

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. AND LUPIN PHARMACEUTICALS INC.
Petitioners

v.

POZEN, INC.
Patent Owner

CASE IPR: UNASSIGNED

PETITION FOR INTER PARTES REVIEW OF

U.S. PATENT NO. 8,852,636

CLAIMS 1-6 AND 13-15

UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §§ 42.1-.80, 42.100-.123

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PETITIONERS' EXHIBIT LIST

Exhibit Number	Exhibit
1001	U.S. Patent No. 8,852,636
1002	Declaration of Dr. Umesh V. Banakar
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”)
1013	U.S. Patent No. 5,840,737 (“the ’737 patent”)
1014	July 3, 2014 Citizen Petition Denial from FDA to Horizon Pharma (“Horizon Citizen Petition”)
1015	Horizon Pharma, Inc. 2014 Annual Report

I. INTRODUCTION

In this petition for *Inter Partes* Review, Lupin Ltd. and Lupin Pharmaceuticals Inc. seek cancellation of claims 1-6 and 13-15 of U.S. Patent No. 8,852,636 (“the ‘636 patent”). The challenged claims are directed to a naproxen/esomeprazole combination tablet wherein the esomeprazole is not enteric coated and the naproxen is enteric coated so that esomeprazole is immediate release and naproxen is not released until a particular pH of the surrounding medium is reached. Lupin and the patent owner dispute only one aspect of the challenged claims because of the following incontrovertible facts.

Naproxen and esomeprazole are drugs that, as of the time of the alleged invention, were well-known and widely described in the prior art. Naproxen is a well-known nonsteroidal anti-inflammatory drug (“NSAID”), a class of drugs known to treat pain. Esomeprazole was known to be in the class of drugs called proton pump inhibitors (“PPIs”), which raise the pH of the stomach to treat and protect against gastric injury caused by NSAIDs such as naproxen. The prior art disclosed their use in combination as it was a straightforward and obvious choice for a person of ordinary skill in the art (“POSA”) to combine these two drugs in a single tablet. Enteric coated naproxen was a standard treatment and well-known from the prior art. Likewise, as admitted by the ‘636 patent itself, the methods to make a tablet with an enteric coated drug combined with a non-enteric coated drug

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