

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case IPR2018-01676
Patent No. 8,603,044

MYLAN PHARMACEUTICALS INC.
OBJECTIONS TO EVIDENCE
37 CFR §42.64(b)(1)

I. OBJECTIONS

Petitioner (“Mylan”) submits the following objections:

1. EX2001 – Press Release, “Mylan Enhances Partnership with Biocon through Strategic Collaboration for Insulin Products,” Feb. 13, 2013 (PR Newswire)

Grounds for objection: FRE 402-403.

EX2001 is offered to show Mylan’s clinical development and commercialization of a follow-on insulin glargine product. Paper 10, 6. That Mylan is developing such a product is not relevant to any contested issue in this proceeding. Thus, EX2001 lacks relevance and risks confusing the issues. To the extent EX2001 is admitted, its scope should be restricted to the purpose for which it was originally submitted. FRE 105.

2. EX2002 – Press Release, “Mylan Commences Phase III Clinical Trials for its Generic Version of Advair Diskus® and Insulin Analog to Lantus®,” Sept. 16, 2014 (PR Newswire)

Grounds for objection: FRE 402-403.

EX2002 is offered to show Mylan’s clinical development and commercialization of a follow-on insulin glargine product. Paper 10, 6. That Mylan is developing such a product is not relevant to any contested issue in this proceeding. Thus, EX2002 lacks relevance and risks confusing the issues. To the extent EX2002 is admitted, its scope should be restricted to the purpose for which it was originally submitted. FRE 105.

3. EX2003 – Press Release, “Mylan and Biocon Present Clinical Data on Insulin Glargine at the American Diabetes Association’s 77th Scientific Sessions,” June 10, 2017 (PR Newswire)

Grounds for objection: FRE 402-403.

EX2003 is offered to show Mylan’s clinical development and commercialization of a follow-on insulin glargine product. Paper 10, 6. That Mylan is developing such a product is not relevant to any contested issue in this proceeding. Thus, EX2003 lacks relevance and risks confusing the issues. To the extent EX2003 is admitted, its scope should be restricted to the purpose for which it was originally submitted. FRE 105.

4. EX2004 – Complaint for Patent Infringement, *Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH v. Eli Lilly and Company*, C.A. No. 1-14-cv-00113-RGA (D. Del.), Dkt. No. 1

Grounds for objection: FRE 402-403.

EX2004 is offered to show that Patent Owner (“Sanofi”) has previously asserted the ’044 patent against another competitor. Paper 10, 6. Whether the ’044 patent has been previously asserted in litigation is not relevant to any contested issue in this proceeding. Thus, EX2004 lacks relevance and risks confusing the issues. To the extent EX2004 is admitted, its scope should be restricted to the purpose for which it was originally submitted. FRE 105.

5. EX2005 – Complaint for Patent Infringement, *Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH, and Sanofi Winthrop Industrie v. Merck Sharp & Dohme Corp.*, C.A. No. 1-16-cv-00812-RGA (D. Del.), Dkt. No. 1

Grounds for objection: FRE 402-403.

EX2005 is offered to show that Sanofi has previously asserted the '044 patent against another competitor. Paper 10, 6. Whether the '044 patent has been previously asserted in litigation is not relevant to any contested issue in this proceeding. Thus, EX2005 lacks relevance and risks confusing the issues. To the extent EX2005 is admitted, its scope should be restricted to the purpose for which it was originally submitted. FRE 105.

6. EX2006 – Stipulation and Proposed Order, *Sanofi-Aventis U.S. LLC v. Mylan, N.V.*, Civil Action No. 17-9105-SRC-SLW (D.N.J. Feb. 5, 2018), Dkt. No. 45

Grounds for objection: FRE 402-403.

EX2006 is offered to show the joint request for a trial date in the co-pending district court case. Paper 10, 8; Paper 15, 2. The parties' request for a trial date in the district court litigation is not relevant to any contested issue in this proceeding. Thus, EX2006 lacks relevance and risks confusing the issues. To the extent EX2006 is admitted, its scope should be restricted to the purpose for which it was originally submitted. FRE 105.

7. EX2007 – Complaint for Patent Infringement, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW (D.N.J. Oct. 24, 2017), Dkt. No. 1

Grounds for objection: FRE 402-403.

EX2007 is offered to show that Sanofi has asserted the '044 patent in the co-pending district court case. Paper 10, 10. The assertion of the '044 patent in the district court case is not relevant to any contested issue in this proceeding. Thus, EX2007 lacks relevance and risks confusing the issues. To the extent EX2007 is admitted, its scope should be restricted to the purpose for which it was originally submitted. FRE 105.

8. EX2008 – Excerpts from Defendants' Invalidity Contentions, dated Jan. 25, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)

Grounds for objection: FRE 402-403.

EX2008 is offered to show that Mylan has referenced overlapping prior art as a basis for invalidity in the co-pending district court case. Paper 10, 11, 13, 15. That Mylan has referenced overlapping prior art in its invalidity contentions in the district court case is not relevant to any contested issue in this proceeding. Thus, EX2008 lacks relevance and risks confusing the issues. To the extent EX2008 is admitted, its scope should be restricted to the purpose for which it was originally submitted. FRE 105.

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