

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and
DR. REDDY'S LABORATORIES, INC.
Petitioners,

v.

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

Case No. IPR2018-00272¹
Patent No. 9,393,208

PATENT OWNERS' EXHIBIT LIST

¹ Petitioner Dr. Reddy's Laboratories, Inc. from IPR2018-01341, has been joined as a Petitioner to this proceeding.

PATENT OWNERS' EXHIBIT LIST

Exhibit No.	Description of Document
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	U.S. Patent No. 9,220,698 Prosecution History Excerpt: Response to Final Office Action Mailed March 26, 2015 (Sept. 25, 2015)
2005	U.S. Patent No. 9,220,698 Prosecution History Excerpt: Advisory Action (Oct. 9, 2015)
2006	Pozen Inc. Bankruptcy Petition dated August 10, 2018
2007-2011	Exhibits Not Used
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 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> , <i>Archives of Internal Medicine</i> , 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> , <i>The American Journal of Medicine</i> , 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.)

Exhibit No.	Description of Document
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)
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. 9,393,208
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. 9,393,208
2027	IPR2017-01995, May 25, 2018 Deposition Transcript of David C. Metz
2028	Redacted Amended Memorandum Opinion (D.I. 498), Case 3:11-cv-

Exhibit No.	Description of Document
	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)
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> ,

Exhibit No.	Description of Document
	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
2051	L. Olbe et al., <i>Reviews: A Proton-pump inhibitor expedition: The case histories of omeprazole and esomeprazole</i> , Nature 2:132-139 (2003)
2052	C.W. Howden, <i>Clinical pharmacology of omeprazole</i> , Clin. Pharmacokinet 20(1):38-49 (1991).
2053	J.Q. Huang & R.H. Hunt, <i>Pharmacological and pharmacodynamic essentials of H₂-receptor antagonists and proton pump inhibitors for the practising physician</i> , Best Prac. & Res. Clin. Gastroenterol. 15(3):355-370 (2001)
2054	H. Koop, <i>Review article: metabolic consequences of long-term inhibition of acid secretion by omeprazole</i> , Aliment. Pharmacol. Ther. 6:399–406 (1992)
2055	Donnellan C., Preston C., Moayyedi P., Sharma N., <i>Medical treatments for the maintenance therapy of reflux oesophagitis and endoscopic negative reflux disease (Review)</i> , The Cochrane Library,

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