4/1980	Alvarez
4,221,787	A	9/1980	Bodor et al.
4,261,984	A	4/1981	Alvarez
4,263,289	A	4/1981	Edwards
4,267,173	A	5/1981	Draper
4,285,937	A	8/1981	Kalvoda
4,310,466	A	1/1982	Edwards
4,335,121	A	6/1982	Phillipps et al.
4,377,575	A	3/1983	Stache et al.
4,472,393	A	9/1984	Shapiro
4,607,028	A	8/1986	Schmidlin
4,710,495	A	12/1987	Bodor
4,861,765	A	8/1989	Mitsukuchi et al.
4,992,474	A	2/1991	Skidmore et al.

5,063,222	A	11/1991	Komoto et al.
5,081,113	A	1/1992	Claussner et al.
5,086,050	A	2/1992	Hettche et al.
5,164,194	A	11/1992	Hettche
5,202,316	A	4/1993	Claussner et al.
5,232,919	A	8/1993	Scheffler et al.
5,271,946	A	12/1993	Hettche
5,362,721	A	11/1994	Stache et al.
5,420,120	A	5/1995	Boltralik
5,608,093	A	3/1997	Stache et al.
5,658,549	A	8/1997	Akehurst et al.
5,658,919	A	8/1997	Ratnaraj et al.
5,707,984	A	1/1998	Tjoeng et al.
5,837,699	A	11/1998	Sequeira et al.
5,849,265	A	12/1998	Li-Bovet et al.
5,889,015	A	3/1999	Sequeira et al.
5,914,122	A	6/1999	Otterbeck et al.
5,972,920	A	10/1999	Seidel
5,981,517	A	11/1999	Bodor
6,017,963	A	1/2000	Alfonso et al.
6,057,307	A	5/2000	Sequeira et al.
6,127,353	A	10/2000	Yuen et al.
6,136,294	A	10/2000	Adjei et al.
6,197,761	B1	3/2001	Biggadike et al.

(Continued)

FOREIGN PATENT DOCUMENTS

AU 2003244799 B2 12/2003

(Continued)

OTHER PUBLICATIONS

Schmidt et al., The new topical steroid ciclesonide is effective in the treatment of allergic rhinitis, *Journal of Clinical Pharmacology*, vol. 39, No. 10, pp. 1062-1069, 1999.*

Applicants response to foreign communication—EP 03738280.1, May 22, 2006, 36 pages.

Applicants response to foreign communication—EP 03738280.1, Jan. 18, 2008, 14 pages.

Busse, W. W., et al., "Corticosteroid-sparing effect of azelastine in the management of bronchial asthma," *American Journal of Respiratory and Critical Care Medicine*, 1996, pp. 122-127, vol. 153, No. 1, American Lung Association, New York, NY, XP-000604179.

Foreign communication from the priority application—Search Report, GB 0213739.6, Nov. 22, 2002, 4 pages.

Foreign communication from the priority application—International Search Report, PCT/GB03/02557, Sep. 17, 2003, 3 pages.

(Continued)

Primary Examiner — James H. Alstrum-Acevedo

Assistant Examiner — Thor Nielsen

(74) *Attorney, Agent, or Firm* — Conley Rose, P.C.; Rodney B. Carroll

(57) **ABSTRACT**

A pharmaceutical product or formulation, which comprises azelastine or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and a steroid, or a pharmaceutical acceptable salt, solvate or physiologically functional derivative thereof, preferably the product or formulation being in a form suitable for nasal or ocular administration.

