

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.

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

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Case IPR2017-01995  
Patent 9,220,698

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**PATENT OWNER'S EXHIBIT LIST**

**PATENT OWNER EXHIBIT LIST**

| 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.)<br><b>PROTECTIVE ORDER MATERIAL</b>                                                                                                                                       |
| 2017        | PN400-104 Clinical Study Report<br><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.)<br><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.)<br><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.)<br><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.)<br><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<br>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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