

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.
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 8,624,556 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)

**PETITIONER MYLAN PHARMACEUTICALS INC.'S
NOTICE OF OBJECTION TO EVIDENCE¹**

¹ 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), Mylan Pharmaceuticals Inc. (“Petitioner”) submits the following objections to Allergan, Inc. (“Patent Owner”)’s Exhibits 2001, 2003, 2006, and 2008 as listed on each List of Exhibits filed by Patent Owner in each of Patent Owner’s Preliminary Responses (“Preliminary Responses”) on September 9, 2016, and any reference to or reliance on the foregoing Exhibits in the Preliminary Responses or future 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 Ex. 2001, 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).

Patent Owner describes EX. 2001 as “NDA 21-023 Cyclosporine Ophthalmic Emulsion 0.05%, Original NDA Filing, Vol. 1 (Feb. 24, 1999).” However, EX. 2001 does not purport to have been published in 1999 or on any particular date before the claimed priority date of the invention of the patent at

issue. To the extent that the publication date of EX. 2001 is later than the alleged date of invention for the patent at issue, the fact that the content of EX. 2001 was published on the asserted date, 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, EX. 2001 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.

To the extent that Patent Owner relies on EX. 2001 or on any statements in EX. 2001 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.

2. Objections to Ex. 2003, 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).

Patent Owner describes EX. 2003 as “Said et al., Investigative Ophthalmology & Visual Science, vol. 48, No. 11 (Nov. 2007): 5000-5006.” However, EX. 2003 does not purport to have been published before the claimed priority date of the invention of the patent at issue. To the extent that the publication date of EX. 2003 is later than the alleged date of invention for the patent at issue, the fact that the content of EX. 2003 was published on the asserted date, 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, EX. 2003, which appears to have been created years after the alleged date of invention, 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.

To the extent that Patent Owner relies on any statements in EX. 2003 for the truth of the matter asserted, such statements are inadmissible hearsay 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.

3. Objections to Ex. 2006, 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

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