

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
PETITIONER

v.

COSMO TECHNOLOGIES LIMITED,
PATENT OWNER

CASE IPR2017-01035
Patent 9,320,716

PATENT OWNER'S EXHIBIT LIST

Mail Stop: PATENT BOARD
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

TABLE OF EXHIBITS

Patent Owners Exhibit No.	Description
2001	M. Brunner et al., "Gastrointestinal transit, release and plasma pharmacokinetics of a new oral budesonide formulation", <i>British Journal of Clinical Pharmacology</i> , 2005; 61:1, 31-38.
2002	I. Wilding, "Bioequivalence Testing for Locally Acting Gastrointestinal Products: What Role for Gamma Scintigraphy?", <i>JClin Pharmacol</i> 2002; 42:1200-1210.
2003	Redacted letter re joint status report filed June 7, 2017 in <i>Cosmo Technologies Limited, et al. v. Mylan Pharmaceuticals Inc., et al</i> , CA No. 16-152-LPS (D. Delaware).
2004	R. Hamedani et al., "Review article: Drug development in inflammatory bowel disease: budesonide - a model of targeted therapy", <i>Aliment Pharmacol Ther</i> 1997; 11 (Suppl. 3): 98-108.
2005	I. Koutroubakis. "Recent advances in the management of distal ulcerative colitis", <i>World J Gastrointest Pharmacol Ther</i> 2010 April 6; 1(2): 43-50.
2006	W. Sandborn, "Step-Up Versus Top-Down Therapy in the Treatment of Ulcerative Colitis" <i>Gastroenterology & Hepatology</i> Volume 3, Issue 1, January 2007.
2007	W. Sandborn et al., "Once-Daily Budesonide MMX® Extended-Release Tablets Induce Remission in Patients With Mild to Moderate Ulcerative Colitis: Results From the CORE I Study", <i>Gastroenterology</i> 2012;143:1218–1226.
2008	C. J. Kenyon et al., "Colonic delivery of dexamethasone: a pharmacoscintigraphic evaluation", <i>Aliment Pharmacol Ther</i> 1997; 11: 205-213.
2009	R. Lofberg, "New data on inflammatory bowel disease treatment with topical steroids", <i>Research and Clinical Forums</i> , Volume 20, Number 1, 1998.
2010	R. Lofberg, "Reviewing Steroids in the Treatment of IBD", <i>Research and Clinical Forums</i> , Volume 15, Number 5, 1993.

Patent Owners Exhibit No.	Description
2011	Amendment and Response submitted July 1, 2013 in prosecution of U.S. App. No. 13/617,138.
2012	Amendment and Response submitted February 21, 2014 in prosecution of U.S. App. No. 13/617,138.
2013	Amendment and Remarks submitted February 17, 2016 in prosecution of U.S. App. No. 14/308,279.
2014	Merriam-Webster's Collegiate Dictionary, Tenth Edition, 1993.
2015	McGraw-Hill Dictionary of Scientific and Technical Terms, Fifth Edition, 1994.
2016	U.S. Pat. No. 8,293,273; issued Oct. 23, 2012
2017	A. J. Greenstein et al., "Differences in pathogenesis, incidence and outcome of perforation in inflammatory bowel disease", Surgery – Gynecology & Obstetrics, January 1985, Volume 160, Number 1.
2018	M.E. Aulton, "Pharmaceutics – The science of dosage form design", 1988.
2019	J. N. Staniforth., "Ordered Mixing or Spontaneous Granulation?", Powder Technology, 45 (1985) 73-77 .
2020	H. C. Ansel et al., "Pharmaceutical Dosage Forms and Drug Delivery Systems", Seventh Edition, 1999.
2021	M. J. Crooks et al., "Ordered Mixing in Direct Compression of Tablets", Powder Technology, 14 (1976) 161 – 167.
2022	J. A. Hersey, "Ordered Mixing: A New Concept in Powder Mixing Practice", Powder Technology. 11 (1975) 41-44.
2023	W. Shi et al., "Macro- and micro-mixing of a cohesive pharmaceutical powder during scale up", Powder Technology 274 (2015) 319–323.
2024	U.S. Pat. No. 3,974,249; issued Aug. 10, 1976.
2025	Transcript of court proceedings held May 23, 2017 in <i>Cosmo Technologies Limited, et al. v. Actavis Laboratories, et al.</i> , CA No. 15-164-LPS (D. Delaware).

Patent Owners Exhibit No.	Description
2026	R. Lofberg, "Oral Budesonide Versus Prednisolone in Patients With Active Extensive and Left-Sided Ulcerative Colitis", <i>Gastroenterology</i> 1996; 110:1713–1718.
2027	J. Corren, "Intranasal corticosteroids for allergic rhinitis: How do different agents compare?" <i>J Allergy Clin Immunol</i> 1999; 104:S144-9.
2028	D. R. Friend, "Review article: issues in oral administration of locally acting glucocorticosteroids for treatment of inflammatory bowel disease", <i>J Allergy Clin Immunol</i> 1999; 104:S144-9.
2029	"Handbook of Pharmaceutical Excipients", 1987.
2030	A. Nicholls, "Bioavailability profile of Uceris [®] MMX [®] extended release tablets compared with Entocort [®] EC capsules in healthy volunteers", <i>Journal of International Medical Research</i> 0(0), 2013, 1-9.
2031	H. N. E. Stevens, "Pulsincap [™] and Hydrophilic Sandwich Capsules: Innovative Time-Delayed Oral Drug Delivery Technologies", <i>Modified-Release Drug Delivery Technology, Second Edition, Volume 1</i> , 2013.
2032	J. M. Hebden, "Regional Differences in Quinine Absorption from the Undisturbed Human Colon Assessed Using a Timed Release Delivery System", <i>Pharmaceutical Research</i> , Vol. 16, No. 7, 1999.
2033	International Patent Application Publication WO 92/16206, published October 1, 1992.
2034	National Library of Medicine – PubMed Health entry for “Colon (Bowel)”, last accessed June 22, 2017 from https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0022229/
2035	“Textbook of Gastroenterology” (Yamada, Ed.) 1991

IPR2017-01035
Patent No. 9,320,716

Respectfully submitted,

Dated: June 22, 2017

By: /s/ Gary N. Frischling
Gary N. Frischling, Reg. No. 35,515
Yite John Lu, Reg. No. 63,158
IRELL & MANELLA LLP

*Attorneys for Patent Owner
Cosmo Technologies Limited*

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.