

Filed: May 8, 2019

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
U.S. Patent No. 9,393,208 B2

UPDATED LIST OF PETITIONERS' EXHIBITS

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

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

| Exhibit | Description |
|---------|--|
| 1001 | U.S. Patent No. 9,393,208, <i>Method for Delivering a Pharmaceutical Composition to Patient in need thereof</i> (filed Dec. 28, 2015) (issued Jul. 19, 2016) (“the ’208 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, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&AppNo=020067 (last visited Aug. 23, 2017) |
| 1009 | EC-Naprosyn prescribing information (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 (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 (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) |
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| Exhibit | Description |
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| 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 | Nexium Prescribing Information (2001), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2001/211531bl.pdf (last visited Nov. 22, 2017) |
| 1044 | Prilosec Prescribing Information (2002), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/19810s0741bl.pdf (last visited Nov. 22, 2017) |
| 1045 | Opinion & Order, <i>Horizon Pharma, Inc. v. Dr. Reddy's Labs., Inc.</i> , No. 15-cv-3324-SRC-CLW (consolidated) (D.N.J. Nov. 14, 2017), ECF No. 82 |
| 1046 | U.S. Patent No. 9,393,208 Prosecution History Excerpts |
| 1047 | Intentionally Left Blank |
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| 1051 | Order (A) Authorizing the Sale of Certain of the Debtors' Assets Pursuant to the Stalking Horse Agreement Free and Clear of Liens, Claims, Encumbrances, and Other Interests to the Fullest Extent Permitted by Law; (B) Approving the Assumption and Assignment of Certain Executory Contracts; and (C) Granting Related Relief, <i>In re Aralez Pharmaceuticals US Inc.</i> , No. 18-2425-mg (Bankr. S.D.N.Y. Dec. 27, 2018), ECF No. 412 |

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