

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

COSMO TECHNOLOGIES LIMITED,
Patent Owner.

U.S. Patent No. 9,320,716 to Villa et al.
Case No.: IPR2017-01035

U.S. Patent No. 8,784,888 to Villa et al.
Case No.: IPR2017-01034

Petitioner's Exhibit List

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Petitioner's Exhibit List

<i>Petitioner Exhibit #</i>	<i>Description</i>
1001	U.S. Patent No. 9,320,716 to Villa et al., "Controlled Release and Taste Masking Oral Pharmaceutical Compositions"
1002	U.S. Patent No. 8,784,888 to Villa et al., "Controlled Release and Taste Masking Oral Pharmaceutical Composition"
1003	Reserved
1004	Reserved
1005	Reserved
1006	Declaration of Anthony Palmieri III, Ph.D., R.Ph.
1007	Curricula Vitae of Anthony Palmieri, Ph.D., R.Ph.
1008	U.S. Patent No. 5,681,584 to Savastano et al., "Controlled Release Drug Delivery Device"
1009	U.S. Patent No. 5,811,388 to Friend et al., "Delivery of Drugs to the Lower GI Tract"
1010	U.S. Patent No. 6,239,120 to Hallgren et al., "Method and Means for Treating Glomerulonephritis"
1011	U.S. Patent Appl. Pub. No. 2006/0134208 to Villa et al., "Controlled Release and Taste Masking Oral Pharmaceutical Composition"
1012	Markman Opinion and Order in <i>Cosmo Technologies Limited v. Alvogen Pine Brook, LLC.</i> , C.A. No. 15-193-LPS, ECF Nos. 167, 168 (D. Del. Sept. 7, 2016).
1013	Amendment and Response to Advisory Action filed on February 21, 2014 in U.S. Patent Appl. No. 13/617,138
1014	Substitute Specification (Clean Copy) filed on April 29, 2013 in U.S. Patent Appl. No. 13/617,138
1015	Amendment After Final filed on April 29, 2013 in U.S. Patent Appl. No. 13/617,138
1016	Amendment and Response to Office Action filed on July 1, 2013 in U.S. Patent Appl. No. 13/617,138
1017	U.S. Patent No. 6,607,751 to Odidi et al., "Controlled Release Delivery Device for Pharmaceutical Agents Incorporating Microbial Polysaccharide Gum"
1018	Campieri et al., <i>Oral Budesonide is as Effective as Oral Prednisolone in Active Crohn's Disease</i> , Gut, 41:209-214 (1997)
1019	Reserved
1020	Reserved

1021	Reserved
1022	PCT International Publication No. WO 96/36318, "Three-Phase Pharmaceutical Form With Constant and Controlled Release of Amorphous Active Ingredient for Single Daily Application"
1023	U.S. Patent No. 5,342,625 to Hauer et al., "Pharmaceutical Compositions Comprising Cyclosporins"
1024	PCT International Publication No. WO 99/39700, "Pharmaceutical compositions in form of nanoparticles comprising lipidic substances and amphiphilic substances and related preparation process"
1025	FDA Inactive Ingredient Guide 1996/1997
1026	Handbook of Pharmaceutical Excipients (Wade and Weller, eds., 2d ed. 1994)
1027	Reserved
1028	Remington: The Science and Practice of Pharmacy, Vol. 1 (1995)
1029	Reserved
1030	Hawley's Condensed Chemical Dictionary (John Wiley & Sons, Inc., 13th ed. 1997)
1031	Reserved
1032	Entocort® EC Highlights of Prescribing Information
1033	Svensson et al., <i>Hydration of an Amphiphilic Excipient</i> , Gelucire 44/14, 2004, <hal-00015990>
1034	U.S. Patent No. 6,395,300 to Straub et al., "Porous Drug Matrices and Methods of Manufacture Thereof"
1035	Flanders et al., <i>The Control of Drug Release From Conventional Melt Granulation Matrices</i> , Drug Development & Industrial Pharmacy, 13(6):1001-1022 (1987)
1036	Gandhi et al., <i>Extrusion and Spheronization in the Development of Oral Controlled-Release Dosage Forms</i> , Pharmaceutical Sci. & Tech. Today 2(4):160 (1999)
1037	US Patent No. 4,880,830 to Alan Rhodes, "Slow Release Formulation"
1038	Daly et al., <i>The Effect of Anionic Surfactants on the Release of Chlorpheniramine from a Polymer Matrix Tablet</i> , Int'l J. of Pharmaceutics, 18:201-05 (1984)
1039	S.S. Davis, <i>The Design and Evaluation of Controlled Release Dosage Forms for Oral Delivery</i> , S.T.P. Pharma 3(5):412-417 (1987)
1040	U.S. Patent No. 5,849,327 to Berliner et al., "Delivery of Drugs to the Lower Gastrointestinal Tract"

1041	U.S. Patent No. 5,643,602 to , “Oral Composition for the Treatment of Inflammatory Bowel Disease”
1042	U.S. Provisional Application No. 60/080,274 filed on April 1, 1998
1043	Gliko-Kabir et al., <i>Low Swelling, Crosslinked Guar and Its Potential Use as a Colon-Specific Drug Carrier</i> , Pharm. Research 15(7):1019-1025 (1998)
1044	See A Blume, B Arnold, HU Weltzien, <i>Effects of a synthetic lysolecithin analog on the phase transition of mixtures of phosphatidylethanolamine and phosphatidylcholine</i> , FEBS Letters (1976)
1045	Qiu et al., <i>Design of sustained-release matrix systems for a highly water-soluble compound, ABT-089</i> , Int’l J. of Pharmaceutics 157:43-52 (1997)
1046	M. Efentakis et al., <i>The Influence of Surfactants on Drug Release from a Hydrophobic Matrix</i> , Int’l J. Pharm. 70:153-58 (1991)
1047	Uceris® website, https://www.uceris.com/tablet/ (accessed on March 5, 2017)
1048	Santarus’ CEO Discusses FDA Approval Of UCERIS (Budesonide) For The Induction Of Remission In Patients With Active, Mild To Moderate Ulcerative Colitis (Transcript) (Jan. 15, 2013)
1049	Uceris® Instant Savings Program
1050	Transcript of the Second Quarter 2014 Earnings Conference Call of Salix Pharmaceuticals, Ltd.
1051	L.W. Doner, <i>Determining Sugar Composition of Food Gum Polysaccharides by HPTLC</i> , Chromatographia 2001, 53, May (No. 9/10)
1052	Amendment filed on January 15, 2013 in U.S. Patent Appl. No. 13/617,138
1053	Specification of U.S. Patent Application No. 10/009,532
1054	Specification of 12/210,969 application
1055	Specification of 13/249,839 application
1056	Specification of 13/462,409 application
1057	Final Office Action of March 6, 2013 in U.S. Patent Appl. No. 13/617,138
1058	Applicant-Initiated Interview Summary of April 23, 2013 in U.S. Patent Appl. No. 13/617,138

1059	Original Specification as filed on September 14, 2012 in U.S. Patent Appl. No. 13/617,138
1060	Orange Book Listing of Uceris® (accessed on March 8, 2017)
1061	Hawley's Condensed Chemical Dictionary (John Wiley & Sons, Inc., 13th ed. 1997)
1062	N. Robinson, <i>Surface Interaction of Lecithin and Lysolecithin</i> , J. of Pharmacy and Pharmacology, 12(1) 609-616 (1960)