Exhibit 1167

- Foreign communication from a related counterpart application— Examination Report, EP Application 03738280.1, Jul. 18, 2007, 5 pages.
- May, Percy, et al., “May’s Chemistry of Synthetic Drugs,” Fifth Edition, 1964, pp. 12-17, Longmans.
- Patent application entitled “Combination of azelastine and steroids,” by Amar Lulla, et al., filed Jul. 23, 2009 as U.S. Appl. No. 12/508,388.
- Portman, D. et al., “Acceptability of local treatment of allergic rhinitis with a combination of a corticoid (beclomethasone) and an antihistaminic (azelastine),” Database Medline, 2000, vol. 121, No. 4, pp. 273-279, XP-002252974.
- Office Action dated Jan. 23, 2009, (27 pages), U.S. Appl. No. 10/518,016, filed Jul. 6, 2005.
- ABPI Compendium of Data Sheets and Summaries of Product Characteristics, 1999-2000, Cover page, p. 43 and Index p. 1882, Datapharm Publications Limited, London, Great Britain.
- 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, Nov. (Part II) 1998, pp. 478-518.
- Foreign communication from a related counterpart application— Notice of Opposition, EP Application 03738280.1, Feb. 22, 2010, 22 pages.
- Office Action (Final) dated Apr. 28, 2010, (29 pages), U.S. Appl. No. 10/518,016, filed Jul. 6, 2005.
- Preservative, definition of. Composite definition of preservative in the Medical dictionary, from internet site <http://medical-dictionary.thefreedictionary.com/preservative>, dated Nov. 4, 2009, 3 pages.
- Herrero, Vanrell, R., “Preservatives in Ophthalmic Formulations: An Overview,” *Arch. Soc. Esp. Oftalmol*, 2007, vol. 82., pp. 531-532.
- Hodges, Norman, et al., “Antimicrobial Preservative Efficacy Testing,” *Handbook of Microbiological Quality Control, Pharmaceuticals and Medical Devices*, 2000, p. 168 Plus cover page and publication page, Taylor & Francis Publisher, USA and Canada.
- Johnson, Malcom, “Development of fluticasone propionate and comparison with other inhaled corticosteroids,” *J. Allergy Clin. Immunol.*, Apr. 1998, vol. 101, No. 4, Part 2, pp. S434-S439.
- Patent Application entitled “Combination of Azelastine and Steroids,” by Amar Lulla, et al., filed Sep. 10, 2010 as U.S. Appl. No. 12/879,515.
- Office Action dated Sep. 30, 2010, U.S. Appl. No. 12/508,388, filed Jul. 23, 2009, 22 pages.
- Product Information, Nasonex®, Aug. 2001, 22 pages, Schering Corporation, Kenilworth, NJ, US.
- Product Specification Bulletin, Avicel® RC-591, Bulletin AVC591-SPEC-02/09.RS, 2 pages, FMC BioPolymer.
- Product Specification Bulletin, Avicel® CL-611, Bulletin AVC611-SPEC-02/09.RS, 2 pages, FMC BioPolymer.
- 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*, Jan. 2008, vol. 100, Cover page, publishing page, pp. 74-81.
- Ratner, Paul H., 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,” *The Journal of Family Practice*, Aug. 1998, vol. 47, No. 2, pp. 118-125, Appleton & Lange.
- Reddy, Indra K., ed., “Ocular Therapeutics and Drug Delivery: A Multi-Disciplinary Approach,” 1996, pp. 382-385 plus cover page and publication page, Technomic Publishing Company, Inc.
- Safety Data Sheet, SDS No. 110556, Jul. 4, 2008, V14, Flonase Nasal Spray, 5 pages, GlaxoSmithKline.
- Safety Data Sheet, SDS No. 110536, Jun. 23, 2008, V13, Beconase Hayfever Allergy Spray, 5 pages, GlaxoSmithKline.
- Salib Rami Jean, et al., “Safety and Tolerability Profiles of Intranasal Antihistamines and Intranasal Corticosteroids in the Treatment of Allergic Rhinitis,” *Drug Safety* 2003, vol. 26, No. 12, Cover page, publication page, pp. 863-893, ADIS Data Information BV.
- Simpson, Richard J., “Budesonide and terfenadine, separately and in Spector, Sheldon, “Ideal pharmacotherapy for allergic rhinitis,” *J Allergy Clin Immunol*, 1999, vol. 103, No. 3, Part 2, pp. S386-S387, Mosby, Inc.
