

Filed: January 25, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,

Petitioner

v.

POZEN INC. and HORIZON PHARMA USA, INC.,

Patent Owners

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Case No. IPR2017-01995  
U.S. Patent No. 9,220,698

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**UPDATED LIST OF PETITIONER'S EXHIBITS**

Pursuant to 37 C.F.R. § 42.63(e), Petitioner submits the following current exhibit list.

| <b>Exhibit</b> | <b>Description</b>   |
|----------------|--|
| 1001           | U.S. Patent No. 9,220,698, <i>Method for Delivering a Pharmaceutical Composition to Patient in need thereof</i> (filed Sept. 3, 2009) (issued Dec. 29, 2015) (“the ’698 patent”) |
| 1002           | Declaration of David C. Metz, M.D. (“Metz Decl.”)  |
| 1003           | Declaration of Michael Mayersohn, Ph.D. (“Mayersohn Decl.”)  |

| Exhibit | Description  |
|---------|--|
| 1004    | U.S. Patent No. 6,926,907, <i>Pharmaceutical Compositions for the Coordinated Delivery of NSAIDS</i> (filed May 31, 2002) (issued Aug. 9, 2005)  |
| 1005    | U.S. Patent No. 8,557,285, <i>Pharmaceutical Compositions for the Coordinated Delivery of NSAIDS</i> (filed Aug. 23, 2011) (issued Oct. 15, 2013)  |
| 1006    | Howden, <i>Review Article: Immediate-Release Proton-Pump Inhibitor Therapy – Potential Advantages</i> , 22 (Suppl. 3) ALIMENT. PHARMACOL. THER. 25 (2005)  |
| 1007    | U.S. Patent No. 5,877,192, <i>Method for the Treatment of Gastric Acid-Related Diseases and Production of Medication using (-) Enantiomer of Omeprazole</i> (filed Apr. 11, 1997) (issued Mar. 2, 1999)  |
| 1008    | <i>Products on NDA 020067 (EC-Naprosyn)</i> , FDA.GOV, <a href="https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&amp;ApplNo=020067">https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&amp;ApplNo=020067</a> (last visited Aug. 23, 2017)  |
| 1009    | EC-Naprosyn prescribing information (Jan. 2007)  |
| 1010    | Zegerid approval letter and prescribing information (2004)   |
| 1011    | Goldstein et al., <i>116 A Single Tablet Multilayer Formulation of Enteric-Coated Naproxen Coupled with Non-Enteric Coated OMEPRAZOLE is Associated with a Significantly Reduced Incidence of Gastric Ulcers vs. Enteric-Coated Naproxen: A Prospective, Randomized, Double-Blind Study</i> , 134(4) GASTROENTEROLOGY A19 (2008)                         |
| 1012    | Hochberg et al., <i>A Novel, Single-Tablet Formulation that Delivers Immediate-Release Omeprazole Followed by Enteric-Coated (EC) Naproxen Significantly Reduces the Incidence of Gastric Ulcers Compared with EC Naproxen Alone: Results of a Prospective, Randomised, Double-Blind, 6-Month Study including Patients with OA and RA</i> , EULAR (2008) |

| Exhibit | Description  |
|---------|--|
| 1013    | U.S. Patent No. 9,220,698 Prosecution History Excerpt: Amendment C and Response to Final Office Action (Jan. 30, 2013)   |
| 1014    | Wolfe et al., <i>Acid Suppression: Optimizing Therapy for Gastroduodenal Ulcer Healing, Gastroesophageal Reflux Disease, and Stress-Related Erosive Syndrome</i> , 118 GASTROENTEROLOGY S9 (2000)                  |
| 1015    | Bell et al., <i>Appropriate Acid Suppression for the Management of Gastro-Oesophageal Reflux Disease</i> , 51(suppl. 1) DIGESTION 59 (1992)  |
| 1016    | Hassan-Alin et al., <i>Lack of Pharmacokinetic Interaction between Esomeprazole and the Nonsteroidal Anti-Inflammatory Drugs Naproxen and Rofecoxib in Healthy Subjects</i> , 25(11) CLIN. DRUG INVEST. 731 (2006) |
| 1017    | Khosravan et al., <i>Pharmacokinetic Interactions of Concomitant Administration of Febuxostat and NSAIDs</i> , 46 J. CLIN. PHARMA. 855 (2006)  |
| 1018    | Jung et al., <i>Steady-State Pharmacokinetics of Enteric-Coated Naproxen Tablets Compared with Standard Naproxen Tablets</i> , 16(6) CLIN. THER. 923 (1994)  |
| 1019    | Davies et al., <i>Clinical Pharmacokinetics of Naproxen</i> , 32(4) CLIN. PHARMACOKINET. 268 (1997)  |
| 1020    | Naprosyn/EC-Naprosyn/Anaprox DS Prescribing Information (Mar. 2017)  |
| 1021    | Dan M. Roden, <i>Principles of Clinical Pharmacology</i> , in HARRISON'S PRINCIPLES OF INTERNAL MEDICINE 13 (Dennis L. Kasper et al. eds., 16th ed. 2005)  |
| 1022    | Malcolm Rowland & Thomas N. Tozer, CLINICAL PHARMACOKINETICS (3d ed. 1995)   |

