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Paper 15
Entered: March 1, 2016

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.

Case IPR2015-01774
Patent 8,852,636 B2

Before TONI R. SCHEINER, LORA M. GREEN, and JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively "Petitioner") filed a Corrected Petition (Paper 4, "Pet.")[1] on August 31, 2015, requesting an *inter partes* review of claims 1–6 and 13–15 of U.S. Patent No. 8,852,636 B2 (Ex. 1001, "the '636 patent"). Pozen Inc. ("Patent Owner") filed a Preliminary Response (Paper 14, "Prelim. Resp.") on December 2, 2015. We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Upon consideration of the information presented in the Petition and the Preliminary Response, we are not persuaded that Petitioner has established a reasonable likelihood that it would prevail in its challenges to claims 1–6 and 13–15 of the '636 patent. Accordingly, we decline to institute an *inter partes* review of those claims.

A. Related Proceedings

Petitioner represents it is aware of a number of judicial matters involving the '636 patent (e.g., *Horizon Pharma, Inc. v. Actavis Labs. FL, Inc.*, 3:15-cv-03322 (D.N.J.); *Horizon Pharma, Inc. v. Dr. Reddy's Labs.*,

[1] We note that the Exhibit List in Petitioner's Corrected Petition (Paper 4) is incorrect. The Exhibit numbers on page iii of the Corrected Petition do not match the entries in PRPS, or the designations in the body of the Corrected Petition.

Inc., No. 3:15-cv-03324 (D.N.J.); *Horizon Pharma, Inc. v. Lupin Ltd.*, 3:15-cv-03326 (D.N.J.)), as well as a number of judicial and administrative matters involving the '636 patent (*Coalition for Affordable Drugs VII LLC v. Pozen, Inc.*, Case IPR2015-01680), and patents related to the '636 patent (e.g., *Dr. Reddy's Labs., Inc. v. Pozen Inc.*, Case IPR2015-00802 (PTAB)). Pet. 3–4. Patent Owner makes a similar representation. Paper 8, 8–9. Petitioner also filed other Petitions for *inter partes* review involving related patents directed to similar subject matter—IPR2015-01773, IPR2015-01775.

B. The Asserted Grounds of Unpatentability

Petitioner asserts the challenged claims are unpatentable on the following grounds. Pet. 10–58.[2]

References	**Basis**	**Claims Challenged**
Chen[3] and Chandramouli[4]	§ 103(a)	1–6 and 13–15

[2] Petitioner supports its challenges with the Declaration of Umesh V. Banakar, Ph.D., executed August 18, 2015 ("Banakar Declaration") (Ex. 1002).

[3] U.S. Patent No. 6,544,556 B1, issued April 8, 2003 to Chen et al. ("Chen") (Ex. 1004).

[4] Jane C. Chandramouli & Keith G. Tolman, *Prevention and Management of NSAID-Induced Gastropathy*, 8 J. PHARM. CARE PAIN & SYMPTOM CONTROL 27–40 (2000) ("Chandramouli") (Ex. 1011).

References	Basis	Claims Challenged
Chen and Gimet[5]	§ 103(a)	1–6 and 13–15
Goldman[6] and Gimet	§ 103(a)	1–6 and 13–15
Goldman, Gimet, and Lindberg[7]	§ 103(a)	1–6 and 13–15
Gimet, Chandramouli, and Phillips[8]	§ 103(a)	1–6 and 13–15

C. The '636 Patent (Ex. 1001)

The '636 patent, titled "PHARMACEUTICAL COMPOSITIONS FOR THE COORDINATED DELIVERY OF NSAIDS," discloses pharmaceutical compositions "that provide for the coordinated release of an acid inhibitor and a non-steroidal anti-inflammatory drug (NSAID)" (Ex. 1001, 1:22–24), such that there is "a reduced likelihood of causing unwanted side effects, especially gastrointestinal side effects, when administered as a treatment for pain" (*id.* at 1:24–26).

[5] U.S. Patent No. 5,698,225, issued December 16, 1997 to Gimet et al. ("Gimet") (Ex. 1007).

[6] U.S. Patent No. 5,204,118, issued April 20, 1993 to Goldman et al. ("Goldman") (Ex. 1010).

[7] U.S. Patent No. 5,877,192, issued March 2, 1999 to Lindberg et al. ("Lindberg") (Ex. 1005).

[8] PCT Int'l Patent Appl. WO 00/26185, published May 11, 2000, by Phillips ("Phillips") (Ex. 1012).

Specifically, the '636 patent discloses "a pharmaceutical composition in unit dosage form . . . contain[ing] an acid inhibitor present in an amount effective to raise the gastric pH of a patient to at least 3.5" (*id.* at 3:27–31), and an NSAID "in an amount effective to reduce or eliminate pain or inflammation" (*id.* at 3:67–4:1). "The term 'unit dosage form' . . . refers to a single entity for drug administration. For example, a single tablet or capsule combining both an acid inhibitor and an NSAID would be a unit dosage form." *Id.* at 4:42–45.

> A unit dosage form of the present invention preferably provides for coordinated drug release, in a way that elevates gastric pH and reduces the deleterious effects of the NSAID on the gastroduodenal mucosa, i.e., the acid inhibitor is released first and the release of NSAID is delayed until after the pH in the GI tract has risen.
>
> In a preferred embodiment, the unit dosage form is a multilayer tablet, having an outer layer comprising the acid inhibitor and an inner core which comprises the NSAID. In the most preferred form, coordinated delivery is accomplished by having the inner core surrounded by a polymeric barrier coating that does not dissolve unless the surrounding medium is at a pH of at least 3.5[.]

Id. at 4:45–58.

The claims of the '636 patent are directed to unit dosage forms where the acid inhibitor is esomeprazole (*id.* at 3:46), and the NSAID is naproxen (*id.* at 4:6).

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