- Wang, De-Yun, “Treatment of Allergic Rhinitis: H1-Antihistamines and Intranasal Steroids,” *Current Drug Targets—Inflammation & Allergy*, 2002, vol. 1, pp. 215-220, Bentham Science Publishers Ltd.
- Wiseman, Lynda R., et al., “Intranasal Fluticasone Propionate: A Reappraisal of its Pharmacology and Clinical Efficacy in the Treatment of Rhinitis,” *Drugs*, 1997, vol. 53, No. 5, pp. 885-907, Adis International Limited.
- World Review 2001: The Pharmaceutical Market, vol. 1 International, IMS Health, 2001, cover, preface, and copyright pages plus pp. 4-42 and 5-1 through 5-11, IMS A.G.
- Applicant Response to foreign communication EP Patent 1519731, Aug. 11, 2011, 252 pages.
- ABPI Data Sheet Compendium, 1995-96, cover page plus pp. 38-39, Datapharm Publications Limited, London, Great Britain.
- Akerlund, Anders, et al., “Clinical trial design, nasal allergen challenge models, and considerations of relevance to pediatrics, nasal polyposis, and different classes of medication,” *J. Allergy Clin. Immunol.*, Mar. 2005, vol. 115, No. 3, pp. S460-S482.
- Applicants response to foreign communication—KR10-2004-7020819, Dec. 27, 2010, 18 pages.
- Applicants response to foreign communication—EP 03738280.1 (EP Patent 1519731), Sep. 6, 2010, 15 pages.
- Applicants response to foreign communication—CA 2489427, Dec. 20, 2010, 10 pages.
- Avicel® RC/CL, Microcrystalline Cellulose and Carboxymethylcellulose Sodium, NF Dispersible Cellulose, BP, Specifications and Analytical Methods, RC-16 Updated Oct. 1995 (Feb. 1999), 6 pages, FMC BioPolymer.
- Opposition to EP 1518731, Aug. 8, 2011, 19 pages.
- Aurora, Jack, “Nasal Delivery; Development of Nasal Delivery Systems: A Review,” *Drug Delivery Technology*, vol. 2, No. 7, Oct. 2002, 8 pages, <http://www.drugdeliverytech.com/ME2/Segments/Publications:Article&id=9EB19EB2F29F462089CE081473F5F3CA>.
- Baena-Cagnani, Carlos E., “Safety and Tolerability of Treatments for Allergic Rhinitis in Children,” *Drug Safety* 2004, vol. 27, No. 12, pp. 883-898, ADIS Data Information BV.
- Barnes, M. L., et al., “Effects of levocetirizine as add-on therapy to fluticasone in seasonal allergic rhinitis,” *Clinical and Experimental Allergy*, Jan. 27, 2006, vol. 36, pp. 676-684, Blackwell Publishing Ltd.
- Berge, Stephen M., et al., “Pharmaceutical Salts,” *Journal of Pharmaceutical Sciences*, vol. 66, No. 1, Jan. 1977, pp. 1-19.
- Block, John H., et al., “Inorganic Medicinal and Pharmaceutical Chemistry,” 1986, cover, publication, and preface pages plus p. 100, Indian Edition, Varghese Publishing House, Bombay, India.
- Cipla Sixty-Ninth Annual Report 2004-2005, cover pages, information page, plus pp. 3, 5, and 44.
- Di Lorenzo, G., et al., “Randomized Placebo-controlled Trial Comparing fluticasone aqueous nasal spray in mono-therapy, fluticasone plus cetirizine, fluticasone plus montelukast and cetirizine plus montelukast for seasonal allergic rhinitis,” *Clin. Exp. Allergy*, 2004, vol. 34, pp. 259-267., Blackwell Publishing Ltd.
- Duonase Data Sheet, “The Complete Rhinitis Control,” 6 pages, Cipla Limited, Mumbai, India, 1900.
- Drouin, Michel A., et al., “Adding Loratadine to Topical Nasal Steroid Therapy Improves Moderately Severe Seasonal Allergic Rhinoconjunctivitis,” *Advances in Therapy*, vol. 12, No. 6, Nov./Dec. 1995, pp. 340-349, Health Communications Inc.
- File history of Australian Patent Application No. AU2003244799, 38 pages, 1900.
- File history of Brazilian Patent Application No. PI 0312128-3, 27 pages, 1900.
- File history of Canadian Patent Application No. 2,489,427, 19 pages, 1900.
- File history of Korean Patent Application No. 10-2004-7020819, 89 pages.

