Filed: March 22, 2018

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 No. IPR2017-01995
U.S. Patent No. 9,220,698

PETITIONER'S OBJECTIONS TO PATENT OWNERS' EXHIBITS

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 Pozen Inc. and Horizon Pharma USA, Inc. ("Patent Owners") in the Patent Owners' Preliminary 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 ten business days of the institution of trial in this matter, on March 8, 2018. (Paper No. 18.) 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 "'698 patent" means U.S. Patent No. 9,220,698. 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," Annals of Internal Medicine, Vol. 115, No. 10, pp. 787-796 (1991) ("Gabriel")	A, B, 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," Archives of Internal Medicine, Vol. 152, pp. 1145-1155 (1992) ("Cryer")	A, B, N, O
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")	A, B, N, O
2004	Second Amended Complaint for Patent Infringement, *Horizon Pharma, Inc. v. Mylan Pharmaceuticals Inc.*, Civil Action No. 2:15-cv-03327 (D.N.J. Feb. 10, 2016)	A, B, N, O
2005	Answer to Second Amended Complaint, Separate Defenses, And Counterclaims by Defendants Mylan Pharmaceuticals Inc., Mylan Laboratories Limited and Mylan Inc., *Horizon Pharma, Inc. v. Mylan Pharmaceuticals Inc.*, Civil Action No. 2:15-cv-03327 (D.N.J. Feb. 19, 2016)	B, N, O
2006	Plaintiffs' Answer to Defendants' Counterclaims to Second Amended Complaint, *Horizon Pharma, Inc. v. Mylan Pharmaceuticals Inc.*, Civil Action No. 2:15-cv-03327 (D.N.J. Mar. 7, 2016)	A, B, N, O
2007	157 Cong. Rec. S5429 (daily ed. Sept. 8, 2011) (statement of Sen. Kyl)	A, B, N, O

Petitioner objects to paragraphs in the Patent Owners' Preliminary Response that rely on exhibits objected to in this Petitioner's Objection to Evidence.

Objection Key:

A: FRE 801/802/803 (hearsay)

B: FRE 901/902 (lacking authentication)

C: FRE 402 (relevance) the document is not relevant to any issue in this IPR proceeding because the purported date of the document is after the filing date of the '698 patent or the prior art status is not clear

D: FRE 402 (relevance) to the extent the document is relied upon for secondary considerations of nonobviousness, there is no nexus to the claimed compositions and methods

E: FRE 403 (confusing, waste of time) the document is not relevant to any issue in this IPR proceeding because the purported date of the document is after the filing date of the '698 patent or the prior art status is not clear

F: FRE 403 (confusing, waste of time) to the extent the document is relied upon for secondary considerations of nonobviousness, there is no nexus to the claimed compositions and methods

G: FRE 702 (improper expert testimony) expert testimony that relies on the document is not based on sufficient facts or data and/or is not the product of reliable principles and methods

H: FRE 703 (bases of expert opinion) expert testimony that relies on the document is unreliable because the document is not of a type reasonably relied upon by experts in the field

I: FRE 106 (completeness) the document is incomplete and includes only a select portion of a larger document that in fairness should be considered along with this document

J: FRE 701, 702 (improper expert testimony) improper expert testimony by a lay witness

K: FRE 1001-1003 (best evidence)

L: FRE 403, 901 (improper compilation)

M: FRE 403 (cumulative)

N: FRE 402 (relevance) the document is not relevant to any issue in the IPR proceeding

O: FRE 403 (confusing, waste of time) the document is not relevant to any issue in the IPR proceeding

P: No exhibit filed.

Q: Expert testimony fails to identify with particularity the underlying facts or data on which the opinion is based, violating 37 C.F.R. § 42.65(a)

R: FRE 602 (lack of personal knowledge)

S: FRE 702/703 to the extent that the expert declarant relies on an exhibit objected to under grounds G and H, the testimony is (i) not based on sufficient facts or data and/or is not the product of reliable principles and methods and/or is (ii) is unreliable because the exhibit is not of a type reasonably relied upon by experts in the field

T: FRE 1006 (improper summary)

U: 37 C.F.R. § 42.65 (fails to provide underlying facts or data on which opinion is based)

Respectfully submitted,

March 22, 2018

/Brandon M. White/

Brandon M. White, Esq.
Reg. No. 52,354
Perkins Coie LLP
700 Thirteenth Street, N.W.
Suite 600
Washington, DC 20005-3960
bmwhite@perkinscoie.com
Tel: 202-654-6206
Fax: 202-654-9681

Counsel for Petitioner
Mylan Pharmaceuticals Inc.

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