

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

**MYLAN PHARMACEUTICALS INC.,
Petitioner,**

v.

**POZEN INC. and HORIZON PHARMA USA, INC.,
Patent Owners.**

**Case IPR2018-00272
Patent 9,393,208**

**PATENT OWNERS POZEN INC. AND HORIZON PHARMA USA, INC.'S
PATENT OWNER PRELIMINARY RESPONSE
PURSUANT TO 37 C.F.R. § 42.120**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	PETITIONER HAS NOT ESTABLISHED THAT THE '285 PATENT IS § 102(e) PRIOR ART	5
A.	Legal Standard.....	6
B.	Petitioner Has Not Met Its Burden to Show That the '285 Patent Is § 102(e) Prior Art	7
III.	THE PTO HAS PREVIOUSLY REJECTED SUBSTANTIALLY THE SAME ARGUMENTS DURING PROSECUTION OF THE PARENT '698 PATENT	8
A.	Institution of an <i>Inter Partes</i> Review Is Discretionary	9
B.	Petitioner Has Failed to Explain Why the Board Should Reconsider Obviousness Over a Plachetka Patent	10
IV.	CONCLUSION.....	11

TABLE OF AUTHORITIES

Page(s)

Cases

<i>Apple Inc. v. Papst Licensing GmbH & Co. KG</i> , IPR2016-01841, Paper 10 (P.T.A.B. Apr. 17, 2017)	9
<i>Applied Materials, Inc. v. Gemini Research Corp.</i> , 835 F.2d 279 (Fed. Cir. 1988)	6
<i>Ariosa Diagnostics, Inc. v. Illumina, Inc.</i> , IPR2014-01093, Paper 69 (P.T.A.B. Jan. 7, 2016)	8
<i>In re DeBaun</i> , 687 F.2d 459 (C.C.P.A. 1982)	7
<i>Riverwood Int’l Corp. v. R.A. Jones & Co.</i> , 324 F.3d 1346 (Fed. Cir. 2003)	7
<i>Robert Bosch Tool Corp. v. SD3, LLC</i> , IPR2016-01750, Paper 15 (P.T.A.B. Apr. 3, 2017)	6
<i>Unified Patents Inc. v. Berman</i> , IPR2016-01571, Paper 10 (P.T.A.B. Dec. 14, 2016)	10

Statutes

35 U.S.C. § 313	1
35 U.S.C. § 314(a)	5
35 U.S.C. § 325(d)	5, 9, 10, 11

Other Authorities

37 C.F.R. § 42.108(a), (b)	9
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EXHIBIT LIST

Exhibit No.	Description of Document
2001	Gabriel, S.E., et al., “Risk for Serious Gastrointestinal Complications Related to Use of Nonsteroidal Anti-inflammatory Drugs,” <i>Annals of Internal Medicine</i> , Vol. 115, No. 10, pp. 787-796 (1991) (“Gabriel”)
2002	Cryer, B. and Feldman, M., “Effects of Nonsteroidal Anti-inflammatory Drugs on Endogenous Gastrointestinal Prostaglandins and Therapeutic Strategies for Prevention and Treatment of Nonsteroidal Anti-inflammatory Drug-Induced Damage,” <i>Archives of Internal Medicine</i> , Vol. 152, pp. 1145-1155 (1992) (“Cryer”)
2003	Fries, J.F., et al., “Nonsteroidal Anti-Inflammatory Drug-Associated Gastropathy: Incidence and Risk Factor Models,” <i>The American Journal of Medicine</i> , Vol. 91, pp. 213-222 (1991) (“Fries”)
2004	U.S. Patent No. 9,220,698 Prosecution History Excerpt: Response to Final Office Action Mailed March 26, 2015 (Sept. 25, 2015)
2005	U.S. Patent No. 9,220,698 Prosecution History Excerpt: Advisory Action (Oct. 9, 2015)

Horizon Pharma USA, Inc. and Pozen Inc. (hereinafter, “Patent Owner”) respectfully submit this preliminary response under 35 U.S.C. § 313 to Mylan Pharmaceuticals Inc.’s (hereinafter, “Petitioner”) request for inter partes review (“IPR”) of claims 1-7 of U.S. Patent No. 9,393,208 (“the ’208 patent”). Petitioner’s Petition fails to demonstrate a reasonable likelihood that claims 1-7 of the ’208 patent are unpatentable. Each of the three proposed grounds includes U.S. Patent No. 8,557,285 (“the ’285 patent”) and Petitioner has not established that the ’285 patent is § 102(e) prior art to the ’208 patent. Petitioner therefore has not shown that there is a reasonable likelihood that it would prevail with respect to any of the challenged claims and institution should be denied.

I. INTRODUCTION

Non-steroidal anti-inflammatory drugs, or NSAIDs, have long been used for the management of inflammatory conditions including osteoarthritis, rheumatoid arthritis, and other musculoskeletal conditions. (Ex. 2001 at 787.) In fact, NSAIDs are one of the most widely used medicines in the world. (*Id.*) But NSAID use has long been known to increase the risk of serious damage to the gastrointestinal track, such as ulcers and bleeding. (*Id.*) This is believed to be the case because NSAIDs inhibit prostaglandin synthesis, which in turn, leads to toxic gastrointestinal effects. (Ex. 2002 at 1145.) The use of NSAIDs is recognized as causing the most prevalent serious drug toxicity in the United States, resulting in an estimated 2,600 deaths and

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