- File history of Polish Patent Application No. P-373001, 95 pages, 1900.
- File history of Russian Patent Application No. RU 2361593 C2, 65 pages, 1900.
- File history of South African Patent Application No. 2005/0331 (now Patent No. 2005/0331), 18 pages.
- Foreign communication from a related counterpart application—CA2,489,427, Examination Report, Jun. 18, 2010, 3 pages.
- Foreign communication from a related counterpart application—CA2,489,427, Examination Report, Mar. 24, 2011, 2 pages.
- Foreign communication from a related counterpart application—EP Application 03738280.1, Examination Report, Nov. 10, 2005, 4 pages.
- Foreign communication from a related counterpart application—EP Application 03738280.1, Examination Report, Jul. 18, 2007, 5 pages.
- Foreign communication from a related counterpart application—EP Application 03738280.1, Notice of Intent to Grant, Oct. 23, 2008, 6 pages.
- Foreign communication from a related counterpart application—Summons to Attend Oral Proceedings, EP Application 03738280.1, Feb. 8, 2011, 1 page.
- Foreign communication from a related counterpart application—AU2003244799, Examination Report, Nov. 20, 2007, 2 pages.
- Foreign communication from a related counterpart application—KR 10-2004-7020819, Examination Report, Aug. 26, 2010, 8 pages.
- Foreign communication from a related counterpart application—Examination Report, RU 2005100781, Apr. 23, 2007, 6 pages.
- Foreign communication from a related counterpart application—Examination Report, RU 2005100781, May 23, 2008, 3 pages.
- Foreign communication from a related counterpart application—Translation of Office Action, Israel Patent Application 165771, Jul. 11, 2011, 3 pages.
- Galant, Stanley P., et al., “Clinical Prescribing of Allergic Rhinitis Medication in the Preschool and Young School-Age Child, What are the Options?,” *BioDrugs* 2001, vol. 15, No. 7, pp. 453-463, ADIS International Ltd.
- Gennaro, Alfonso R., ed., et al., *Remington: The Science and Practice of Pharmacy*, 2000, 20th edition, vol. 1, pp. 785, 830, 831 plus cover page and publication page, Lippincott Williams & Wilkins.
- Gilbert, Peter, et al., “Preservation of Pharmaceutical Products,” *Encyclopedia of Pharmaceutical Technology*, 2002, 2nd edition, vol. 3, p. 2278 plus cover page and publication page, Marcel Dekker, Inc.
- Hodges, N. A., et al., “Preservative Efficacy Tests in Formulated Nasal Products: Reproducibility and Factors Affecting Preservative Activity,” *J. Pharm. Pharmacol.*, 1996, vol. 48, pp. 1237-1242.
- Howarth, P. H., “A comparison of the anti-inflammatory properties of intranasal corticosteroids and antihistamines in allergic rhinitis,” *Allergy* 2000, vol. 62, pp. 6-11, Munksgaard 2000.
- 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*, Mar. 1989, vol. 83, No. 3, Cover page, Publications page, pp. 627-633, American Academy of Allergy and Immunology, C.V. Mosby Co.
- McNeely, Wendy, et al., “Intranasal Azelastine: A Review of its Efficacy in the Management of Allergic Rhinitis,” *Drugs*, 1998, vol. 56, No. 1, pp. 91-114.
- Meltzer, Eli O., “Allergic rhinitis: Managing the pediatric spectrum,” *Allergy and Asthma Proceedings*, Jan.-Feb. 2006, vol. 27, No. 1, pp. 2-8, Oceanside Publications, Inc., USA.
- Nielsen, Lars P., “Comparison of Intranasal Corticosteroids and Antihistamines in Allergic Rhinitis. A Review of Randomized, Controlled Trials,” *Am. J. Respir Med.* 2003, vol. 2, No. 1, Cover page, publishing page, pp. 55-65., ADIS International Limited.
- Nielsen, Lars Peter, et al., “Intranasal Corticosteroids for Allergic Rhinitis, Superior Relief?,” *Drugs* 2001, vol. 61, No. 11, pp. 1563-1579, ADIS International Ltd.
- Office Action dated Feb. 16, 2011, (22 pages), U.S. Appl. No. 10/518,016, filed Jul. 6, 2005.
- Office Action (Final) dated Feb. 18, 2011 (23 pages), U.S. Appl. No. 12/508,388, filed Jul. 23, 2009.
- Prescribing Information for Astepro®, Nov. 2010, 20 pages, Meda Pharmaceuticals Inc., Somerset, NJ, US.
