

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner,

v.

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

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Case IPR2017-01995  
Patent 9,220,698

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**PATENT OWNERS POZEN INC. AND HORIZON PHARMA USA, INC.'S  
OBJECTIONS TO PETITIONER'S EVIDENCE  
PURSUANT TO 37 C.F.R. § 42.64(b)(1)**

## I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(b)(1) and the Federal Rules of Evidence (“FRE”), Patent Owners Horizon Pharma USA, Inc. (“Horizon”) and Pozen Inc. (“Pozen”) (collectively, “Patent Owner”) submit the following objections to evidence filed by Mylan Pharmaceuticals, Inc. (“Mylan” or “Petitioner”) with Mylan’s Petition for *Inter Partes* Review of U.S. Patent No. 9,220,698 (the “Petition”). These objections are timely filed within ten business days of the institution of the trial, March 8, 2018. (Paper 18.)

## II. IDENTIFICATION OF CHALLENGED EXHIBITS AND GROUNDS FOR OBJECTIONS

### A. Exhibit 1006

Exhibit 1006 is purportedly an article authored by Howden and published in the journal *Alimentary Pharmacology & Therapeutics* in 2005. Patent Owner objects to Exhibit 1006 as not properly authenticated under FRE 901. Petitioner has produced insufficient evidence to support a finding that this exhibit is what Petitioner claims it is. Patent Owner further objects to this exhibit as inadmissible hearsay under FRE 802 and as not supporting Petitioner’s characterization of the truth of the matter asserted. (*See, e.g.*, Pet. at 28-29; Ex. 1002 at 24 (citing Ex. 1006); Ex. 1003 at 56 (citing Ex. 1006).)

**B. Exhibit 1008**

Exhibit 1008 is a webpage printout purportedly from <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020067>. Patent Owner objects to Exhibit 1008 as not properly authenticated under FRE 901. Petitioner has produced insufficient evidence to support a finding that this exhibit is what Petitioner claims it is. Patent Owner further objects to this exhibit as inadmissible hearsay under FRE 802 and as not supporting Petitioner's characterization of the truth of the matter asserted. (*See, e.g.,* Pet. at 48-49; Ex. 1002 at 25 (citing Ex. 1008).)

**C. Exhibit 1009**

Exhibit 1009 is purportedly an EC-Naprosyn® (delayed-release naproxen) package insert published in 2007. Patent Owner objects to Exhibit 1009 as not properly authenticated under FRE 901. Petitioner has produced insufficient evidence to support a finding that this exhibit is what Petitioner claims it is. Petitioner has not submitted sufficient evidence that this exhibit originated from a package of EC-Naprosyn® sold in 2007. Patent Owner further objects to this exhibit as inadmissible hearsay under FRE 802 and as not supporting Petitioner's characterization of the truth of the matter asserted. (*See, e.g.,* Pet. at 29-31; Ex. 1002 at 25-26 (citing Ex. 1009); Ex. 1003 at 52-53 (citing Ex. 1009).)

**D. Exhibit 1010**

Exhibit 1010 is purportedly a Zegerid® (omeprazole) label published in 2004. Patent Owner objects to Exhibit 1010 as not properly authenticated under FRE 901. Petitioner has produced insufficient evidence to support a finding that this exhibit is what Petitioner claims it is. Petitioner has not submitted sufficient evidence that this exhibit originated from a package of Zegerid® sold in 2004. Patent Owner further objects to this exhibit as inadmissible hearsay under FRE 802 and as not supporting Petitioner's characterization of the truth of the matter asserted. (*See, e.g.*, Pet. at 29-31; Ex. 1002 at 26-27 (citing Ex. 1010); Ex. 1003 at 557-58 (citing Ex. 1010).)

**E. Exhibit 1011**

Exhibit 1011 is purportedly an article authored by Goldstein and published in the journal *Gastroenterology* in 2004. Patent Owner objects to Exhibit 1011 as not properly authenticated under FRE 901. Petitioner has produced insufficient evidence to support a finding that this exhibit is what Petitioner claims it is. Patent Owner further objects to this exhibit as inadmissible hearsay under FRE 802 and as not supporting Petitioner's characterization of the truth of the matter asserted. (*See, e.g.*, Pet. at 26-27; Ex. 1002 at 27-28 (citing Ex. 1011); Ex. 1003 at 70 (citing Ex. 1011).)

**F. Exhibit 1012**

Exhibit 1012 is purportedly a publication by Hochberg published in 2008. Patent Owner objects to Exhibit 1012 as not properly authenticated under FRE 901. Petitioner has produced insufficient evidence to support a finding that this exhibit is what Petitioner claims it is. Patent Owner further objects to this exhibit as inadmissible hearsay under FRE 802 and as not supporting Petitioner's characterization of the truth of the matter asserted. (*See, e.g.*, Pet. at 25-26; Ex. 1002 at 28 (citing Ex. 1012); Ex. 1003 at 48 (citing Ex. 1012).)

**G. Exhibit 1014**

Exhibit 1014 is purportedly an article authored by Wolfe and published in the journal *Gastroenterology* in 2000. Patent Owner objects to Exhibit 1014 as not properly authenticated under FRE 901. Petitioner has produced insufficient evidence to support a finding that this exhibit is what Petitioner claims it is. Patent Owner further objects to this exhibit as inadmissible hearsay under FRE 802 and as not supporting Petitioner's characterization of the truth of the matter asserted. (*See, e.g.*, Pet. at 61; Ex. 1002 at 39 (citing Ex. 1014); Ex. 1003 at 97 (citing Ex. 1014).)

**H. Exhibit 1015**

Exhibit 1015 is purportedly an article authored by Bell and published in the journal *Digestion* in 1992. Patent Owner objects to this exhibit as inadmissible hearsay under FRE 802 and as not supporting Petitioner's characterization of the

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