

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.
Petitioner,

v.

MERCK SHARP & DOHME CORP.
Patent Owner.

U.S. Patent No. 7,326,708 to Cypes *et al.*
Issue Date: February 5, 2008

Title: Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor

Inter Partes Review No.: IPR2020-00040

PETITIONER'S OBJECTIONS TO EVIDENCE

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Pursuant to 37 C.F.R. § 42.64(b)(1), Mylan Pharmaceuticals Inc. (“Mylan” or “Petitioner”) timely objects under the Federal Rules of Evidence (“FRE”) to the admissibility of Exhibits 2002, 2003, 2004, 2005, 2011, 2012 and 2013 (and accompanying appendices). Collectively, these exhibits (“Challenged Evidence”) were served by Merck, Sharpe & Dohme Corp. (“Merck” or “Patent Owner”) with its Patent Owner Complete Response filed on February 14, 2020.

Petitioner’s objections are timely under 37 C.F.R. § 42.64(b)(1) because they are being filed and served within ten business days. Petitioner files these objections to provide notice to Patent Owner that Petitioner may move to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c), unless timely cured by Patent Owner.

**IDENTIFICATION OF CHALLENGED EVIDENCE AND GROUNDS FOR
OBJECTIONS**

A. Multiple Exhibits Are Inadmissible as Being Irrelevant, and/or Containing Hearsay, and Are Therefore More Prejudicial Than Probative as to Any Fact of Consequence.

1. Exhibit 2002:

Petitioner objects to Exhibit 2002 in its entirety as inadmissible hearsay and hearsay within hearsay under FRE 801 and 802 because it is relied upon for the truth of the matter asserted (POR at 35, 37-39) and Petitioner has not had the opportunity to subject the declarant (Vicky K. Vydra) to cross-examination.

Petitioner also objects to the Appendices of Exhibit 2002 under FRE 901 for lack of authentication and lack of foundation because there is no evidence authenticating or providing foundation for Appendices A & B. Petitioner further objects to Exhibit 2002 and Appendices A and B under FRE 602 and 901 because there is no evidence that declarant is competent to testify regarding events that occurred 18 years ago and Patent Owner has not provided evidence sufficient to support a finding that Appendix A “is what [Patent Owner] claims it is.” *See* FRE 901. Petitioner further objects to Appendix B as inadmissible hearsay and hearsay within hearsay under FRE 801, 802 and/or 805. Appendix B is relied upon for the truth of the matter asserted (POR at 35, 37-39; EX2002 at ¶ 21) and Petitioner has not had the opportunity to subject Michael Palucki to cross-examination. Petitioner also objects to Appendices A & B of EX2002 under FRE106 because the documents are improper compilations and incomplete. Finally, Petitioner objects to the Declaration of Vicky K. Vydra as improper expert opinion under FRE 702.

2. Exhibit 2003:

Petitioner objects to Exhibit 2003 in its entirety as inadmissible hearsay under FRE 801 and 802 because it is relied upon for the truth of the matter asserted (POR at 35, 37-39) and Petitioner has not had the opportunity to subject the declarant (Robert M. Wenslow) to cross-examination. In addition, the Declaration of Dr. Wenslow further cites to other materials or individuals for the truth of the

matter asserted. Therefore, Petitioner objects to the extent EX2003 contains hearsay with hearsay under FRE 801, 802 and/or 805. Petitioner also objects to the Appendices of Exhibit 2003 under FRE 901 for lack of authentication and lack of foundation because there is no evidence authenticating or providing foundation for the materials contained therein. Petitioner objects to Exhibit 2003 in its entirety under FRE 602 because there is no evidence that declarant is competent to testify regarding events that occurred 18 years ago.

Petitioner objects to Appendix A in Exhibit 2003 as inadmissible hearsay under FRE 801,802 and/or 805. The document is relied upon for the truth of the matter asserted (POR at 35-39; EX2003 at ¶ 12) and Petitioner has not had the opportunity to subject Leigh Shultz to cross-examination. Petitioner also objects to Appendix A under FRE 901 because Patent Owner has not provided evidence sufficient to support a finding that Appendix A “is what [Patent Owner] claims it is.” *See* FRE 901. In addition, Dr. Wenslow, in ¶ 12 of Exhibit 2003, relies on Appendix A for the truth of the matter asserted, and is therefore inadmissible under FRE 801, 802, and 805.

Petitioner objects to Appendix B in Exhibit 2003 as inadmissible hearsay under FRE 801, 802 and/or 805. The document is relied upon for the truth of the matter asserted (POR at 35-39; EX2003 at ¶ 13) and Petitioner has not had the opportunity to subject Yun Liu to cross-examination. Petitioner also objects to

Appendix B under FRE 901 because Patent Owner has not provided evidence sufficient to support a finding that Appendix B “is what [Patent Owner] claims it is.” *See* FRE 901. In addition, Dr. Wenslow, in ¶ 13 of Exhibit 2003, relies on Appendix B for the truth of the matter asserted and is therefore inadmissible under FRE 801, 802, and 805.

Petitioner objects to Appendix C in Exhibit 2003 as inadmissible hearsay under FRE 801,802 and/or 805. The document is relied upon for the truth of the matter asserted (POR at 35-39; EX2003 at ¶ 15) and Petitioner has not had the opportunity to subject Cindy Starbuck to cross examination. Petitioner also objects to Appendix C under FRE 901 because Patent Owner has not provided evidence sufficient to support a finding that Appendix C “is what [Patent Owner] claims it is.” *See* FRE 901. No exception applies. In addition, Dr. Wenslow, in ¶ 15 of Exhibit 2003, relies on Appendix C for the truth of the matter asserted, and is therefore inadmissible under FRE 801, 802, and 805.

Petitioner objects to Appendix D in Exhibit 2003 as inadmissible hearsay under FRE 801,802 and/or 805. The document is relied upon for the truth of the matter asserted (POR at 35-39; EX2003 at ¶ 16) and Petitioner has not had the opportunity to subject Cindy Starbuck to cross examination. Petitioner also objects to Appendix D under FRE 901 because Patent Owner has not provided evidence sufficient to support a finding that Appendix D “is what [Patent Owner] claims it

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