- Prescribing Information for Rhinocort Aqua™, Dec. 2010, 32 pages, AstraZeneca LP, Wilmington, DE, US.
- “Azelastine,” STN Registry No. 58581-89-8, STN Registry File, Retrieved Nov. 23, 2010, p. 1.
- “Fluticasone Furoate,” STN Registry No. 397864-44-7, STN Registry File, Retrieved Nov. 23, 2010, p. 1.
- Astelin (azelastine hydrochloride) Nasal Spray, MedPointe Pharmaceuticals, 2006, U.S. Physicians Desk Reference, pp. 1876-1877.
- Veramyst (fluticasone furoate) Nasal Spray, GlaxoSmithKline, 2007, Summary Sheet, pp. 1-20.
- Astebro (azelastine HCl) Nasal Spray 0.15%, Meda Pharmaceuticals Inc., 2009, Press Release, pp. 1-4.
- Aigbirhio, Franklin I., et al., “Automated radiosynthesis of no-carrier-added [S-fluoromethyl-18F]Fluticasone propionate as a radiotracer for lung deposition studies with PET,” *Journal of Labelled Compounds and Radiopharmaceuticals*, vol. 39, No. 7, 1997, pp. 569-584.
- Austin, et al., “Mometasone furoate is a less specific glucocorticoid than fluticasone propionate,” *Eur. Respir. J.*, 2002, vol. 20, pp. 1386-1392.
- Banov, et al., “Once daily intranasal fluticasone propionate is effective for perennial allergic rhinitis,” *Annals of Allergy*, 1994, vol. 73, pp. 240-246.
- Barnes, Peter J., “Chronic obstructive pulmonary disease: new opportunities for drug development,” *Trends in Pharmacological Sciences*, vol. 19, No. 10, 1998, pp. 415-423.
- Barnes, Peter J., “Novel approaches and targets for treatment of chronic obstructive pulmonary disease,” *American Journal of Respiratory and Critical Care Medicine*, vol. 160, 1999, pp. S72-S79.
- Barnes, Peter J., “Efficacy of inhaled corticosteroids in asthma,” *The Journal of Allergy and Clinical Immunology*, vol. 102, No. 4, 1998, pp. 531-538, 1998.
- Baumgarten, C., et al., “Initial treatment of symptomatic mild to moderate bronchial asthma with the salmeterol/fluticasone propionate (50/250µg) combination product (SAS 40023),” *European Journal of Medical Research*, 2002, vol. 7, pp. 1-7.
- Berstein, et al., “Treatment with intranasal fluticasone propionate significantly improves ocular symptoms in patients with seasonal allergic rhinitis,” *Clin. Exp. Allergy*, 2004, vol. 34, pp. 952-957.
- Bowler, Simon, “Long acting beta agonists,” *Australian Family Physician*, vol. 27, No. 12, 1998, pp. 1115, 1117-1118, plus cover.
- Brooks, et al., “Spectrum of seasonal allergic rhinitis symptom relief with topical corticoid and oral antihistamine given singly or in combination,” *American Journal of Rhinology*, 1996, vol. 10, No. 3, pp. 193-199.
- Bryson, et al., “Intranasal fluticasone propionate: a review of its pharmacodynamic and pharmacokinetic properties, and therapeutic potential in allergic rhinitis,” *Drugs*, 1992, vol. 43, No. 5, pp. 760-775.
- Busse, William, et al., “Steroid-sparing effects of fluticasone propionate 100µg and salmeterol 50 µg administered twice daily in a single product in patients previously controlled with fluticasone propionate 250 µg administered twice daily,” *J. Allergy Clin. Immunol.*, vol. 111, No. 1, Jan. 2003, pp. 57-65.
- CAS Registry No. 102113-40-6, 2004.
- CAS Registry No. 90566-53-3, “Fluticasone,” Nov. 16, 1984.
- Chapman, et al., “Anti-inflammatory activity of inhaled mometasone furoate in allergic mice,” *Arzneimittelforschung (“Drug Research”)*, 1998, vol. 48, No. 4, pp. 384-391.
- Daley-Yates, et al., “Systemic bioavailability of fluticasone propionate administered as nasal drops and aqueous nasal spray formulations,” *Br. J. Clin. Pharmacol.*, 2001, vol. 51, pp. 103-105.
- Derby, et al., “Risk of cataract among users of intranasal corticosteroids,” *J. Allergy Clin. Immunol.*, 2000, vol. 105, No. 5, pp. 912-916.
- Dewester, et al., “The efficacy of intranasal fluticasone propionate in relief of ocular symptoms associated with seasonal rhinitis,” *Allergy and Asthma Proc.*, 2003, vol. 24, No. 5, pp. 331-337.
- Dictionary of Organic Compounds, 6th Ed., vol. 1, p. 3234 plus cover

