

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.

HORIZON PHARMA USA, INC. and NUVO PHARMACEUTICALS (IRELAND)  
DESIGNATED ACTIVITY COMPANY  
Patent Owners.

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Case IPR2017-01995  
Patent 9,220,698

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**PATENT OWNER'S EXHIBIT LIST**

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EXHIBIT No.	DESCRIPTION
2001	Gabriel, S.E., et al., “Risk for Serious Gastrointestinal Complications Related to Use of Nonsteroidal Anti-inflammatory Drugs,” <i>Annals of Internal Medicine</i> , Vol. 115, No. 10, pp. 787-796 (1991) (“Gabriel”)
2002	Cryer, B. and Feldman, M., “Effects of Nonsteroidal Anti-inflammatory Drugs on Endogenous Gastrointestinal Prostaglandins and Therapeutic Strategies for Prevention and Treatment of Nonsteroidal Anti-inflammatory Drug-Induced Damage,” <i>Archives of Internal Medicine</i> , Vol. 152, pp. 1145-1155 (1992) (“Cryer”)
2003	Fries, J.F., et al., “Nonsteroidal Anti-Inflammatory Drug-Associated Gastropathy: Incidence and Risk Factor Models,” <i>The American Journal of Medicine</i> , Vol. 91, pp. 213-222 (1991) (“Fries”)
2004	Second Amended Complaint for Patent Infringement, <i>Horizon Pharma, Inc. v. Mylan Pharmaceuticals Inc.</i> , Civil Action No. 2:15-cv-03327 (D.N.J. Feb. 10, 2016)
2005	Answer to Second Amended Complaint, Separate Defenses, And Counterclaims by Defendants Mylan Pharmaceuticals Inc., Mylan Laboratories Limited and Mylan Inc., <i>Horizon Pharma, Inc. v. Mylan Pharmaceuticals Inc.</i> , Civil Action No. 2:15-cv-03327 (D.N.J. Feb. 19, 2016)
2006	Plaintiffs’ Answer to Defendants’ Counterclaims to Second Amended Complaint, <i>Horizon Pharma, Inc. v. Mylan Pharmaceuticals Inc.</i> , Civil Action No. 2:15-cv-03327 (D.N.J. Mar. 7, 2016)
2007	157 Cong. Rec. S5429 (daily ed. Sept. 8, 2011) (statement of Sen. Kyl)
2008	Declaration of Jonathan G. Graves in Support of <i>Pro Hac Vice Motion</i>
2009	Declaration of Susan Krumplitsch in Support of <i>Pro Hac Vice Motion</i>
2010	Email string from Mylan’s counsel, Robert D. Swanson from February 6, 2017 to February 15, 2017
2011	Declaration of Ellen Scordino in Support of <i>Pro Hac Vice Motion</i>
2012	Gabriel, S.E., et al., <i>Risk for Serious Gastrointestinal Complications Related to Use of Nonsteroidal Anti-inflammatory Drugs</i> , <i>Annals of Internal Medicine</i> , Vol. 115, No. 10, pp. 787-796 (1991) (with

EXHIBIT No.	DESCRIPTION
	publication information)
2013	Cryer, B. and Feldman, M., <i>Effects of Nonsteroidal Anti-inflammatory Drugs on Endogenous Gastrointestinal Prostaglandins and Therapeutic Strategies for Prevention and Treatment of Nonsteroidal Anti-inflammatory Drug-Induced Damage</i> , Archives of Internal Medicine, Vol. 152, pp. 1145-1155 (1992) (with publication information)
2014	Fries, J.F., et al., <i>Nonsteroidal Anti-Inflammatory Drug-Associated Gastropathy: Incidence and Risk Factor Models</i> , The American Journal of Medicine, Vol. 91, pp. 213-222 (1991) (with publication information)
2015	Jan. 12, 2017 Trial Testimony of John R. Plachetka in the <i>Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.</i> , Case No. 3:11-cv-02317 (D.N.J.)
2016	Jan. 24, 2018 Deposition Testimony of Dr. John R. Plachetka in the <i>Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.</i> , Case No. 3:15-cv-03324 (D.N.J.) <b>PROTECTIVE ORDER MATERIAL</b>
2017	PN400-104 Clinical Study Report <b>PROTECTIVE ORDER MATERIAL</b>
2018	Oct. 12, 2017 Deposition Testimony of Everardus Orlemans, Ph.D. in the <i>Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.</i> , Case No. 3:15-cv-03324 (D.N.J.)
2019	Oct. 27, 2017 Deposition Testimony of Mark Sostek, MD in the <i>Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.</i> , Case No. 3:15-cv-03324 (D.N.J.) <b>PROTECTIVE ORDER MATERIAL</b>
2020	Oct. 25, 2017 Deposition Testimony of Brian Ault, Ph.D. in the <i>Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.</i> , Case No. 3:15-cv-03324 (D.N.J.) <b>PROTECTIVE ORDER MATERIAL</b>
2021	Norman, A. and Hawkey, C.J., <i>What you need to know when you prescribe a proton pump inhibitor</i> , Frontline Gastroenterology, Vol. 2, pp. 199-205 (2011)
2022	Stollman, N. and Metz, D.C., <i>Pathophysiology and prophylaxis of stress ulcer in intensive care unit patients</i> , J. Critical Care, Vol. 20, pp. 35-45 (2005)

