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 MOTION TO EXCLUDE EVIDENCE

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[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(c) and Section II.K of the Office Patent Trial Practice Guide, Patent Owner Yeda Research and Development Co. ("Yeda" or "Patent Owner") hereby moves to exclude Exhibits 1068, 1086, 1089, 1098, and 1140 submitted by Petitioners Mylan Pharmaceuticals Inc. and Amneal Pharmaceuticals LLC ("Petitioners").

I. Statement of Precise Relief Requested

Patent Owner seeks to exclude Petitioners' Exhibits 1068, 1086, 1089, 1098, and 1140. *See* 37 C.F.R. § 42.22(a)(1).

Exhibit 1068 is a copy of a 2009 abstract by O. Khan *et al.*, entitled *Glatiramer acetate 20mg subcutaneous twice-weekly versus daily injections: results of a pilot, prospective, randomised, and rater-blinded clinical and MRI 2-year study in relapsing-remitting multiple sclerosis*, published in MULTIPLE SCLEROSIS. Petitioners refer to this abstract as "Khan 2009."

Exhibit 1086 is a printout from the Shared Solutions® website sponsored by Teva Neuroscience, Inc., which provides online resources and support for Copaxone® users.

Exhibit 1089 is a copy of a 2009 abstract by O. Khan *et al.*, entitled *Glatiramer acetate 20mg subcutaneous twice-weekly versus daily injections: results of a pilot, prospective, randomised, and rater-blinded clinical and MRI 2-*

year study in relapsing-remitting multiple sclerosis, published in MULTIPLE SCLEROSIS. It is the same abstract identified in Exhibit 1068.[3]

Exhibit 1098 is a copy of a 2012 article by Lauren LeBano entitled *Gray Matter Atrophy in Multiple Sclerosis: A Longitudinal Study*, published in ANNALS OF NEUROLOGY.

Exhibit 1140 is the redacted transcript of the February 15, 2016 deposition of Jerry S. Wolinsky, M.D., in connection with the consolidated, related district court litigation, *In re Copaxone 40 mg*, Case No. 14-1171-GMS (D. Del.) ("Wolinsky Deposition Transcript").

II. Evidence Relied Upon In Support Of This Motion

The evidence relied upon in support of this motion includes: (1) Petitioners' Reply filed on March 9, 2015 (IPR2015-00643, Paper 58 ("Petitioners' Reply")); (2) Patent Owner's Objections to Evidence Pursuant to 37 C.F.R. § 42.64, filed March 16, 2016 (*id.* at Paper 64); (3) the Expert Report of Ari Green, M.D. In Support Of Petitioner's Reply To Patent Owner's Response (Exhibit 1085, or the "Green Reply Report"); and (4) the transcript of the April 6, 2016 deposition of Ari Green, M.D. (Exhibit 1142).

[3] Exhibit 1068 is the deposition copy of Khan 2009, used in the Deposition of Edward J. Fox, M.D. (*see* Ex. 2146 at 86:10-23).

III. Identification Of Original Objections

Patent Owner timely objected to Exhibits 1068, 1086, 1089, and 1098 on March 16, 2016. IPR2015-00643, Paper 64 at ¶¶ 2, 16, 19, 28; *see* 37 C.F.R. § 42.64(b)(1). In its timely-filed objections, Patent Owner maintained that Exhibits 1068, 1086, 1089, and 1098 were, *inter alia*, dated after August 20, 2009, and thus irrelevant under Federal Rules of Evidence ("FRE") 402 and 403 to the extent they were relied upon for any teaching prior to August 20, 2009. The Petitioner did not respond, with supplemental evidence or otherwise, to these objections.

Petitioners introduced Exhibit 1140 during the deposition of their own expert, Dr. Ari Green. Exhibit 1142 at 396:12-16. Patent Owner timely objected to Exhibit 1140 during the deposition as not being part of the record of the proceeding and outside the scope of Dr. Green's opinion and Mylan's Reply. Exhibit 1142 at 396:6-10 ("Before you ask any further questions, I want to object to this document being offered. It's not part of the record in this proceeding. So I just object to any testimony on the document."); *see also id.* at 396:23-397:7. The Petitioners did not provide evidence to cure this objection at the deposition, as required by 37 C.F.R. § 42.64(a).

IV. Identification Of Where Evidence Was Relied Upon By Petitioner

Petitioners cite to Exhibits 1068/1089, the 2009 abstract authored by O. Khan, on pages 17-18 of the Green Reply Report. *See* Exhibit 1085 at ¶ 32. The abstract is cited in support of the following assertions made in the Green Reply Report: "[B]efore the priority date, POSAs had completed a clinical trial investigating 20 mg administered twice weekly, for a total weekly dose of only 40 mg" and "Although the results suggesting that 20 mg administered twice weekly is safe, efficacious, and well-tolerated were not officially published until three weeks after the priority date, [Exhibit 1068/1089] demonstrates that—counter to what Patent Owner claims—POSAs were motivated before the priority date to explore less frequent alternative dosing regimens." *Id.* This portion of the Green Reply Report is cited by Petitioners on Pages 9 and 13-14 of the Petitioners' Reply, in support of the following statements: "As of 2009, the prior art expressly taught that less frequent administration of GA was efficacious, and further development was warranted" (Page 9); "And for the greatest expectation of success, a POSA would choose a total weekly dose (120 mg) comparable to the known 20 mg daily regimen (140 mg)" (Pages 13-14); and "[An 80 hour] half-life is consistent with the clinical data, which suggests that less frequent dosing may be efficacious" (Page 14).

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