

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

POZEN INC. and HORIZON PHARMA USA, INC.,
Patent Owners.

Case IPR2017-01995
Patent 9,220,698

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.) PROTECTIVE ORDER MATERIAL
2017	PN400-104 Clinical Study Report PROTECTIVE ORDER MATERIAL
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.) PROTECTIVE ORDER MATERIAL
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.) PROTECTIVE ORDER MATERIAL
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.) PROTECTIVE ORDER MATERIAL
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.) PROTECTIVE ORDER MATERIAL
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 http://www.niddk.nih.gov/health-information/health-topics/digestive-diseases/bleeding-in-the-digestive-tract/Pages/facts.aspx (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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