- Dolovich, et al., "Multicenter trial of fluticasone propionate aqueous nasal spray in ragweed allergic rhinitis," *Annals of Allergy*, 1994, vol. 73, No. 2, pp. 147-153.
- Fowler, Stephen J., et al., "Step-down therapy with low-dose fluticasone-salmeterol combination or medium-dose hydrofluoroalkane 134a-beclomethasone alone," *J. Allergy Clin. Immunol.*, vol. 109, No. 6, Jun. 2002, pp. 929-935.
- Garner, R. C., et al., "A validation study comparing accelerator MS and liquid scintillation counting for analysis of ¹⁴C-labelled drugs in plasma, urine and faecal extracts," *Journal of Pharmaceutical and Biomedical Analysis*, vol. 24, 2000, pp. 197-209.
- Gawchik, et al., "Comparison of intranasal triamcinolone acetonide with oral loratadine in the treatment of seasonal ragweed-induced allergic rhinitis," *Am. J. Man. Care*, 1997, vol. 3, No. 7, pp. 1052-1058.
- Harding, "The human pharmacology of fluticasone propionate," *Respiratory Medicine*, 1990, vol. 84, Suppl. A, pp. 25-29.
- Howland, "Fluticasone propionate: topical or systemic effects?" *Clinical and Experimental Allergy*, 1996, vol. 26, Suppl. 3, pp. 18-22.
- Isogai, et al., "Binding affinities of mometasone furoate and related compounds including its metabolites for the glucocorticoid receptor of rat skin tissue," *J. Steroid Biochem. Mol. Biol.*, 1993, vol. 44, pp. 141-145.
- Johansson, Gunnar, et al., "Comparison of salmeterol/fluticasone propionate combination with budesonide in patients with mild-to-moderate asthma," *Clin. Drug Invest.*, vol. 21, No. 9, 2001, pp. 633-642, 11 pages, Adis International Limited.
- Juniper, Elizabeth F., et al., "Impact of inhaled salmeterol/fluticasone propionate combination product versus budesonide on the health-related quality of life of patients with asthma," *Am. J. Respir. Med.*, vol. 1, No. 6, 2002, pp. 435-440.
- Kenley, Richard A., et al., "An automated, column-switching HPLC method for analyzing active and excipient materials in both cream and ointment formulations," *Drug Development and Industrial Pharmacy*, vol. 11 (9 & 10), 1985, pp. 1781-1796.
- Kertesz, Denis J., et al., "Thiol esters from steroid 17 β -carboxylic acids: carboxylate activation and internal participation by 17 α -acylates," *J. Org. Chem.*, vol. 51, 1986, 14 pages.
- Knobil, K., et al., "Adding salmeterol is more effective than increasing the dose of fluticasone for patients with asthma who are symptomatic on low dose fluticasone," *European Respiratory Review*, Copenhagen, DK, vol. 12, Suppl. 29, Dec. 1998, pp. 19S-20S plus cover page.
- Kooreman, et al., "The synthesis of 17-esters of corticosteroids protection of 11 β -hydroxyl of the trimethylsilyl group," *Synthetic Communications*, vol. 1, No. 2, pp. 81-87, 1971.
