

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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MYLAN PHARMACEUTICALS INC.,  
PETITIONER

v.

COSMO TECHNOLOGIES LIMITED,  
PATENT OWNER

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CASE IPR2017-01035  
Patent 9,320,716

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**PATENT OWNER'S EXHIBIT LIST**

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P.O. Box 1450  
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**TABLE OF EXHIBITS**

<b>Patent Owners Exhibit No.</b>	<b>Description</b>
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 &amp; 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.
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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.
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2029	"Handbook of Pharmaceutical Excipients", 1987.
2030	A. Nicholls, "Bioavailability profile of Uceris <sup>®</sup> MMX <sup>®</sup> extended release tablets compared with Entocort <sup>®</sup> EC capsules in healthy volunteers", <i>Journal of International Medical Research</i> 0(0), 2013, 1-9.
2031	H. N. E. Stevens, "Pulsincap <sup>™</sup> and Hydrophilic Sandwich Capsules: Innovative Time-Delayed Oral Drug Delivery Technologies", <i>Modified-Release Drug Delivery Technology, Second Edition, Volume 1</i> , 2013.
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2035	“Textbook of Gastroenterology” (Yamada, Ed.) 1991
2036	Redacted email chain re protective order between counsel for Patent Owner to Petitioner

Dated: July 20, 2017

Respectfully submitted,

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