UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC.

Petitioner

v.

YEDA RESEARCH AND DEVELOPMENT CO. LTD.

Patent Owner

Case No. IPR2015-00644
Patent No. 8,399,413

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

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 Petitioner during the preliminary proceedings, for the following reasons:

1. Petitioner's Exhibit 1007[1] is objected to because it has not been properly authenticated as required by Federal Rule of Evidence (FRE) 901 and there is no admissible evidence establishing that this exhibit was in fact sufficiently publicly accessible such that this document qualifies as a prior art printed publication. Exhibit 1007 is also objected to as being hearsay.

2. Patent Owner Yeda also objects to the statements regarding Exhibit 1007 in the Petition (Paper 2) and Exhibits 1003 (Declaration of Stephen Peroutka) and 1004 (Declaration of Ari Green). For example, neither Dr. Peroutka nor Dr. Green provide testimony from personal knowledge regarding whether Exhibit 1007 is authentic or qualifies as a printed publication. Thus, all statements in the Petition and testimony by Drs. Peroutka and Green concerning this exhibit lack foundation and assume facts not in evidence.

3. Exhibit 1003 (Declaration of Stephen Peroutka) is objected to as unreliable under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Dr. Peroutka does not possess the

[1] "Summary Basis of Approval for the New Drug Application for 20 mg daily

requisite credentials or expertise to render opinions in this case.

3. Exhibits 1017 (FDA Guidelines for Industry), 1021 (Goodman & Gilman), 1023 (Haines), 1027 (Boissel 2002), 1034 (Beringer 2005), 1035 (Franklin), 1040 (Kragt 2006), 1041 (Manso), 1048 (Betaseron label), 1049 (Rebif label), 1050 (Avonex label), 1051 (Tysabri prescribing information), 1053 (Extavia monograph), 1054 (Jacobs), 1055 (dictionary), 1057 (Concepts in Clinical Science), 1059 (FDA Guidance) and 1060 (Rebif label) are objected to under Federal Rules of Evidence 401/403.

These objections have been timely made within ten business days from the institution of trial.

Respectfully Submitted,

Date: September 9, 2015

/Elizabeth J. Holland/

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CERTIFICATE OF SERVICE

I hereby certify that on September 9, 2015, I caused a true and correct copy of the foregoing **PATENT OWNER'S OBJECTIONS TO EVIDENCE PURSUANT TO 37 C.F.R. § 42.64** to be served via email on the following attorneys of record for Petitioner:

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/Eleanor Yost/

Dated: September 9, 2015