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Paper 40
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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 JACQUELINE WRIGHT BONILLA, *Vice Chief Administrative Patent Judge*, TONI R. SCHEINER, and LORA M. GREEN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318 AND 37 C.F.R. § 42.73

I. INTRODUCTION

Coalition for Affordable Drugs VII, LLC ("Coalition" or "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. ("Pozen" or "Patent Owner") filed a Preliminary Response (Paper 15, "Prelim. Resp.") on November 23, 2015. On February 22, 2016, we instituted trial as to all of the challenged claims (Paper 17, "Decision" or "Dec.") on the following grounds.[1]

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

[1] Petitioner supported 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 (Ex. 1004, "Plachetka").

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

[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) (Ex. 1006, "Goldstein").

Pozen filed a Patent Owner Response (Paper 25, "PO Resp."),[5] and Coalition filed a Reply (Paper 31, "Reply"). Pozen did not move to amend any claim of the '621 patent.

We heard oral argument on November 16, 2016. A transcript of the argument has been entered into the record as Paper 39.

We have jurisdiction under 35 U.S.C. § 6. Petitioner bears the burden of proving unpatentability of the challenged claims, and that burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must establish facts supporting its challenge by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Coalition has not proved by a preponderance of the evidence that claims 1–16 are unpatentable.

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

[5] Pozen supports its position with the Declarations of Robert W. Makuch, Ph.D., dated June 22, 2016 (Ex. 2021, "Makuch Declaration") and David A. Johnson, M.D., dated June 23, 2016 (Ex. 2022, "Johnson Declaration").

involving patents also listed in the Orange Book for Vimovo®, including Petitions filed in Case Nos. IPR2015-01241, IPR2015-01344, and IPR2015-01680. Pet. 2–3; *see also* Paper 7 (listing four district court matters involving Horizon Pharma USA, Inc., a real party-in-interest of Pozen) 2, 8–9.

B. The '621 Patent (Ex. 1001)

The '621 patent—titled "METHOD FOR TREATING A PATIENT AT RISK FOR DEVELOPING AN NSAID-ASSOCIATED ULCER"—issued on February 3, 2015, listing inventors Brian Ault, Clara Hwang, Everardus Orlemans, John R. Plachetka, and Mark Sostek.

According to the '621 patent, the 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.

C. 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,

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