

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS INC.
Petitioner

v.

POZEN, INC.
Patent Owner

Inter Partes Review No.: UNASSIGNED

**Declaration of Umesh V. Banakar, Ph.D., in Support of Petition
for Inter Partes Review of Claims 1-6 and 13-15 of U.S. Patent No. 8,852,636**

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Exhibits Referenced In This Declaration

Exhibit No.	Description
1001	U.S. Patent No. 8,852,636
1003	U.S. Patent Application No. 14/045,156 (“the ’156 application”)
1004	U.S. Patent No. 6,544,556 (“the ’556 patent”)
1005	U.S. Patent No. 5,877,192 (“the ’192 patent”)
1006	Howden et al., Effects of Single and Repeated Doses of Omeprazole in Gastric Acid and Pepsin Secretion in Man, Gut, Vol. 25, 707-710 (1984) (“Howden”)
1007	U.S. Patent No. 5,698,225 (“the ’225 patent”)
1008	Pilbrant et al., Development of an Oral Formulation of Omeprazole, Scand. J. Gastroenterol., 20(Suppl. 108):113-120 (1985)(“Pilbrant”)
1009	Preliminary Patent Owner Response to Petition for Inter Partes Review of U.S. Patent No. 8,557,285 submitted by Pozen Inc.
1010	U.S. Patent No. 5,204,118 (“the ’118 patent”)
1011	Chandramouli et al., Prevention and management of NSAID-Induced Gastropathy, Journal of Pharmaceutical Pain and Symptom Control, 8(4):27-40, 2000 (“Chandramouli”)
1012	WO/2000/026185 (“WO’185”)
1014	July 3, 2014 Citizen Petition Denial from FDA to Horizon Pharma (“Horizon Citizen Petition”)
1016	Curriculum Vitae of Umesh V. Banakar
1017	Pozen Website – John R. Plachetka educational background
1018	<i>Naprosyn</i> , Physicians’ Desk Reference, Medical Economics Company, 2631-32 (2000)
1019	Acid Suppression: Optimizing Therapy for Gastroduodenal Ulcer Healing, Gastroesophageal Reflux Disease, and Stress-Related Erosive Syndrome, Wolfe, et al., Gastroenterology, 118:S9-S31 (2000) (“Wolfe”).
1020	Prichard et al., “Omeprazole: A Study of Its Inhibition of Gastric pH and Oral Pharmacokinetics After Morning or Evening Dosage,” Gastroenterol., 88:64-69 (1985) (“Prichard”)
1021	Clissold, et al. Omeprazole- A Preliminary Review of its Pharmacodynamic and Pharmacokinetic Properties, and Therapeutic Potential in Peptic Ulcer Disease and Zollinger-Ellison Syndrome, Drugs 32: 15-47 (1986) (“Clissold”)

1022	Tolman et al., "The Effects of Oral Doses of Lansoprazole and Omeprazole on Gastric pH," J. Clin. Gastroenterol, 24(2):65-70 (1997) ("Tolman")
1023	<i>Prilosec</i> , Physicians' Desk Reference, Medical Economics Company, 617-621 (2000)
1024	Claim Chart with '556 Patent, Chandramouli, and '225 patent disclosures
1025	Nexium Label
1026	U.S. Patent No. 6,331,316
1027	Petition for Inter Partes Review of U.S. Patent No. 8,557,285 And Mandatory Notices Under 37 C.F.R. § 42.8 submitted by Dr. Reddy's Laboratories, Inc.
1028	Fassihi, SA Pharm. J., July 1990, 259-265 ("Fassihi")
1029	Gupta, et al., Ch. 6, Oral Controlled-Release Delivery, Treatise on Controlled Drug Delivery, A Kydonieus, Ed., Marcel Dekker, Inc., NY, NY: 1992; 256-274. ("Gupta")
1030	Claim Chart with '118, '225, and '192 Patent disclosures
1031	Claim Chart with '225 Patent, Chandramouli, and WO'185 disclosures

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