

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

**MYLAN PHARMACEUTICALS, INC. and
AMNEAL PHARMACEUTICALS LLC**

Petitioners

v.

YEDA RESEARCH AND DEVELOPMENT CO. LTD.

Patent Owner

**Case IPR2015-00643 (Patent 8,232,250 B2)
Case IPR2015-00644 (Patent 8,399,413 B2)
Case IPR2015-00830 (Patent 8,969,302 B2)^{1,2}**

**PATENT OWNER'S OBJECTIONS TO EVIDENCE
PURSUANT TO 37 C.F.R. §42.64**

¹ The word-for-word identical paper is filed in each proceeding identified in the caption.

² Cases IPR2015-01976, IPR2015-01980, and IPR2015-01981 have been joined with IPR2015-00643, IPR2015-00644, and IPR2015-00830, respectively.

Pursuant to 37 C.F.R. § 42.64, Patent Owner Yeda Research and Development Co., Ltd. (“Yeda”) objects to the admissibility of the documents identified below that were submitted by Petitioners Mylan Pharmaceuticals, Inc. and Amneal Pharmaceuticals LLC (collectively, “Petitioners”) on March 9, 2016, for the following reasons:

1. Petitioners’ Exhibit 1067 is objected to under Federal Rules of Evidence 402/403 because it is not relevant to any issue in the above-captioned proceedings.

2. Petitioners’ Exhibit 1068 is objected to under Federal Rules of Evidence 402/403 to the extent that it is relied upon for any teaching prior to August 20, 2009. This Exhibit is also objected to under Federal Rules of Evidence 402/403 as being cumulative over Exhibit 1089.

3. Petitioners’ Exhibit 1070 is objected to under Federal Rules of Evidence 402/403 to the extent that it is relied upon for any teaching prior to August 20, 2009. This Exhibit is also objected to as hearsay (subject to no exception) under Federal Rules of Evidence 801/802.

4. Petitioners’ Exhibit 1071 is objected to under Federal Rules of Evidence 402/403 as being cumulative over Exhibit 1097.

5. Petitioners' Exhibit 1072 is objected to under Federal Rules of Evidence 402/403 because it relates to a separate judicial proceeding and is not relevant to any issue in the above-captioned proceedings. This Exhibit is also objected to as hearsay (subject to no exception) under Federal Rules of Evidence 801/802.

6. Petitioners' Exhibit 1073 is objected to under Federal Rules of Evidence 402/403 to the extent that it is relied upon for any teaching prior to August 20, 2009. This Exhibit is also objected to as hearsay (subject to no exception) under Federal Rules of Evidence 801/802.

7. Petitioners' Exhibit 1074 is objected to under Federal Rules of Evidence 402/403 to the extent that it is relied upon for any teaching prior to August 20, 2009. This Exhibit is also objected to as hearsay (subject to no exception) under Federal Rules of Evidence 801/802.

8. Petitioners' Exhibit 1076 is objected to under Federal Rules of Evidence 402/403 because it relates to a separate judicial proceeding and is not relevant to any issue in the above-captioned proceedings. This Exhibit is also objected to as hearsay (subject to no exception) under Federal Rules of Evidence 801/802.

9. Petitioners' Exhibit 1077 is objected to under Federal Rules of Evidence 402/403 because it relates to a separate judicial proceeding and is not relevant to any issue in the above-captioned proceedings. This Exhibit is also objected to as hearsay (subject to no exception) under Federal Rules of Evidence 801/802.

10. Petitioners' Exhibit 1079 is objected to under Federal Rules of Evidence 402/403 to the extent that it is relied upon for any teaching prior to August 20, 2009. This Exhibit is also objected to as hearsay (subject to no exception) under Federal Rules of Evidence 801/802.

11. Petitioners' Exhibit 1080 is objected to under Federal Rules of Evidence 402/403 to the extent that it is relied upon for any teaching prior to August 20, 2009. This Exhibit is also objected to as hearsay (subject to no exception) under Federal Rules of Evidence 801/802.

12. Petitioners' Exhibit 1081 is objected to under Federal Rules of Evidence 402/403 to the extent that it is relied upon for any teaching prior to August 20, 2009. This Exhibit is also objected to as hearsay (subject to no exception) under Federal Rules of Evidence 801/802. This Exhibit is also objected to because it has not been properly authenticated as required by Federal Rule of Evidence 901.

13. Petitioners' Exhibit 1082 is objected to under Federal Rules of Evidence 402/403 to the extent that it is relied upon for any teaching prior to August 20, 2009. This Exhibit is also objected to as hearsay (subject to no exception) under Federal Rules of Evidence 801/802.

14. Petitioners' Exhibit 1083 is objected to under Federal Rules of Evidence 402/403 to the extent that it is relied upon for any teaching prior to August 20, 2009. This Exhibit is also objected to as hearsay (subject to no exception) under Federal Rules of Evidence 801/802. This Exhibit is also objected to because it has not been properly authenticated as required by Federal Rule of Evidence 901.

15. Petitioners' Exhibit 1085 (Declaration of Ari Green) is objected to as unreliable under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Dr. Green is not an expert on, for example, glatiramer acetate or the mechanism of action of glatiramer acetate. He does not possess the requisite credentials or expertise to render opinions in this case. This Exhibit is further objected to as unreliable under Federal Rules of Evidence 702/703 because its bases are not of the type reasonably relied upon by experts in the field in forming an opinion. Patent Owner further objects to this Exhibit to the extent that the opinions offered

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