

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 No. IPR2015-01718
Patent No. 8,945,621

PATENT OWNER'S PRELIMINARY RESPONSE
37 C.F.R. § 42.107

TABLE OF CONTENTS

- I. BACKGROUND1
- II. CLAIM INTERPRETATION5
 - A. “Low Dose Aspirin” and “LDA”5
 - B. “Unit Dosage Form”5
- III. THE USPTO HAS ALREADY CONSIDERED THE PRIOR ART6
- IV. THE BOARD SHOULD DENY CFAD’S PETITION BECAUSE IT FAILS TO DEMONSTRATE A REASONABLE LIKELIHOOD OF PREVAILING11
 - A. Ground 1: The Petition has Not Established a Reasonable Likelihood That Claims 1-16 are Obvious Over Plachetka in View of Graham and Goldstein.....11
 - B. Ground 2: The Petition has Not Established a Reasonable Likelihood That Claims 1-16 are Obvious Over Plachetka18
 - C. The Objective Indicia of Nonobviousness Support the Patentability of the Claims22
 - 1. Surprising and Unexpected Results23
 - 2. The Petition’s Discussion of “Secondary Considerations” is Irrelevant and Should be Disregarded.....29
- V. CONCLUSION.....30

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Anova Food, LLC. v. Sandau,</i> IPR2013-00114, Paper No. 11 (P.T.A.B. June 25, 2014)	27
<i>Crocs, Inc. v. Int’l Trade Comm’n,</i> 598 F.3d 1294 (Fed. Cir. 2010)	23
<i>Excelsior Med. Corp. v. Lake,</i> IPR2013-00494, Paper No. 10 (P.T.A.B. Feb. 6, 2014).....	6
<i>Hulu LLC v. Intertainer, Inc.,</i> IPR2014-01456, Paper No. 8 (P.T.A.B. Mar. 6, 2015).....	6
<i>In re Huai-Hung Kao,</i> 639 F.3d 1057 (Fed. Cir. 2011)	23
<i>Numatics, Inc. v. Balluff, Inc.,</i> 66 F. Supp. 3d 934 (E.D. Mich. 2014)	18
<i>Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.,</i> 520 F.3d 1358 (Fed. Cir. 2008)	23
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<i>Prism Pharma Co. v. Choongwae Pharma Corp.,</i> IPR2014-00315, Paper No. 14 (P.T.A.B. July 8, 2014).....	6
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Statutes

35 U.S.C. § 325(d) 6, 7, 11

Rules

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37 C.F.R. § 42.107(c).....27

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Ex. No.	Description
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2003	PREVACID® (lansoprazole) Delayed-Release Capsules, Prescribing Information (May 1, 2001), downloaded from http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist on November 17, 2015 (“PREVACID 2001”)
2004	Laine <i>et al.</i> , <i>Assessment of Upper Gastrointestinal Safety of Etoricoxib and Diclofenac in Patients with Osteoarthritis and Rheumatoid Arthritis in the Multinational Etoricoxib and Diclofenac Arthritis Long-term (MEDAL) Programme: a Randomised Comparison</i> , <i>Lancet</i> 369:465-473 (2007) (“Laine 2007”)
2005	Angiolillo <i>et al.</i> , <i>Impact of Concomitant Low-Dose Aspirin on the Safety and Tolerability of Naproxen and Esomeprazole Magnesium Delayed-Release Tablets in Patients Requiring Chronic Nonsteroidal Anti-Inflammatory Drug Therapy: an Analysis from 5 Phase III Studies</i> , <i>J Thromb Thrombolysis</i> 38(1):11-23 (2014; first published 12/25/2013) (“Angiolillo 2013”)
2006	Declaration of Lee S. Simon, MD, FACP, FACR, submitted May 22, 2015 from File History of U.S. Patent Application No. 14/593,212 (“Simon Declaration 2015”)
2007	Goldstein, <i>et al.</i> , <i>PN400 Significantly Reduces the Incidence of Gastric Ulcers Compared With Enteric-Coated Naproxen in Patients Requiring Chronic NSAID Therapy Regardless of Low-Dose Aspirin Use: Results from Two Prospective, Randomized Controlled Trials</i> , <i>Arthritis Rheum</i> 60 Suppl. 10:842 (2009) (“Goldstein 2 2009”)

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