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 IPR2017-01995 Patent 9,220,698

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



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Apple Inc. v. Papst Licensing GmbH & Co. KG, IPR2016-01841, Paper 10 (P.T.A.B. Apr. 17, 2017)	.16
Apple Inc. v. Rensselaer Polytechnic Inst., IPR2014-00319, Paper 12 (P.T.A.B. June 12, 2014)	.12
Applied Materials, Inc. v. Gemini Research Corp., 835 F.2d 279 (Fed. Cir. 1988)13,	14
Ariosa Diagnostics, Inc. v. Illumina, Inc., IPR2014-01093, Paper 69 (P.T.A.B. Jan. 7, 2016)	.15
In re DeBaun, 687 F.2d 459 (C.C.P.A. 1982)	.15
Johnson Health Tech Co. v. Icon Health & Fitness, Inc., IPR2014-01242, Paper 16 (P.T.A.B. Feb. 11, 2015)	7
Riverwood Int'l Corp. v. R.A. Jones & Co., 324 F.3d 1346 (Fed. Cir. 2003)	.14
Robert Bosch Tool Corp. v. SD3, LLC, IPR2016-01750, Paper 15 (P.T.A.B. Apr. 3, 2017)	.14
St. Jude Med., Cardiology Div., Inc. v. Volcano Corp., IPR2013-00258, Paper 29 (P.T.A.B. Oct. 16, 201310,	11
Tristar Prods., Inc. v. Choon's Design, LLC, IPR2015-01883, Paper 6 (PTAB Mar. 9, 2016)	8
Unified Patents Inc. v. Berman, IPR2016-01571, Paper 10 (P.T.A.B. Dec. 14, 2016)	.17
Statutes	
35 U.S.C. § 313	1
35 U.S.C. § 314(a)	5



35 U.S.C. § 315	5, 7
35 U.S.C. § 315(a)	1, 8
35 U.S.C. § 315(b)	1, 10
35 U.S.C. § 325(d)	5, 16
Other Authorities	
37 C.F.R. § 42.104(a)	7
37 C.F.R. § 42.108(a)	16
37 C.F.R. § 42.108(b)	16
157 Cong. Rec. S5429 (daily ed. Sept. 8, 2011) (stmt of Sen. Kyl)	8



EXHIBIT LIST

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Exhibit No.	Description of Document			
2001	Gabriel, S.E., et al., "Risk for Serious Gastrointestinal Complications Related to Use of Nonsteroidal Anti-inflammatory Drugs," Annals of Internal Medicine, 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," Archives of Internal Medicine, Vol. 152, pp. 1145- 1155 (1992) ("Cryer")			
2003	Fries, J.F., et al., "Nonsteroidal Anti-Inflammatory Drug-Associated Gastropathy: Incidence and Risk Factor Models," The American Journal of Medicine, Vol. 91, pp. 213-222 (1991) ("Fries")			
2004	Second Amended Complaint for Patent Infringement, <i>Horizon Pharma, Inc. v. Mylan Pharmaceuticals Inc.</i> , Civil Action No. 2:15-cv-03327 (D.N.J. Feb. 10, 2016)			
2005	Answer to Second Amended Complaint, Separate Defenses, And Counterclaims by Defendants Mylan Pharmaceuticals Inc., Mylan Laboratories Limited and Mylan Inc., <i>Horizon Pharma, Inc. v. Mylan Pharmaceuticals Inc.</i> , Civil Action No. 2:15-cv-03327 (D.N.J. Feb. 19, 2016)			
2006	Plaintiffs' Answer to Defendants' Counterclaims to Second Amended Complaint, <i>Horizon Pharma, Inc. v. Mylan</i> <i>Pharmaceuticals Inc.</i> , Civil Action No. 2:15-cv-03327 (D.N.J. Mar. 7, 2016)			
2007	157 Cong. Rec. S5429 (daily ed. Sept. 8, 2011) (statement of Sen. Kyl)			



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