

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC. and  
DR. REDDY'S LABORATORIES, INC.

Petitioners

v.

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

Patent Owners

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Case No. IPR2018-00272<sup>1</sup>  
U.S. Patent No. 9,393,208

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**PATENT OWNERS' OBJECTIONS TO PETITIONER'S EVIDENCE  
PURSUANT TO 37 C.F.R. § 42.64(b)(1)**

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<sup>1</sup> Petitioner Dr. Reddy's Laboratories, Inc., from IPR2018-01341, has been joined as a Petitioner to this proceeding.

## **I. INTRODUCTION**

Pursuant to 37 C.F.R. § 42.64(b)(1) and the Federal Rules of Evidence (“FRE”), Patent Owners submit the following objections to evidence filed by Mylan Pharmaceuticals, Inc. (“Mylan” or “Petitioner”) with Petitioner’s Reply to Patent Owner’s Response (“Reply”). These objections are timely filed within five business days of service of the Reply, May 8, 2019. (Paper 49).

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

### **A. Exhibit 1060**

Exhibit 1060 is purportedly an article authored by Hawkey and published in the journal *New England Journal of Medicine* in 1998. Patent Owner objects to Exhibit 1060 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.*, Ex. 1059 at 9, 11, 12 (citing Ex. 1060).)

### **B. Exhibit 1061**

Exhibit 1061 is purportedly an article authored by Yeomans and published in the journal *New England Journal of Medicine* in 1998. Patent Owner objects to Exhibit 1061 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.*, Ex. 1059 at 9, 10, 11, 12 (citing Ex. 1061).)

**C. Exhibit 1062**

Exhibit 1062 is purportedly an article authored by Agrawal and published in the journal *Annals of Internal Medicine* in 1991. Patent Owner objects to Exhibit 1062 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.*, Ex. 1059 at 10 (citing Ex. 1062).)

**D. Exhibit 1063**

Exhibit 1063 is purportedly an article authored by Brown and published in the journal *Drug Safety* in 1999. Patent Owner objects to Exhibit 1063 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.*, Ex. 1059 at 5, 6, 10, 12 (citing Ex. 1063).)

**E. Exhibits 1064, 1076, and 1088**

Exhibits 1064, 1076, and 1088 are purportedly an excerpt from the Physicians' Desk Reference (54 ed. 2000). Exhibits 1064, 1076, and 1088 are purportedly submitted as an earlier version of Exhibit 1009, submitted in Petitioner's Petition. Patent Owner objects to these exhibits as untimely and new prior art evidence, in violation of 37 C.F.R. § 42.23(b). 37 C.F.R. § 42.23(b) does not authorize or otherwise provide a means for supplementing the evidence of record. Petitioner does not contend that Exhibits 1064, 1076, and 1088 were not available to Petitioner at the time of filing of Petitioner's Petition. Patent Owner further objects to Exhibits 1064, 1076, and 1088 as not properly authenticated under FRE 901. Petitioner has produced insufficient evidence to support a finding that these exhibits are what Petitioner claims they are. Patent Owner further objects to these exhibits under the best evidence rule under FRE 1001-1003. Patent Owner further objects to these exhibits as irrelevant under FRE 402/403. Patent Owner further objects to these exhibits as inadmissible hearsay under FRE 802 and as not supporting Petitioner's characterization of the truth of the matter asserted. (*See, e.g.*, Reply at 20; Ex. 1059 at 18, 19, 25 (citing Ex. 1064).)

**F. Exhibit 1065**

Exhibit 1065 is purportedly the Nexium prescribing information. Exhibit 1065 is purportedly submitted as another version of Exhibit 1043, submitted in

Petitioner's Petition. Patent Owner objects to this exhibit as untimely and new prior art evidence, in violation of 37 C.F.R. § 42.23(b). 37 C.F.R. § 42.23(b) does not authorize or otherwise provide a means for supplementing the evidence of record. Petitioner does not contend that Exhibit 1065 was not available to Petitioner at the time of filing of Petitioner's Petition. Patent Owner further objects to Exhibit 1065 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 irrelevant under FRE 402/403. 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.*, Ex. 1059 at 19 (citing Ex. 1065).)

**G. Exhibit 1066**

Exhibit 1066 is purportedly the EC-Naprosyn prescribing information. Exhibit 1066 is purportedly submitted as another version of Exhibit 1009, submitted in Petitioner's Petition. Patent Owner objects to this exhibit as untimely and new prior art evidence, in violation of 37 C.F.R. § 42.23(b). 37 C.F.R. § 42.23(b) does not authorize or otherwise provide a means for supplementing the evidence of record. Petitioner does not contend that Exhibit 1066 was not available to Petitioner at the time of filing of Petitioner's Petition. Patent Owner further objects to Exhibit 1066 as not properly authenticated under FRE 901. Petitioner has produced

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