

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
and PFIZER INC.,
Petitioners,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

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

**PATENT OWNER'S OBJECTIONS TO DOCUMENTS SERVED BY
PETITIONER**

Pursuant to 37 C.F.R. § 42.64(b), Patent Owner Sanofi-Aventis Deutschland GmbH hereby makes the following objections to the admissibility of documents submitted with Petitioner Mylan Pharmaceuticals Inc.’s Reply.

Evidence	Petitioner’s Description	Objections
1044	Nat’l. Diabetes Statistic Report 2017, “Estimates of Diabetes and Its Burden in the United States, CDC, p.1-20	<p>FRE 401/402: This evidence is not relevant as it is not cited in the Petition.</p> <p>FRE 801, 802: This exhibit is an out of court statement offered for its truth, and because it does not fall within any exception to the rule against hearsay, it is inadmissible hearsay.</p> <p>FRE 901: This exhibit is an unauthenticated document and is not self-authenticating under FRE 902.</p>
1045	Teresa L. Pearson, “Practical Aspects of Insulin Pen Devices”, Journal of Diabetes Science and Technology, Vol. 4, Issue 3, May 2010, p.522-531	<p>FRE 401/402: This evidence is not relevant as it is not cited in the Petition or in the portions of the expert declaration relied upon by the Petition.</p> <p>FRE 403: The exhibit’s probative value to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues and wasting resources.</p> <p>FRE 801, 802: This exhibit is an out of court statement offered for its truth, and because it does not fall within any exception to the rule against hearsay, it is inadmissible hearsay.</p> <p>FRE 901: This exhibit is an unauthenticated document and is not self-authenticating under FRE 902.</p>

Evidence	Petitioner's Description	Objections
1046	<p>Nancy J.V. Bohannon, "Insulin Delivery Using Pen Devices", Postgraduate Medicine, Vol. 106, No.5, Oct. 15, 1999, p. 57-68, ISSN: 0032-5481 (Print) 1941-9260 – (Online) Journal homepage: https://www.tandfonline.com/loi/ipgm20</p>	<p>FRE 401/402: This evidence is not relevant as it is not cited in the Petition or in the portions of the expert declaration relied upon by the Petition.</p> <p>FRE 403: The exhibit's probative value to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues and wasting resources.</p> <p>FRE 801, 802: This exhibit is an out of court statement offered for its truth, and because it does not fall within any exception to the rule against hearsay, it is inadmissible hearsay.</p> <p>FRE 901: This exhibit is an unauthenticated document and is not self-authenticating under FRE 902.</p>
1047	<p>Marilyn R. Graff, RN, CDE et al., "Assessment by Patients with Diabetes Mellitus of Two Insulin Pen Delivery Systems Versus a Vial and Syringe", Clinical Therapeutics, Vol. 20, No. 3, 1998, p.486-196</p>	<p>FRE 401/402: This evidence is not relevant as it is not cited in the Petition.</p> <p>FRE 801, 802: This exhibit is an out of court statement offered for its truth, and because it does not fall within any exception to the rule against hearsay, it is inadmissible hearsay.</p> <p>FRE 901: This exhibit is an unauthenticated document and is not self-authenticating under FRE 902.</p>

Evidence	Petitioner's Description	Objections
1048	Expert Declaration of William Curtis Biggs, M.D., FACE, ECNU in Support of Mylan-Pfizer Reply	FRE 701/702/703: Patent Owner objects to Ex. 1048 as being improper expert testimony because paragraphs 25-58 comprise testimony not based on sufficient facts or data, that is irrelevant, that is not based on a reliable foundation, and that constitutes conclusory opinions without sufficient support. It includes opinions that are not admissible under FRE 701, 702, or 703 or <i>Daubert v. Merrell Dow Pharms., Inc.</i> , 509 U.S. 579 (1993).
1057	Benita Lee, MPH, "How Much Does Insulin Cost? Here's How 23 Brands Compare", Good RX, Aug. 23, 2019, pp. 1-11, https://www.goodrx.com/glo/how-much-does-insuling-cost,compare-brands/	FRE 401/402: This evidence is not relevant as it is not cited in the Petition. FRE 801, 802: This exhibit is an out of court statement offered for its truth, and because it does not fall within any exception to the rule against hearsay, it is inadmissible hearsay. FRE 901: This exhibit is an unauthenticated document and is not self-authenticating under FRE 902.
1058	Certified English Translation of DE Patent 102 37 258A1, Dr. Roney Graf (Issued Mar. 182004)	FRE 401/402: This evidence is not relevant as it is not cited in the Petition or in the portions of the expert declaration relied upon by the Petition. 37 C.F.R. § 42.63(b): This exhibit does not contain an adequate attestation to the "accuracy" of the translation. FRE 801, 802: This exhibit lacks an original copy of the allegedly translated document. The certification statement contained in the exhibit is thus an out of court statement offered for its truth, and because it does not fall within any exception to the rule against hearsay, it is inadmissible hearsay.

Evidence	Petitioner's Description	Objections
1059	M. Eledrisi, et al., "Twice-Daily Insulin Glargine for Patients with Uncontrolled Type 2 Diabetes Mellitus, <i>Journal of Clinical & Translational Endocrinology</i> 15 (2019), p. 35-36	<p>FRE 401/402: This evidence is not relevant as it is not cited in the Petition.</p> <p>FRE 801, 802: This exhibit is an out of court statement offered for its truth, and because it does not fall within any exception to the rule against hearsay, it is inadmissible hearsay.</p> <p>FRE 901: This exhibit is an unauthenticated document and is not self-authenticating under FRE 902.</p>
1060	Declaration and c.v. of DeForrest McDuff, Ph.D.	<p>FRE 401/402: This evidence is not relevant as it is not cited in the Petition or in the portions of the expert declaration relied upon by the Petition.</p> <p>FRE 701/702/703: Patent Owner objects to Ex. 1060 as being improper expert testimony because paragraphs 16-71 comprise testimony not based on sufficient facts or data, that is irrelevant, that is not based on a reliable foundation, and that constitutes conclusory opinions without sufficient support. It includes opinions that are not admissible under FRE 701, 702, or 703 or <i>Daubert v. Merrell Dow Pharms., Inc.</i>, 509 U.S. 579 (1993).</p>
1061	2011 Orange Book (Excerpts)	FRE 401/402: This evidence is not relevant as it is not cited in the Petition or in the portions of the expert declaration relied upon by the Petition.
1062	2019 Orange Book (Excerpt – ADA 132 of 263)	FRE 401/402: This evidence is not relevant as it is not cited in the Petition or in the portions of the expert declaration relied upon by the Petition.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.