

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VII LLC,
Petitioner,

v.

POZEN INC.,
Patent Owner.

IPR2015-01344
Patent 8,858,996

PETITIONER'S EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Petitioner submits this current list of exhibits.

Exhibit No.	Description
1001	U.S. Patent No. 8,858,996 (“the ’996 Patent”)
1002	File History of the ’996 Patent, U.S. Patent App. No. 14/244,471 (“the ’471 Application”)
1003	Declaration of Leon Shargel, Ph.D., R.Ph.
1004	U.S. Patent No. 5,204,118 (“Goldman”)
1005	“Remington’s Pharmaceutical Sciences,” Alfonso R. Gennaro, et al., Mack Publ’g Co., Seventeenth Edition, 1985 (“Remington”)
1006	U.S. Patent No. 5,698,225 (“Gimet”)
1007	U.S. Patent No. 5,714,504 (“Lindberg”)
1008	U.S. Patent App. Pub. No. US 2003/0069255 (“the ’255 Plachetka Publication”)
1009	U.S. Patent Prov. App. No. 60/294,588 (“the ’588 Application”)
1010	U.S. Patent App. No. 10/158,216 (“the ’216 Application”)
1011	U.S. Patent App. No. 11/129,320 (“the ’320 Application”)
1012	U.S. Patent No. 4,757,060
1013	“The Mechanism of Action of Aspirin,” J.R. Vane, et al., Pergamon (2003)
1014	G.B. Patent No. 1211134
1015	“Drug-Induced Peptic Ulcer Disease,” Valerie Vella, Journal of the Malta College of Pharmacy Practice (2005)

Exhibit No.	Description
1016	“Goodman & Gilman’s The Pharmacological Basis of Therapeutics,” Joel G. Hardman, et al., McGraw-Hill Publ’g Co., Ninth Edition (1996)
1017	“Upper Gastrointestinal (GI) pH in Young, Healthy Men and Women,” Jennifer B. Dressman, et al., Pharmaceutical Research, Vol. 7, No. 7, 756-761 (1990)
1018	“Effect of Orally Administered Prostaglandin E2 and its 15-Methyl Analogues on Gastric Secretion,” Karim, et al., British Med. Journal (Jan. 20, 1973)
1019	“Tagamet: The Discovery of Histamine H2-Receptor Antagonists,” SmithKlein Beecham Pharmas., Am. Chem. Soc. (Nov. 24, 1997)
1020	“Inhibition of Gastric ($H^+ + K^+$)-ATPase by the Substituted Benzimidazole Picoprazole,” B. Wallmark, et al., Biochimica et Biophysica Acta, Vol. 728, at 31-38 (1983)
1021	U.S. Patent No. 4,255,431
1022	Notice of Final Determination, In re: Patent Term Extension for U.S. Patent No. 6,143,771
1023	“Drug Discovery: Practices, Processes, and Perspectives,” Jie Jack Li, et al., John Wiley & Sons (Apr. 3, 2013)
1024	“Prevention of the Gastrointestinal Adverse Effects of Nonsteroidal Anti-Inflammatory Drugs, Gregor J.E. Brown, et al., Drug Safety (6): 503-512 (December 21, 1999)
1025	U.S. Patent App. Pub. 2002/0045184 (“Chen”)
1026	“Management of NSAID-Related Gastrointestinal Mucosal Injury,” A.F. Barrison, et al., Inflammopharmacology 7(3), at 277-86 (1999)
1027	“Prevention of NSAID-Induced Gastroduodenal Ulcers,” A. Rostom, et al., Cochrane Database of Systematic Reviews (2000)

Exhibit No.	Description
1028	“Abolition by Omeprazole of Aspirin Induced Gastric Mucosal Injury in Man,” T K Daneshmend et al., Gut, Vol. 31, 514-517 (1990) (“Daneshmend”)
1029	U.S. Patent No. 6,319,519
1030	U.S. Patent No. 6,365,184 (“Depui”)
1031	VIMOVO® (Naproxen and Esomeprazole Magnesium) Tablets Horizon Pharma, http://www.horizonpharma.com/vimovo/ (last visited May 9, 2015)
1032	Horizon Pharma plc 2014 Irish Statutory Accounts,” Horizon Pharma Public Limited Company (Apr. 9, 2015)
1033	Shargel Walmart Receipts
1034	April 4, 2014 Patent Owner Responses to Invalidity Contentions
1035	Inhibit, http://www.merriam-webster.com/dictionary/inhibit (last visited Feb. 17, 2015)
1036	Organic Chemistry, Robert Thornton Morrison, Sixth Edition, 1992
1037	The Random House Dictionary of the English Language, Random House, First Printing, 1966
1038	The Oxford Encyclopedic English Dictionary, Joyce M. Hawkins, et al., 1991
1039	WO 98/54171
1040	U.S. Patent No. 6,262,085
1041	U.S. Patent Pub. No. 2001/0000468
1042	U.S. Patent No. 5,051,262
1043	U.S. Patent No. 5,314,697

Exhibit No.	Description
1044	“Effects of Misoprostol on Gastric Acid and Mucus Secretion in Man,” Donald E. Wilson, et al., Digestive Diseases and Sciences, Vol. 31, No. 2, Feb. 1986.
1045	“Measurement of Gastrointestinal pH Profiles in Normal Ambulant Human Subjects,” D. F. Evans, et al., Gut, Vol. 29, 1035-1041 (1988) (“Evans”)
1046	Prevent, http://www.merriam-webster.com/dictionary/prevent (last visited June 4, 2015)
1047	“Omeprazole,” Stephen P. Clissold, et al., Drugs, vol. 32 (1986) (“Clissold”)
1048	“Development of an Oral Formulation of Omeprazole,” Pilbrant and Cederberg, Scand. J. Gastroenterol., 20(Suppl. 108):113-120 (1985) (“Pilbrant”)
1049	“Effects of Single and Repeated Doses of Omeprazole in Gastric Acid and Pepsin Secretion in Man,” Howden et al., Gut, Vol. 25, 707-710 (1984) (“Howden”)
1050	“Omeprazole: A Study of Its Inhibition of Gastric pH and Oral Pharmacokinetics After Morning or Evening Dosage,” Prichard et al., Gastroenterol., 88:64-69 (1985) (“Prichard”)
1051	“The Effects of Oral Doses of Lansoprazole and Omeprazole on Gastric pH,” Tolman et al., J. Clin. Gastroenterol, 24(2):65-70 (1997) (“Tolman”)
1052	Citizen Petition, Horizon Pharma (February 4, 2014)

Exhibit No.	Description
1053	“Clinical Trial: Evaluation of Gastric Acid Suppression with Three Doses of Immediate-Release Esomeprazole in the Fixed-Dose Combination of PN 400 (Naproxen/Esomeprazole Magnesium) Compared with Naproxen 500 mg and Enteric-Coated Esomeprazole 20 mg: A Randomized, Open-Label, Phase I Study in Healthy Volunteers,” Miner et al., Alim. Pharmacol. Ther., 32:414-424 (2010) (“Miner”)
1054	FDA Response to Horizon’s Citizen Petition (July 3, 2014)

Date: June 5, 2015

Respectfully submitted,

/Amy E. LaValle/

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on June 5, 2015 a copy of the foregoing PETITIONER'S EXHIBIT LIST and copies of the listed Exhibits were provided via FedEx, overnight delivery, to the Patent Owner by serving the correspondence address of record for the '996 Patent:

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Date: June 5, 2015

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