

Filed: February 22, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.

and

DR. REDDY'S LABORATORIES, INC.,

Petitioner

v.

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

Patent Owners

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Case No. IPR2017-01995<sup>1</sup>

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.

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<sup>1</sup> Petitioner Dr. Reddy's Laboratories, Inc., from IPR2018-00894, has been joined as a Petitioner to this proceeding

Exhibit	Description
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.”)
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)

Exhibit	Description
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)
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)

Exhibit	Description
1022	Malcolm Rowland & Thomas N. Tozer, CLINICAL PHARMACOKINETICS (3d ed. 1995)
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)

Exhibit	Description
1036	U.S. Patent No. 9,220,698 Prosecution History Excerpt: Office Action Summary (June 16, 2014)
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
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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
1048	Declaration of Bryan D. Beel in Support of Motion for <i>Pro Hac Vice</i> Admission of Bryan D. Beel
1049	Declaration of Robert D. Swanson in Support of Motion for <i>Pro Hac Vice</i> Admission of Robert D. Swanson
1050	Declaration of Autumn N. Nero in Support of Motion for <i>Pro Hac Vice</i> Admission of Autumn N. Nero

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