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|---------|--|
| 1023    | Clissold et al., <i>Omeprazole A Preliminary Review of its Pharmacodynamic and Pharmacokinetic Properties, and Therapeutic Potential in Peptic Ulcer Disease and Zollinger-Ellison Syndrome</i> , 32 DRUGS 15 (1986) |
| 1024    | U.S. Patent No. 7,411,070, <i>Form of S-Omeprazole</i> (filed Sept. 25, 2003) (issued Aug. 12, 2008)   |
| 1025    | U.S. Patent No. 5,714,504, <i>Compositions</i> (filed Jan. 23, 1995) (issued Feb. 3, 1998)   |
| 1026    | Michael Mayersohn, <i>Principles of Drug Absorption</i> , in MODERN PHARMACEUTICS 21 (3d ed. 1996)   |
| 1027    | Howden, <i>Clinical Pharmacology of Omeprazole</i> , 20(1) CLIN. PHARMACOKINET. 38 (1991)  |
| 1028    | Lind et al., <i>Esomeprazole Provides Improved Acid Control vs. Omeprazole in Patients with Symptoms of Gastro-Oesophageal Reflux Disease</i> , 14 ALIMENT. PHARMACOL. THER. 861 (2000)                              |
| 1029    | Regårdh et al., <i>Pharmacokinetics and Metabolism of Omeprazole in Animals and Man – An Overview</i> , 20(suppl. 108) SCAND. J. GASTROENTEROL 79 (1985)   |
| 1030    | Vimovo prescribing information (Dec. 2014)   |
| 1031    | <i>Target</i> , WEBSTER'S NEW WORLD COLLEGE DICTIONARY (4th ed. 2005)  |
| 1032    | <i>Target</i> , THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (4th ed. 2006)  |
| 1033    | <i>Target</i> , MERRIAM-WEBSTER'S CONCISE DICTIONARY (Large print ed. 2006)  |
| 1034    | U.S. Patent No. 9,220,698 Prosecution History Excerpt: Office Action Summary (Jan. 5, 2012)  |
| 1035    | U.S. Patent No. 9,220,698 Prosecution History Excerpt: Office Action Summary (July 30, 2012)   |
| 1036    | U.S. Patent No. 9,220,698 Prosecution History Excerpt: Office Action Summary (June 16, 2014)   |

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|---------|--|
| 1037    | U.S. Patent No. 9,220,698 Prosecution History Excerpt: Office Action Summary (Mar. 26, 2015)   |
| 1038    | U.S. Patent No. 9,220,698 Prosecution History Excerpt: Amendment B in Response to January 5, 2012 Office Action (May 8, 2012)  |
| 1039    | U.S. Patent No. 9,220,698 Prosecution History Excerpt: Response to Non-Final Office Action Mailed June 16, 2014 (Dec. 12, 2014)  |
| 1040    | U.S. Patent No. 9,220,698 Prosecution History Excerpt: Response to Final Office Action Mailed March 26, 2015 (Sept. 25, 2015)  |
| 1041    | U.S. Patent No. 9,220,698 Prosecution History Excerpt: Advisory Action (Oct. 9, 2015)  |
| 1042    | Goldlust et al., <i>Nighttime Dosing of Omeprazole Immediate-Release Oral Suspension Rapidly Decreases Nocturnal Gastric Acidity</i> , 99(10) AM. J. GASTROENTEROLOGY S39 (2004) |
| 1043    | INTENTIONALLY LEFT BLANK   |
| 1044    | INTENTIONALLY LEFT BLANK   |
| 1045    | INTENTIONALLY LEFT BLANK   |
| 1046    | INTENTIONALLY LEFT BLANK   |
| 1047    | Stipulation and Order to Dismiss Certain Counterclaims, <i>Horizon Pharma, Inc. v. Mylan Pharms. Inc.</i> , No. 15-cv-3327 (D.N.J. Feb. 23, 2017), ECF No. 40                    |

Dated: January 25, 2018

/s/ Brandon M. White  
 Brandon M. White  
 Reg. No. 52,354  
 Perkins Coie LLP  
 700 13th St., NW, Suite 600  
 Washington, D.C. 20005  
 Telephone: (202) 654-6206  
 E-mail: [bmwhite@perkinscoie.com](mailto:bmwhite@perkinscoie.com)

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