- Laforce, et al., "Fluticasone propionate: an effective alternative treatment for seasonal allergic rhinitis in adults and adolescents," *J. Fam. Pract.*, 1994, vol. 38, No. 2, pp. 145-152.
- Lane, S. J., et al., "Evaluation of a new capillary electrochromatography/mass spectrometry interface using short columns and high field strengths for rapid and efficient analyses," *Rapid Communications in Mass Spectrometry*, vol. 10, 1996, pp. 733-736.
- Lewis, Sarah A., et al., "Association of specific allergen sensitization with socioeconomic factors and allergic disease in a population of Boston women," *J. Allergy Clin. Immunol.*, vol. 107, No. 4, Apr. 2001, pp. 615-622.
- Li, et al., "Synthesis of aryl 5-(2-chlorophenyl)-2-furoates under phase transfer catalysis," *Synthetic Communications*, vol. 32, No. 20, pp. 3081-3086, 2002.
- Linder, "Symptom scores as measurements of the severity of rhinitis," *Clinical Allergy*, 1988, vol. 18, pp. 29-37.
- Lumry, William R., "A review of the preclinical and clinical data of newer intranasal steroids in the treatment of allergic rhinitis," *Allergy Clin. Immunol.*, Oct. 1999, 104 (4 Pt 1), pp. S150-S158 plus one correction page.
- Lutsky, et al., "A novel class of potent topical antiinflammatory agents: 17-benzoylated, 7 α -halogeno substituted corticosteroids," *Arzneimittelforschung ("Drug Research")*, 1978, vol. 29, No. 11, pp. 1662-1667.
- Lyseng-Williamson, Katherine A., et al., "Inhaled salmeterol/Mahoney, Janette M., et al., "Drug effects on the neovascularization response to silver nitrate cauterization of the rat cornea," *Current Eye Research*, vol. 4, No. 5, 1985, pp. 531-535.
- Meltzer, et al., "Onset of therapeutic effect of fluticasone propionate aqueous nasal spray," *Ann. Allergy Asthma Immunol.*, 2001, vol. 86, No. 3, pp. 286-291.
- Millard, Jeffrey W., et al., "Solubilization by cosolvents establishing useful constants for the log-linear model," *Int'l Journal of Pharmaceutics*, vol. 245, 2002, pp. 153-166.
- Mistry, Nisha, et al., "Characterisation of impurities in bulk drug batches of fluticasone propionate using directly coupled HPLC-NMR spectroscopy and HPLC-MS," *Journal of Pharmaceutical and Biomedical Analysis*, vol. 16, 1997, pp. 697-705.
- Mistry, Nisha, et al., "Impurity profiling in bulk pharmaceutical batches using 19F NMR spectroscopy and distinction between monomeric and dimeric impurities by NMR-based diffusion measurements," *Journal of Pharmaceutical and Biomedical Analysis*, vol. 19, 1999, pp. 511-517.
- Möllmann, H., et al., *Handbook of pharmacokinetic / pharmacodynamic correlation*, Chapter 14, *Pharmacokinetic-Pharmacodynamic Correlations of Corticosteroids*, 323-336 plus cover and publishing pages, CRC Press, 1995.
