

Filed: March 8, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.

Petitioner

v.

HORIZON PHARMA USA, INC. and NUVO PHARMACEUTICALS
(IRELAND) DESIGNATED ACTIVITY COMPANY,

Patent Owners

Case No. IPR2018-00272

U.S. Patent No. 9,393,208

PETITIONER'S OBJECTIONS TO PATENT OWNERS' EVIDENCE

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Mylan Pharmaceuticals Inc. (“Petitioner”) objects to the admissibility of the following exhibits filed by Patent Owners Horizon Pharma USA, Inc. and Nuvo Pharmaceuticals (Ireland) Designated Activity Company (“Patent Owners”) in the Patent Owners’ Response in the above-captioned *inter partes* review.

Petitioner’s objections are timely under 37 C.F.R. § 42.64(b)(1) because they are being filed and served within five business days. Petitioner’s objections provide notice to Patent Owners that Petitioner may move to exclude these exhibits under 37 C.F.R. § 42.64(c).

In this paper, a reference to “FRE” means the Federal Rules of Evidence, a reference to “CFR” means the Code of Federal Regulations, and “’208 patent” means U.S. Patent No. 9,393,208. All objections under FRE 801-803 (hearsay) apply to the extent Patent Owners rely on the exhibits identified in connection with that objection for the truth of the matter asserted therein.

Exhibit descriptions provided in this table are taken from Patent Owners’ exhibit list and are used for identification purposes only. The use of the description does not indicate that Petitioner agrees with the descriptions or characterizations of the documents.

Exhibit	Description	Objection
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")	A, B, D, F, G, H, M, N, O
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")	A, B, D, F, G, H, M, N, O
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")	A, B, D, F, G, H, M, N, O
2004	U.S. Patent No. 9,220,698 Prosecution History Excerpt: Response to Final Office Action Mailed March 26, 2015 (Sept. 25, 2015)	A, I, M, N, O
2005	U.S. Patent No. 9,220,698 Prosecution History Excerpt: Advisory Action (Oct. 9, 2015)	A, I, M, N, O
2006	Pozen Inc. Bankruptcy Petition dated August 10, 2018	A, C, E, I, M, N, O
2007-2011	Exhibits Not Used	P
2012	Gabriel, S.E., et al., <i>Risk for Serious Gastrointestinal Complications Related to Use of Nonsteroidal Anti-inflammatory Drugs</i> , <i>Annals of Internal Medicine</i> , Vol. 115, No. 10, pp. 787-796 (1991) (with publication information)	A, D, F, G, H, M, N, O
2013	Cryer, B. and Feldman, M., <i>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> , <i>Archives of Internal Medicine</i> , Vol. 152, pp. 1145-1155 (1992) (with publication information)	A, D, F, G, H, M, N, O

Exhibit	Description	Objection
2014	Fries, J.F., et al., <i>Nonsteroidal Anti-Inflammatory Drug-Associated Gastropathy: Incidence and Risk Factor Models</i> , The American Journal of Medicine, Vol. 91, pp. 213-222 (1991) (with publication information)	A, D, F, G, H, M, N, O
2015	Jan. 12, 2017 Trial Testimony of John R. Plachetka in the <i>Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.</i> , Case No. 3:11-cv-02317 (D.N.J.)	A, B, C, D, E, F, G, H, I, J, M, N, O, W
2016	Jan. 24, 2018 Deposition Testimony of Dr. John R. Plachetka in the <i>Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.</i> , Case No. 3:15-cv-03324 (D.N.J.) PROTECTIVE ORDER MATERIAL	A, B, C, D, E, F, G, H, I, J, M, N, O, W
2017	PN400-104 Clinical Study Report PROTECTIVE ORDER MATERIAL	A, B, C, D, E, F, I, M, N, O
2018	Oct. 12, 2017 Deposition Testimony of Everardus Orlemans, Ph.D. in the <i>Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.</i> , Case No. 3:15-cv-03324 (D.N.J.)	A, B, C, D, E, F, G, H, I, J, M, N, O, W
2019	Oct. 27, 2017 Deposition Testimony of Mark Sostek, MD in the <i>Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.</i> , Case No. 3:15-cv-03324 (D.N.J.) PROTECTIVE ORDER MATERIAL	A, B, C, D, E, F, G, H, I, J, M, N, O, W
2020	Oct. 25, 2017 Deposition Testimony of Brian Ault, Ph.D. in the <i>Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.</i> , Case No. 3:15-cv-03324 (D.N.J.) PROTECTIVE ORDER MATERIAL	A, B, C, D, E, F, G, H, I, J, M, N, O, W
2021	Norman, A. and Hawkey, C.J., <i>What you need to know when you prescribe a proton pump inhibitor</i> , Frontline Gastroenterology, Vol. 2, pp. 199-205 (2011)	A, C, D, E, F, G, H, M, N, O
2022	Stollman, N. and Metz, D.C., <i>Pathophysiology and prophylaxis of stress ulcer in intensive care unit patients</i> , J. Critical Care, Vol. 20, pp. 35-45 (2005)	A, D, F, G, H, M, N, O

Exhibit	Description	Objection
2023	Declaration of Michael Mayersohn, Ph.D. in Support of Defendants' Claim Construction Brief filed on April 24, 2014 in <i>Par Pharm., Inc. v. Takeda Pharm. Co.</i> , Case No. 5:13-CV-1927 LHK (PSG)	A, B, C, D, E, F, G, H, I, M, N, O
2024	January 30, 2013 Amendment C and Response to Final Office Action, Application No. 12/553,107	A, I, M, N, O
2025	Declaration of David R. Taft PH.D. In Support of Patent Owner Response to Petition for <i>Inter Partes</i> Review of U.S. Patent No. 9,393,208	A, D, F, G, H, I, N, O, Q, S, T, U
2026	Declaration of David A. Johnson. M.D. In Support of Patent Owner Response to Petition for <i>Inter Partes</i> Review of U.S. Patent No. 9,393,208	A, D, F, G, H, I, N, O, Q, S, T, U
2027	IPR2017-01995, May 25, 2018 Deposition Transcript of David C. Metz	A, B, D, F, G, H, I, K, L, M, N, O, Q, S, T, U
2028	Redacted Amended Memorandum Opinion (D.I. 498), Case 3:11-cv-02317-MLC-DEA (D.N.J. July 12, 2017)	A, C, E, I, M, N, O
2029	IPR2017-01995, May 24, 2018 Deposition Transcript of Dr. Michael Mayersohn	A, B, D, F, G, H, I, K, L, M, N, O, Q, S, T, U
2030	Oct. 16, 2014 Deposition Testimony of Brian Ault, Ph.D. in the <i>Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.</i> , Case No. 3:11-cv-02317 (D.N.J.) PROTECTIVE ORDER MATERIAL	A, B, C, D, E, F, G, H, I, J, M, N, O, W
2031	Oct. 10, 2014 Deposition Testimony of Dr. Mark Sostek in the <i>Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.</i> , Case No. 3:11-cv-02317 (D.N.J.) PROTECTIVE ORDER MATERIAL	A, B, C, D, E, F, G, H, I, J, M, N, O, W
2032	Email string from Tore Lind to Richard Leff, Doug Levine, David Magner, and Mark Sostek, dated May 27, 2006 to May 31, 2006	A, B, D, F, I, J, K, M, N, O, R

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