Trials@uspto.gov
571-272-7822

Paper 17
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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 IPR2015-01718
Patent 8,945,621 B2

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

SCHEINER, *Administrative Patent Judge*.

DECISION
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 August 12, 2015, requesting an *inter partes* review of claims 1–16 of U.S. Patent No. 8,945,621 B2 (Ex. 1001, "the '621 patent"). Pozen Inc. ("Patent Owner") filed a Preliminary Response (Paper 15, "Prelim. Resp.") on November 23, 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 persuaded that Petitioner has established a reasonable likelihood that it would prevail in its challenges to claims 1–16 of the '621 patent. Accordingly, we institute an *inter partes* review of those claims.

A. Related Proceedings

Petitioner represents it is unaware of any judicial or administrative matters involving the '621 patent. However, Petitioner represents that the '621 patent is listed in the Food and Drug Administration's Orange Book for Vimovo®, and Petitioner has filed other Petitions for *inter partes* review involving patents also listed in the Orange Book for Vimovo®, including

IPR2105-01241, IPR2015-01344, and IPR2015-01680. Pet. 2–3; *see also* Paper 7 (listing four district court matters involving Patent Owner).

B. The Asserted Grounds of Unpatentability

Petitioner asserts the challenged claims are unpatentable on the following grounds. Pet. 4–5, 10–52.[1]

References	**Basis**	**Claims Challenged**
Plachetka,[2] Graham,[3] and Goldstein[4]	§ 103(a)	1–16
Plachetka	§ 103(a)	1–16

C. The '621 Patent (Ex. 1001)

According to the '621 patent—titled "METHOD FOR TREATING A PATIENT AT RISK FOR DEVELOPING AN NSAID-ASSOCIATED ULCER"—the

[1] Petitioner supports its challenges with the Declaration of Leon Shargel, Ph.D., R.Ph., executed August 12, 2015 ("Shargel Declaration") (Ex. 1003).

[2] U.S. Patent No. 6,926,907 B2, issued August 9, 2005 to Plachetka ("Plachetka") (Ex. 1004).

[3] David Y. Graham et al., *Ulcer Prevention in Long-term Users of Nonsteroidal Anti-inflammatory Drugs*, 162 ARCH. INTERN MED. 169–175 (2002) ("Graham") (Ex. 1005).

[4] Jay L. Goldstein et al., *Ulcer Recurrence in High-Risk Patients Receiving Nonsteroidal Anti-Inflammatory Drugs Plus Low-Dose Aspirin: Results of a Post Hoc Subanalysis*, 26 CLINICAL THERAPEUTICS 1637–1643 (2004) ("Goldstein") (Ex. 1006).

cumulative incidence of gastroduodenal ulcers (GDUs) with conventional non-steroidal anti-inflammatory drug (NSAID) use has been reported to be as high as 25–30% at 3 months and 45% at 6 months versus 3–7% for placebo, and at any given time, the incidence of upper gastrointestinal (UGI) ulcers in NSAID users has been estimated to be as high as 30%. *Id.* at 1:25–30. Further according to the '621 patent, "[t]he risk factors associated with an NSAID user developing UGI ulcers include: age ≥ 50 years, history of UGI ulcer or bleeding, or concomitant aspirin use." Ex. 1001, 1:30–32.

The '621 patent discloses a pharmaceutical formulation comprising immediate release esomeprazole (an acid inhibitor, specifically a proton pump inhibitor (PPI)), and enteric-coated naproxen (an NSAID). *Id.* at 1:48–50. According to the '621 patent:

> [T]he pharmaceutical formulation comprising immediate release (IR) esomeprazole magnesium and enteric-coated (EC) naproxen has been found to reduce the incidence of ulcers in patients at risk for developing NSAID-associated ulcers when compared to EC-naproxen. Such a formulation has also been found to reduce the incidence of ulcers in patients taking low dose aspirin (LDA) who are at risk for developing NSAID-associated ulcers when compared to EC-naproxen. Furthermore, patients taking this new formulation of IR esomeprazole and EC-naproxen were able to continue treatment longer than patients taking EC-naproxen.

Id. at 1:48–58. "The term 'low dose aspirin' [LDA] refers to dosages of aspirin that are ≤ 325 mg." *Id.* at 5:9–10.

D. Illustrative Claim

Petitioner challenges claims 1–16 of the '621 patent, of which claims 1, 8, 15, and 16 are independent. Claim 1, reproduced below, is illustrative.

> 1. A method of reducing the incidence of NSAID-associated gastric ulcers in patients taking low dose aspirin who are at risk of developing such ulcers, wherein the method comprises administering to said patient in need thereof a pharmaceutical composition in unit dose form comprising:
>
> (a) 20 mg of esomeprazole, or pharmaceutically acceptable salt thereof, in a form and route sufficient 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, and
>
> (b) 500 mg of naproxen, or pharmaceutically acceptable salt thereof;
>
> wherein said unit dose form provides for coordinated release of the esomeprazole and the naproxen,
>
> wherein at least a portion of said esomeprazole, or pharmaceutically acceptable salt thereof, is released independent of the pH of the surrounding medium,
>
> wherein the unit dosage form releases less than 10% of the naproxen or a pharmaceutically acceptable salt thereof after 2 hours when tested using the USP Paddle Method in 1000 ml of 0.1N HCl at 75 rpm at 37º C.+/-0.5º C.,
>
> wherein said pharmaceutical composition in unit dose form reduces the incidence of NSAID-associated ulcers in said patient and ***wherein administration of the unit dose form is more effective at reducing the incidence of the NSAID-associated ulcers in patients taking LDA than in patients not taking LDA who are administered the unit dose form***.

Ex. 1001, 26:61–27:20 (emphasis added).

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