Trials@uspto.gov
571-272-7822

Paper 18
Entered: February 11, 2016

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.

Case IPR2015-01680
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

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

I. INTRODUCTION

The Coalition for Affordable Drugs VII LLC ("Petitioner") filed a Petition (Paper 2, "Pet.") on August 7, 2015, requesting an *inter partes* review of claims 1–18 of U.S. Patent No. 8,852,636 B2 (Ex. 1001, "the '636 patent"). Pozen Inc. ("Patent Owner") filed a Preliminary Response (Paper 15, "Prelim. Resp.") on November 17, 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 1–18 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. Inc.*, 3:15-cv-03322 (D.N.J.)), as well as a number of judicial and administrative matters involving patents related to the '636 patent (e.g., *Dr. Reddy's Labs., Inc. v. Pozen Inc.*, Case IPR2015-00802 (PTAB)). Pet. 2–3. Patent Owner makes a similar representation. Paper 7, 8–9. Petitioner also filed other Petitions for *inter partes* review involving patents related to the '636 patent

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

or directed to similar subject matter, including Case Nos. IPR2105-01241 and IPR2015-01344.

B. The Asserted Grounds of Unpatentability

Petitioner asserts the challenged claims are unpatentable on the following grounds. Pet. 4–5, 12–60.[1]

References	**Basis**	**Claims Challenged**
Goldman,[2] Remington,[3] and Lindberg[4]	§ 103(a)	1–18
Gimet,[5] Goldman, and Lindberg	§ 103(a)	1–6 and 13–15
Ouali[6] and Lindberg	§ 103(a)	7–12 and 16–18

[1] Petitioner supports its challenges with the Declaration of Leon Shargel, Ph.D., R.Ph., executed August 7, 2015 ("Shargel Declaration") (Ex. 1003).

[2] U.S. Patent No. 5,204,118, issued April 20, 1993 to Goldman et al. ("Goldman") (Ex. 1004).

[3] Robert E. King & Joseph D. Schwartz, *Oral Solid Dosage Forms*, *in* REMINGTON'S PHARMACEUTICAL SCIENCES 1603–43 (Alfonso R. Gennaro et al., eds.) (17th ed. 1985) ("Remington") (Ex. 1005).

[4] U.S. Patent No. 5,714,504, issued February 3, 1998 to Lindberg et al. ("Lindberg") (Ex. 1007).

[5] U.S. Patent No. 5,698,225, issued December 16, 1997 to Gimet et al. ("Gimet") (Ex. 1006)

[6] U.S. Patent No. 6,183,779 B1, issued February 6, 2001 to Ouali et al. ("Ouali") (Ex. 1008).

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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)" (*id.* at 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).

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

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

> 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).

D. Illustrative Claim

Petitioner challenges claims 1–18 of the '636 patent, of which claims 1 and 7 are independent. Claim 1, reproduced below, is illustrative.

> 1. A pharmaceutical composition in unit dose form suitable for oral administration to a patient, comprising:
>
> > (a) esomeprazole present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms;
> >
> > (b) naproxen present in an amount effective to reduce or eliminate pain or inflammation in said patient upon administration of one or more of said unit dosage forms;
>
> and wherein:
>
> > i) said unit dosage form is a tablet in which said naproxen is present in a core;
> >
> > ii) said tablet comprises a coating, wherein said coating surrounds said core and does not release said naproxen until the pH of the surrounding medium is 3.5 or higher; and
> >
> > iii) said esomeprazole is in one or more layers outside said core, wherein said one or more layers:
> >
> > A) do not include an naproxen;

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.