

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
U.S. Patent No. 8,603,044

**PATENT OWNER'S OBJECTIONS TO DOCUMENTS SERVED WITH
THE PETITION**

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 the Petition.

Evidence	Petitioner's Description	Objections
Ex. 1003	U.S. Patent 8,992,486, <i>Pen-Type Injector</i> (issued Mar. 31, 2015)	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.
Ex. 1004	U.S. Patent 9,526,844, <i>Pen-Type Injector</i> (issued Dec. 27, 2016)	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.
Ex. 1005	U.S. Patent 9,604,008, <i>Drive Mechanisms Suitable for Use in Drug Delivery Devices</i> (issued Mar. 28, 2017)	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.
Ex. 1006	File History for U.S. Patent 8,679,069	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. FRE 403: The exhibit's probative value to any ground upon which trial was instituted is substantially outweighed by the danger of confusing the issues and wasting resources.
Ex. 1008	File History for U.S. Patent 8,992,486	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. FRE 403: The exhibit's probative value to any ground upon which trial was instituted is

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		substantially outweighed by the danger of confusing the issues and wasting resources.
Ex. 1009	File History for U.S. Patent 9,526,844	<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 confusing the issues and wasting resources.</p>
Ex. 1010	File History for U.S. Patent. 9,604,008	<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 confusing the issues and wasting resources.</p>
Ex. 1011	Expert Declaration of Karl Leinsing MSME, PE in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent Nos. 8,679,069; 8,603,044; 8,992,486; 9,526,844 and 9,604,008	FRE 701/702/703: Patent Owner objects to Ex. 1011 as being improper expert testimony because paragraphs 113-124, 126, 128-129, 131, 133-135, 137, 139-140, 142-144, 146-147, 150, 152-855 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).
Ex. 1013	U.S. Patent 6,221,046 - A. Burroughs et al., "Recyclable Medication Dispensing Device"	<p>FRE 401/402: This evidence is not relevant as it is not cited in the Petition.</p> <p>FRE 403: The exhibit's probative value to any ground upon which trial was instituted is</p>

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	(issued Apr. 24, 2001)	substantially outweighed by the danger of unfair prejudice, confusing the issues and wasting resources.
Ex. 1016	U.S. Patent 6,932,794 B2 – L. Giambattista & A. Bendek, “Medication Delivery Pen” (issued Aug. 23, 2005)	<p>FRE 401/402: This evidence is not relevant as it is not cited in 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>
Ex. 1017	U.S. Patent 6,582,404 B1 – P.C. Klitgaard et al., “Dose Setting Limiter” (issued June 24, 2003)	<p>FRE 401/402: This evidence is not relevant as it is not cited in 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>
Ex. 1018	File History for U.S. Patent 6,582,404	<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>
Ex. 1019	Plaintiffs’ Preliminary Claim Constructions and Preliminary Identification of Supporting Intrinsic and Extrinsic Evidence, <i>Sanofi-Aventis U.S. LLC v.</i>	<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>

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	<i>Mylan GmbH</i> , No. 2:17-cv-09105 (D.N.J.)	
Ex. 1020	U.S. Patent 4,865,591 – B. Sams, “Measured Dose Dispensing Device” (issued Sep. 12, 1989)	<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>
Ex. 1021	U.S. Patent 6,248,095 B1 – L. Giambattista et al., “Low-cost Medication Delivery Pen” (issued June 19, 2001)	<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>
Ex. 1022	U.S. Patent 6,921,995 B1 – A.A. Bendek et al., “Medication Delivery Pen Having An Improved Clutch Assembly” (issued July 13, 1999)	<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>
Ex. 1023	U.S. Patent 5,226,895 – D.C. Harris, “Multiple Dose Injection Pen” (issued July 13, 1993)	<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>

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