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Paper 22
Entered: December 8, 2015

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 IPR2015-01241
Patent 6,926,907 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

The Coalition for Affordable Drugs VII LLC ("Petitioner") filed a Petition (Paper 1, "Pet.") on May 21, 2015, requesting an *inter partes* review of claims 1–23 of U.S. Patent No. 6,926,907 B2 (Ex. 1001, "the '907 patent"). Pozen Inc. ("Patent Owner") filed a Preliminary Response (Paper 15, "Prelim. Resp.") on September 18, 2015.[1, 2] 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 1–23 of the '907 patent. Accordingly, we decline to institute an *inter partes* review of those claims.

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[1] Patent Owner filed an unopposed Motion for Extension of Time to File Preliminary Response. Paper 10. The motion was granted via an email from the Board dated September 4, 2015, and the due date for the Preliminary Response was extended until September 19, 2015.

[2] Patent Owner filed a Motion to File Under Seal its Preliminary Response and Exhibit 2011, an associated exhibit. Paper 16. Along with the Motion to Seal, Patent Owner filed a redacted version of the Preliminary Response to be available to the public. Paper 13.

A. Related Proceedings

Petitioner represents it is aware of a number of judicial matters involving the '907 patent (e.g., *AstraZeneca AB v. Dr. Reddy's Labs. Inc.*, 3:11-cv-02317 (D.N.J.)), as well as a number of judicial and administrative matters involving patents related to the '907 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. After filing the current Petition, Petitioner also filed other Petitions for *inter partes* review involving patents related to the '907 patent or directed to similar subject matter, including Case Nos. IPR2105-01344, IPR2015-01680, IPR2015-01718.

B. The Asserted Grounds of Unpatentability

Petitioner asserts the challenged claims are unpatentable on the following grounds. Pet. 12–60.[3]

References	**Basis**	**Claims Challenged**
Gimet[4] and Chiverton[5]	§ 103(a)	1, 7, 8, 12, 13, 22, and 23

[3] Petitioner supports its challenge with the Declaration of Leon Shargel, Ph.D., R.Ph., executed May 25, 2015 ("Shargel Declaration") (Ex. 1003).

[4] U.S. Patent No. 5,698,225, issued December 16, 1997 to Gimet et al. ("Gimet") (Ex. 1004).

[5] S.G. Chiverton et al., *Does misoprostol given as a single large dose improve its antisecretory effect?*, 1 ALIMENT. PHARMACOL. 403–07 (1989) ("Chiverton") (Ex. 1007).

References	Basis	Claims Challenged
Gimet, Goldman,[6] and Remington[7]	§ 103(a)	1–5 and 7–23
Goldman, Remington, and Abe[8]	§ 103(a)	1–5, 7–18, 21, and 22
Goldman, Remington, and Fitton[9]	§ 103(a)	1, 5, and 6

C. The '907 Patent (Ex. 1001)

The '907 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 1:11–14), 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 1:14–18).

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[6] U.S. Patent No. 5,204,118, issued April 20, 1993 to Goldman et al. ("Goldman") (Ex. 1005).

[7] Robert E. King & Joseph D. Schwartz, *Oral Solid Dosage Forms*, *in* REMINGTON'S PHARMACEUTICAL SCIENCES 1603–32 (Alfonso R. Gennaro et al., eds.) (17th ed. 1985) ("Remington") (Ex. 1006).

[8] Kazuo Abe et al., *Effect of Oral and Intramuscular Famotidine on pH and Volume of Gastric Contents*, 68 ANESTH. ANALG. 541–44 (1989) ("Abe") (Ex. 1039).

[9] Andrew Fitton & Lynda Wiseman, *Pantoprazole—A Review of its Pharmacological Properties and Therapeutic Use in Acid-Related Disorders*, 51 DRUGS 460–82 (1996) ("Fitton") (Ex. 1048).

Specifically, the '907 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 3:18–22), and an NSAID "in an amount effective to reduce or eliminate pain or inflammation" (*id.* at 3: 40–41). "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 3:60–63.

> 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, preferably at least 4 and more preferably, at least 5.

Id. at 3:63–4:9.

"The term 'acid inhibitor' refers to agents that inhibit gastric acid secretion and increase gastric pH." *Id.* at 3:25–27. According to the '907 patent, preferred acid inhibiters are H_2-blockers, such as famotidine (*id.* at 3:28–30), and "[o]ther agents that may be effectively used include proton pump inhibitors such as . . . esomeprazole" (*id.* at 3:35–37).

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