

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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COALITION FOR AFFORDABLE DRUGS VII, LLC,  
Petitioner,

v.

POZEN INC.,  
Patent Owner.

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Case IPR2015-01718  
Patent 8,945,621

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**PATENT OWNER EXHIBIT LIST**

## PATENT OWNER EXHIBIT LIST

Exhibit No.	Exhibit Description
2001	License Agreement between Patent Owner Pozen Inc. and exclusive licensee Horizon Pharma, Inc.
2002	Bhatt, D., et al., “ACCF/ACG/AHA 2008 Expert Consensus Document on Reducing the Gastrointestinal risks of Antiplatelet Therapy and NSAID Use: A Report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents,” <i>J Am Coll Cardiol</i> , Vol. 52, No. 18, pp. 1502–1517 (2008)
2003	PREVACID® (lansoprazole) Delayed-Release Capsules, Prescribing Information (May 1, 2001), downloaded from <a href="http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist">http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist</a> on November 17, 2015
2004	Laine, L., et al., “Assessment of Upper Gastrointestinal Safety of Etoricoxib and Diclofenac in Patients with Osteoarthritis and Rheumatoid Arthritis in the Multinational Etoricoxib and Diclofenac Arthritis Longterm (MEDAL) Programme: a Randomised Comparison,” <i>Lancet</i> , Vol. 369, pp. 465-473 (2007)
2005	Angiolillo, D., et al., “Impact of Concomitant Low-Dose Aspirin on the Safety and Tolerability of Naproxen and Esomeprazole Magnesium Delayed-Release Tablets in Patients Requiring Chronic Nonsteroidal Anti-Inflammatory Drug Therapy: an Analysis from 5 Phase III Studies,” <i>J Thromb Thrombolysis</i> , Vol. 38, pp. 11-23 (2014; first published 12/25/2013) doi: 10.1007/s11239-013-1035-4
2006	Declaration of Lee S. Simon, MD, FACP, FACR, submitted May 22, 2015 from File History of U.S. Patent Application No. 14/593,212
2007	Goldstein, J.L., et al., “PN400 Significantly Reduces the Incidence of Gastric Ulcers Compared With Enteric-Coated Naproxen in Patients Requiring Chronic NSAID Therapy Regardless of Low-Dose Aspirin Use: Results from Two Prospective, Randomized Controlled Trials,” <i>Arthritis Rheum</i> , 60 Suppl. 10:842 (2009)
2008	Gabriel, S.E., et al., “Risk for Serious Gastrointestinal Complications Related to Use of Nonsteroidal Anti-inflammatory

	Drugs,” <i>Annals of Internal Medicine</i> , Vol. 115, No. 10, pp. 787-796 (1991)
2009	Cryer, B. and Feldman, M., “Effects of Nonsteroidal Anti-inflammatory Drugs on Endogenous Gastrointestinal Prostaglandins and Therapeutic Strategies for Prevention and Treatment of Nonsteroidal Anti-inflammatory Drug-Induced Damage,” <i>Archives of Internal Medicine</i> , Vol. 152, No. 6, pp. 1145-1155 (1992)
2010	Fries, J.F., et al., “Nonsteroidal Anti-inflammatory Drug-Associated Gastropathy: Incidence and Risk Factor Models,” <i>The American Journal of Medicine</i> , Vol. 91, pp. 213-222 (1991)
2011	Sørensen, H.T., et al., “Risk of Upper Gastrointestinal Bleeding Associated With Use of Low-Dose Aspirin,” <i>The American Journal of Gastroenterology</i> , Vol. 95, No. 9, pp. 2218-2224 (2000)
2012	Tamura, A., et al., “Prevalence and independent factors for gastroduodenal ulcers/erosions in asymptomatic patients taking low-dose aspirin and gastroprotective agents: the OITA-GF study,” <i>The Quarterly Journal of Medicine</i> , Vol. 104, pp. 133-139 (2010)
2013	Derry, S. and Loke, Y.K., “Risk of gastrointestinal haemorrhage with long term use of aspirin: meta-analysis,” <i>British Medical Journal</i> , Vol. 321, pp. 1183-1187 (2000)
2014	Rodriguez, L.A.G., et al., “Association between aspirin and upper gastrointestinal complications: Systematic review of epidemiologic studies,” <i>British Journal of Clinical Pharmacology</i> , Vol. 52, pp. 563-571 (2001)
2015	Bellary, S.V., et al., “Upper Gastrointestinal Lesions in Elderly Patients Presenting for Endoscopy: Relevance of NSAID Usage,” <i>The American Journal of Gastroenterology</i> , Vol. 86, No. 8, pp. 961-964 (1991)
2016	Weil, J., et al., “Prophylactic aspirin and risk of peptic ulcer bleeding,” <i>British Medical Journal</i> , Vol. 310, pp. 827-830 (1995)
2017	Goldstein, J.L., et al., “Effects of Concomitant Aspirin (81 mg qd) On Incidence of Gastric and/Or Duodenal Ulcers in Healthy Subjects Taking Celecoxib Or Naproxen: A Randomized, Placebo-Controlled Trial,” <i>Gastroenterology</i> , Vol. 130 (suppl. 2), pp. A-81-A-82 (2006)

