Paper No. ___
Filed: July 20, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC. and AKORN INC.,[1]

Petitioner,

v.

ALLERGAN, INC.
Patent Owner.

Case IPR2016-01127 (US 8,685,930 B2)
Case IPR2016-01128 (US 8,629,111 B2)
Case IPR2016-01129 (US 8,642,556 B2)
Case IPR2016-01130 (US 8,633,162 B2)
Case IPR2016-01131 (US 8,648,048 B2)
Case IPR2016-01132 (US 9,248,191 B2)

PETITIONERS' NOTICE OF OBJECTION TO EVIDENCE

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[1] Cases IPR2017-00576 and IPR2017-00594, IPR2017-00578 and IPR2017-00596, IPR2017-00579 and IPR2017-00598, IPR2017-00583 and IPR2017-00599, IPR2017-00585 and IPR2017-00600, and IPR2017-00586 and IPR2017-00601, have respectively been joined with the captioned proceedings. The word-for-word identical paper is filed in each proceeding identified in the caption pursuant to the Board's Scheduling Order (Paper 10).

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I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioners submit the following objections to Allergan, Inc. ("Patent Owner")'s Exhibits 2077, 2078 and 2079 as listed on each List of Exhibits filed by Patent Owner in each of Patent Owner's Sur-Replies ("Sur-Reply") filed on July 14, 2017, and any reference to or reliance on the foregoing Exhibits in filings by Patent Owner. As required by 37 C.F.R. § 42.62, Petitioner's objections below apply the Federal Rules of Evidence ("F.R.E.").

II. OBJECTIONS

1. Objections to EX2077 and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 602 (Foundation); F.R.E. 701, 702 (Expert Foundation and Opinions).

Patent Owner describes EX2077 as an article cited in EX1011 (Kaswan). Kaswan's discussion regarding what constitutes a therapeutic level of cyclosporin was discussed in the Petitions and Amiji declarations filed therewith. Patent Owner's Responses to the Petitioner were due in March 2017, making Patent Owner's filing of EX2077 almost four months late and contrary to the case scheduling order in this case. Paper 10.

Patent Owner provides no foundation for EX2077 or the statements contained therein. F.R.E. 602, 701, 702. Indeed, none of Allergan's declarants

discusses EX2077 in their declarations, provides any foundation for this document, identifies the source of the document, or purports to have any knowledge regarding the document or the information contained therein. Thus, Allergan offers Exhibit 2077 without foundation or expert analysis, in violation of F.R.E. 602, 701, 702.

2. Objections to EX2078, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 401, 402 (Irrelevant Evidence Inadmissible); F.R.E. 403 (Excluding Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons); F.R.E. 602 (Foundation); F.R.E. 701, 702 (Expert Foundation and Opinions); F.R.E. 801, 802, 803, 805 (Inadmissible Hearsay); F.R.E. 901 (Authenticating Evidence); F.R.E. 1002, 1006 (Summary requires production of original or duplicate of underlying data); 37 C.F.R. § 42.53 (uncompelled testimony); 37 C.F.R. § 42.65 (Disclosure of Underlying Data Required).

Patent Owner describes EX2078 as a Medical Officer's Review of NDA 21-023. Patent Owner's Responses to the Petitioner were due in March 2017, making Patent Owner's filing of EX2078 to provide a bases for establishing criticality or unexpected results of the claimed formulation almost four months late and violates the case scheduling order in this case. Paper 10.

Moreover, EX2078 does not purport to be a published document, let alone published on a date before the claimed priority date of the patent at issue. Rather, EX2078 appears to combine multiple reports in non-chronological order. To the

extent that EX2078 lacks a publication date before the alleged date of invention for the patent at issue, the fact that the context of EX2078 was publically available, even if established by Patent Owner, is irrelevant to whether the claimed subject matter was obvious at the alleged time of the invention. F.R.E. 401, 402. Further, such an exhibit is so attenuated to the question of whether the claimed invention was obvious at the alleged time of the invention, that it is unduly prejudicial, misleading, and a waste of time. F.R.E. 403. Moreover, the document itself lacks foundation and lacks authentication. F.R.E. 602, 902.

To the extent that Patent Owner relies on this exhibit or on any statements in this exhibit for the truth of the matter asserted, such statements are inadmissible hearsay when offered by Patent Owner and also have not been authenticated. F.R.E. 801, 802, 803, 805, 901. Moreover, Patent Owner provides no foundation for the statements as either lay testimony or expert testimony of any particular declarant. F.R.E. 602, 701, 702; 37 C.F.R. § 42.53.

Moreover, Patent Owner has not made "the original or duplicates" of the underlying data being summarized in this document "available for examination or copying, or both" to the Petitioner. F.R.E. 1002, 1006; 37 C.F.R. § 42.65.

3. Objections to EX2079, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 602 (Foundation); F.R.E. 701, 702 (Expert Foundation and Opinions); F.R.E. 801, 802, 803, 805 (Inadmissible Hearsay);

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