- Moreno-Vargas, et al., "Synthesis and glycosidase inhibitory activities of 5-(1',4'-dideoxy-1',4'-imino-D-erythrosyl)-2-methyl-3-furoic acid (=5-[(3S,4R)-3,4-dihydroxypyrolidin-2-yl]-2-methylfuran-3-carboxylic acid) derivatives: new leads as selective alpha-L-fucosidase and beta-galactosidase inhibitors," *Helvetica Chimica Acta*, vol. 86, pp. 1894-1913, 2003.
- Naedele-Risha, R., et al., "Dual components of optimal asthma therapy: scientific and clinical rationale for the use of long acting beta-agonists with inhaled corticosteroids," *The Journal of the American Osteopathic Association*, vol. 101, No. 9, Sep. 2001, pp. 526-533.
- Nathan, et al., "A once daily fluticasone propionate aqueous nasal spray is an effective treatment for seasonal allergic rhinitis," *Annals of Allergy*, 1991, vol. 67, pp. 332-338.
- Nelson, Harold, S., et al., "Fluticasone propionate-salmeterol combination provides more effective asthma control than low-dose inhaled corticosteroid plus montelukast," *J. Allergy Clin. Immunol.*, vol. 106, No. 6, Dec. 2000, pp. 1088-1095.
- O'Conner, B. J., "Combination therapy," *Pulmonary Pharmacology and Therapeutics*, vol. 11, No. 5/6, 1998, pp. 397-399.
- Ong, John T. H., et al., "Micellar solubilization of timobesone acetate in aqueous and aqueous propylene glycol solutions of nonionic surfactants," *Pharmaceutical Research*, vol. 5, No. 11, 1988, pp. 704-708.
- Ong, John T. H., et al., "Intrinsic potencies of novel thiol ester corticosteroids RS-85095 and RS-21314 as compared with clobetasol 17-propionate and fluocinonide," *Arch Dermatol*, vol. 125, Dec. 1989, pp. 1662-1665.
- Onrust, et al., "Mometasone furoate, a review of its intranasal use in allergic rhinitis," *Drugs*, vol. 56, No. 4, Oct. 1998, pp. 725-745, vol. 21.
- Holgate, Stephen T., *Difficult Asthma*, 1999, cover page and publishing information.
- PCT/GB01/03495, International Preliminary Examination Report, date of completion of report: Aug. 30, 2002.
- Pettersson, Bertil, et al., "Re-evaluation of the classical mycoplasma lipophilum cluster (Weisburg, et al., 1989) and description of two new clusters in the hominis group based on 16S rDNA sequences," *Int'l Journal of Systematic & Evolutionary Microbiology*, 2001, vol. 51, pp. 633-643, IUMS, Great Britain.
- Phillips, G. H., et al., "Synthesis and structure activity relationships in a series of anti-inflammatory corticosteroid analogues, halomethyl androstane-17 β -carbothioates and-17 β -carbosenoates," *Journal of Medicinal Chemistry*, 1994, vol. 37, pp. 3717-3729.
- Popper, T. L., et al., "Structure-activity relationships of a series of novel topical corticosteroids," *Journal of Steroid Biochemistry*, 1987, vol. 27, pp. 837-843, Pergamon Journals Ltd.
- Product Information Flonase (Fluticasone propionate) Nasal Spray 50 mcg, Mar. 2004, pp. 1-13, GlaxoSmithKline.

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.