2018	Rahme, E., et al., "Gastrointestinal Effects of Rofecoxib and Celecoxib Versus NSAIDs Among Patients on Low Dose Aspirin," <i>Gastroenterology</i> , 126 (suppl. 2), pp. A-1-A-2 (2004)
2019	Silverstein, F.E., et al., "Gastrointestinal Toxicity With Celecoxib vs Nonsteroidal Anti-inflammatory Drugs for Osteoarthritis and Rheumatoid Arthritis," <i>The Journal of the American Medical Association</i> , Vol. 284, No. 10, pp. 1247-1255 (2000)
2020	Deposition Transcript of Leon Shargel
2021	Declaration of Robert W. Makuch, Ph.D.
2022	Declaration of David A. Johnson, M.D.
2023	Lee M., et al, "Dose effects of aspirin on gastric prostaglandins and stomach mucosal injury," <i>Ann Intern Med</i> , Vol. 120, No. 3, pp. 184-189 (1994)
2024	Serrano P., et al., "Risk of upper gastrointestinal bleeding in patients taking low-dose aspirin for the prevention of cardiovascular diseases," <i>Aliment Pharmacol Ther</i> , Vol. 16, pp. 1945-1953 (2002) doi:10.1046/j.0269-2813.2002.01355.x
2025	Chan, F.K., "Anti-platelet therapy and managing ulcer risk," <i>J Gastroenterol Hepatol</i> , Vol. 27, pp. 195-199 (2012)
2026	Goldstein, J.L., et al, "The impact of low-dose aspirin on endoscopic gastric and duodenal ulcer rates in users of a non-selective non-steroidal anti-inflammatory drug or a cyclooxygenase-2-selective inhibitor," <i>Aliment Pharmacol Ther</i> , Vol. 23, pp. 1489-1498 (2006) doi:10.1111/j.1365-2036.2006.02912.x
2027	Goldstein, J.L., et al, "Clinical trial incidence of NSAID-associated endoscopic gastric ulcers in patients treated with PN 400 (naproxen plus esomeprazole magnesium) vs. enteric-coated naproxen alone," <i>Aliment Pharmacol Ther</i> , Vol. 32, pp. 401-413(2010) doi:10.1111/j.1365-2036.2010.04378.x
2028	Sostres C. and Gargallo C.J., "Gastrointestinal lesions and complications of low-dose aspirin in the gastrointestinal tract," <i>Best Pract Res Clin Gastroenterol.</i> , Vol. 26, pp. 141-151 (2012) doi: 10.1016/j.bpg.2012.01.016
2029	Wolfe, M., et al, "Gastrointestinal Toxicity of Nonsteroidal Antiinflammatory Drugs," <i>The New England Journal of Medicine</i> ,

	Vol. 340, No. 24, pp. 1888-1899 (1999)
2030	Flower, R., "The Development of COX2 Inhibitors," <i>Nature Reviews Drug Discovery</i> , Vol. 2, pp. 179-191 (2003)
2031	Public Health Advisory - FDA Announces Important Changes and Additional Warnings for COX-2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (April 7, 2005), downloaded from <a href="http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm150314.htm">http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm150314.htm</a> on March 23, 2015
2032	Whitlock, C., et al, "Bleeding Risks With Aspirin Use for Primary Prevention in Adults: A Systematic Review for the U.S. Preventive Services Task Force," <i>Annals of Internal Medicine</i> , Vol. 164, No. 12, pp. 826-837 (2016)
2033	Bombardier, E., et al, "Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis," <i>The New England Journal of Medicine</i> , Vol. 343, No. 21, pp. 1520-1528 (2000)

Dated: June 23, 2016

By: /s/ Ricardo Rodriguez  
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