

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.

Petitioner

v.

POZEN INC. and HORIZON PHARMA USA, INC.

Patent Owners

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

**CORRECTED DECLARATION OF BRYAN D. BEEL IN SUPPORT OF
PETITIONER'S EVIDENCE**

1. I, Bryan D. Beel, am over the age of eighteen (18) and otherwise competent to make this Declaration. I am an attorney at Perkins Coie LLP, and counsel for Mylan Pharmaceuticals Inc. (“Petitioner”) in the present action. I make this Declaration based on my personal knowledge of the facts set forth in this Declaration and am competent to testify to the same.

2. All of the exhibits to which Patent Owners objected are either publicly available or derived from documents that are publicly available.

3. Exhibit 1006 is a true and correct copy of an article authored by C. W. Howden titled *Review Article: Immediate-Release Proton-Pump Inhibitor Therapy - Potential Advantages* published in the journal ALIMENTARY PHARMACOLOGY & THERAPEUTICS in 2005 in volume 22, supplement 3, beginning on page 25.

4. Exhibit 1008 is a true and correct copy of pages accessed and printed on August 23, 2017, by me or under my direction from the FDA website (www.accessdata.fda.gov). To print this document, I or someone under my direction first accessed the Drugs@FDA website (www.accessdata.fda.gov) at the URL or webpage address: <https://www.accessdata.fda.gov/scripts/cder/daf/>. NDA No. 20067 was entered into the search box, and the Search button was clicked, yielding a website with the address <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process>, showing basic information for NDA No. 20067, held by Atnahs Pharma US for EC-Naprosyn. Clicking the Print button on the NDA-

information browser page, and selecting PDF as the desired output, yielded the information shown in Exhibit 1008.

5. Exhibit 1009 is a true and correct copy of the EC-Naprosyn prescribing information. It bears the notation “Revised: September 2007” on page 27, and “Revised: January 2007” on page 30. It is publicly available from the FDA website (www.accessdata.fda.gov) at https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/017581s108,18164s58,18965s16,20067s14lbl.pdf. Exhibit 1009 was printed by me or under my direction.

6. Exhibit 1010 is a true and correct copy of the FDA approval letter for Zegerid dated June 15, 2004, and the prescribing information. The approval letter and prescribing information are publicly available from the FDA website (www.accessdata.fda.gov) at <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021636>. Once on this page, under “Approval Date(s) and History, Letters, Labels, Reviews for NDA 021636” there is an option to view a .pdf file of the label and the letter. The label is available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/21636_zegerid_lbl.pdf and the letter is available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/21636ltr.pdf. Exhibit 1010 was printed by me or under my direction.

7. Exhibit 1011 is a true and correct copy of an abstract authored by Jay L. Goldstein et al. titled *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 published in the journal GASTROENTEROLOGY supplement in 2008 in volume 134, number 4, supplement 1, beginning on page A-19.

8. Exhibit 1012 is a true and correct copy of a poster authored by Marc Hochberg et al. titled *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*, which bears the notation “EULAR 2008, Paris, France, 11-14 June 2008.” On its webpage titled “POZEN Pharmaceutical Development Company: Poster Presentations,” Pozen represented that this poster was presented at EULAR 2008. The webpage address listing the poster was <http://www.pozen.com:80/product/poster.asp>, and the web address of the poster itself was http://www.pozen.com:80/product/posters/EULAR%20AZ44531_hochberg.pdf. Pozen has been merged into Aralez Pharmaceuticals, and a version of each of these pages is now available at the Internet Archive. The abstract for the Hochberg poster was also published in *Annals of the Rheumatic Diseases*, vol. 67 (supp. II), 168 (2008), an issue that compiled information about presentations made

at EULAR 2008, which was held June 11-14, 2008.

9. Exhibit 1014 is a true and correct copy of an article authored by M. Michael Wolfe and George Sachs titled *Acid Suppression: Optimizing Therapy for Gastroduodenal Ulcer Healing, Gastroesophageal Reflux Disease, and Stress-Related Erosive Syndrome* published in the journal GASTROENTEROLOGY in 2000 in volume 118, beginning on page S9.

10. Exhibit 1016 is a true and correct copy of an article authored by M. Hassan-Alin et al. titled *Lack of Pharmacokinetic Interaction between Esomeprazole and the Nonsteroidal Anti-Inflammatory Drugs Naproxen and Rofecoxib in Healthy Subjects* published in the journal CLINICAL DRUG INVESTIGATION in 2005 in volume 25, number 11, beginning on page 731.

11. Exhibit 1017 is a true and correct copy of an article authored by Reza Khosravan, Ph.D. et al. titled *Pharmacokinetic Interactions of Concomitant Administration of Febuxostat and NSAIDs* published in the JOURNAL OF CLINICAL PHARMACOLOGY in 2006 in volume 46, beginning on page 855.

12. Exhibit 1020 is a true and correct copy of the Naprosyn/EC-Naprosyn/Anaprox DS prescribing information dated March 2017. It is publicly available from the FDA website (www.accessdata.fda.gov) at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017581s113,018164s063,020067s020lbl.pdf. Exhibit 1020 was printed by me or under my direction.

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