EXHIBIT No.	DESCRIPTION
2023	Declaration of Michael Mayersohn, Ph.D. in Support of Defendants' Claim Construction Brief filed on April 24, 2014 in <i>Par Pharm., Inc. v. Takeda Pharm. Co.</i> , Case No. 5:13-CV-1927 LHK (PSG)
2024	January 30, 2013 Amendment C and Response to Final Office Action, Application No. 12/553,107
2025	Declaration of David R. Taft PH.D. In Support of Patent Owner Response to Petition for <i>Inter Partes</i> Review of U.S. Patent No. 9,220,698
2026	Declaration of David A. Johnson. M.D. In Support of Patent Owner Response to Petition for <i>Inter Partes</i> Review of U.S. Patent No. 9,220,698
2027	IPR2017-01995, May 25, 2018 Deposition Transcript of David C. Metz
2028	Redacted Amended Memorandum Opinion (D.I. 498), Case 3:11-cv-02317-MLC-DEA (D.N.J. July 12, 2017)
2029	IPR2017-01995, May 24, 2018 Deposition Transcript of Dr. Michael Mayersohn
2030	Oct. 16, 2014 Deposition Testimony of Brian Ault, Ph.D. in the <i>Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.</i> , Case No. 3:11-cv-02317 (D.N.J.) <b>PROTECTIVE ORDER MATERIAL</b>
2031	Oct. 10, 2014 Deposition Testimony of Dr. Mark Sostek in the <i>Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.</i> , Case No. 3:11-cv-02317 (D.N.J.) <b>PROTECTIVE ORDER MATERIAL</b>
2032	Email string from Tore Lind to Richard Leff, Doug Levine, David Magner, and Mark Sostek, dated May 27, 2006 to May 31, 2006
2033	Andersson et al., <i>Pharmacokinetic Studies with Esomeprazole, the (S)-Isomer of Omeprazole</i> , CLIN. PHARMACOKINET., 40(6):411-426 (2001)
2034	Tolman et al., <i>The Effects of Oral Doses of Lansoprazole and Omeprazole on Gastric pH</i> , J. CLIN. GASTROENTEROL., 24(2):65-70 (1997)
2035	Hartmann et al., <i>Twenty-four-hour intragastric pH profiles and pharmacokinetics following single and repeated oral administration of the proton pump inhibitor pantoprazole in comparison to omeprazole</i> , ALIMENT PHARMACOL. THER., 10:359-366 (1996)

EXHIBIT No.	DESCRIPTION
2036	Leucuta et al., <i>Pharmacokinetics and Metabolic Drug Interactions</i> , CURRENT CLINICAL PHARMACOLOGY, 1:5-20 (2006)
2037	Meyer, <i>Interaction of Proton Pump Inhibitors with Cytochromes P450: Consequences for Drug Interactions</i> , YALE J. BIOL. MED., 69:203-209 (1996)
2038	Prilosec Label
2039	Vanderhoff et al., <i>Proton Pump Inhibitors: An Update</i> , AMERICAN FAMILY PHYSICIAN, 66:273-280 (2002)
2040	Arnold, <i>Safety of proton pump inhibitors-an overview</i> , Aliment Pharmacol. Ther., 8(Suppl. 1):65-70 (1994)
2041	VIMOVO Prescribing Information
2042	M.M. Wolfe et al., <i>Gastrointestinal toxicity of nonsteroidal antiinflammatory drugs</i> , N. Engl. J. Med., 340(24):1888-1899 (1999)
2043	L. Laine, <i>Nonsteroidal anti-inflammatory drug gastropathy</i> , Gastrointest. Endosc. Clin. North Am., 6(3):489-504 (1996)
2044	F.E. Silverstein et al., <i>Gastrointestinal toxicity with celecoxib vs. nonsteroidal anti-inflammatory drugs for osteoarthritis and rheumatoid arthritis: the CLASS study: A randomized controlled trial</i> , JAMA, 284(10):1247-1255 (2000)
2045	C. Bombardier et al., <i>Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis</i> , N. Engl. J. Med., 343(21):1520-1528 (2000)
2046	G. Singh, <i>Gastrointestinal complications of prescription and over-the-counter nonsteroidal anti-inflammatory drugs: a view from the ARAMIS database</i> , Am. J. Ther., 7:115-121 (2000)
2047	NIH, National Institute of Diabetes and Digestive and Kidney Diseases, <i>Bleeding in the Digestive Tract</i> , available at <a href="http://www.niddk.nih.gov/health-information/health-topics/digestive-diseases/bleeding-in-the-digestive-tract/Pages/facts.aspx">http://www.niddk.nih.gov/health-information/health-topics/digestive-diseases/bleeding-in-the-digestive-tract/Pages/facts.aspx</a> (last accessed March 23, 2015)
2048	K.S. Jain, et al., <i>Recent advances in proton pump inhibitors and management of acid-peptic disorders</i> , Bioorganic & Medicinal Chemistry 15:1181-1205 (2007)
2049	N. Hudson et al., <i>Famotidine for healing and maintenance in nonsteroidal anti-inflammatory drug-associated gastroduodenal ulceration</i> , Gastroenterology, 112:1817-1822 (1997)
2050	Exhibit Not Used

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