

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and,

PFIZER, INC.,
Petitioner

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

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

PETITIONER'S UPDATED EXHIBIT LIST

Case No. IPR2018-01676

Patent No. 8,603,044

<u>Exhibit No.</u>	<u>Description</u>
1001	U.S. Patent 8,679,069, <i>Pen-Type Injector</i> (issued Mar. 25, 2014)
1002	U.S. Patent 8,603,044, <i>Pen-Type Injector</i> (issued Dec. 10, 2013)
1003	U.S. Patent 8,992,486, <i>Pen-Type Injector</i> (issued Mar. 31, 2015)
1004	U.S. Patent 9,526,844, <i>Pen-Type Injector</i> (issued Dec. 27, 2016)
1005	U.S. Patent 9,604,008, <i>Drive Mechanisms Suitable for Use in Drug Delivery Devices</i> (issued Mar. 28, 2017)
1006	File History for U.S. Patent 8,679,069
1007	File History for U.S. Patent 8,603,044
1008	File History for U.S. Patent 8,992,486
1009	File History for U.S. Patent 9,526,844
1010	File History for U.S. Patent. 9,604,008
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
1012	<i>Curriculum Vitae</i> of Karl Leinsing MSME,PE
1013	U.S. Patent 6,221,046 - A. Burroughs et al., “Recyclable Medication Dispensing Device” (issued Apr. 24, 2001)
1014	U.S. Patent 6,235,004 – S. Steinfeldt-Jensen & S. Hansen, “Injection Syringe” (issued May 22, 2001)
1015	U.S. Patent Application US 2002/0053578 A1 – C.S. Møller, “Injection Device” (pub’d May 2, 2002)
1016	U.S. Patent 6,932,794 B2 – L. Giambattista & A. Bendek, “Medication Delivery Pen” (issued Aug. 23, 2005)

<u>Exhibit No.</u>	<u>Description</u>
1017	U.S. Patent 6,582,404 B1 – P.C. Klitgaard et al., “Dose Setting Limiter” (issued June 24, 2003)
1018	File History for U.S. Patent 6,582,404
1019	Plaintiffs’ Preliminary Claim Constructions and Preliminary Identification of Supporting Intrinsic and Extrinsic Evidence, <i>Sanofi-Aventis U.S. LLC v. Mylan GmbH</i> , No. 2:17-cv-09105 (D.N.J.) (filed Sep. 5 2018)
1020	U.S. Patent 4,865,591 – B. Sams, “Measured Dose Dispensing Device” (issued Sep. 12, 1989)
1021	U.S. Patent 6,248,095 B1 – L. Giambattista et al., “Low-cost Medication Delivery Pen” (issued June 19, 2001)
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)
1023	U.S. Patent 5,226,895 – D.C. Harris, “Multiple Dose Injection Pen” (issued July 13, 1993)
1024	U.S. Patent 5,851,079 – R.L. Horstman et al., “Simplified Unidirectional Twist-Up Dispensing Device With Incremental Dosing” (issued Dec. 22, 1998)
1025	Application as filed: U.S. Patent App. 14/946,203 – R.F. Veasey, “Relating to a Pen-Type Injector” (filed Nov. 19, 2015)
1026	GB 0304822.0 – “Improvements in and relating to a pen-type injector” (filed Mar. 3, 2003) (‘844 Priority Doc.)

<u>Exhibit No.</u>	<u>Description</u>
1027	WO 99/38554 – S. Steinfeldt-Jensen & S. Hansen, “An Injection Syringe” (pub’d Aug. 5, 1999) (Steenfeldt-Jensen PCT)
1028	Mylan GmbH and Biocon’s Preliminary Claim Constructions and Supporting Evidence Pursuant to L. Pat. R. 4.2, <i>Sanofi-Aventis U.S., LLC v. Mylan N.V.</i> , C.A. No. 17-cv-09105 (filed Sep. 5, 2018)
1029	Memorandum Opinion, <i>Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.</i> , No. 16-cv-812 (filed Jan. 12, 2018)
1030	Memorandum Opinion, <i>Sanofi -Aventis U.S. LLC v. Eli Lilly and Co.</i> , No. 14-cv-113 (filed Jan. 20, 2015)
1031	N. Sclater & N.P. Chironis, <i>Mechanisms & Mechanical Devices Sourcebook 191-95</i> , “Twenty Screw Devices” (3d ed., July 2, 2001)
1032	EP 0 608 343 B1 – L. Petersen & N.-A. Hansen, “Large Dose Pen” (pub’d Oct. 18, 1991)
1033	A.G. Erdman & G.N. Sandor, “Mechanical Advantage”, §3.7 in <i>1 Mechanism Design: Analysis and Synthesis</i> (1984)
1034	WO 01/83008 – S. Hansen & T.D. Miller., “ <i>An Injection Device, A Preassembled Dose Setting And Injection Mechanism For An Injection Device, And A Method Of Assembling An Injection Device</i> ” (pub’d Nov. 8, 2001)
1035	K.J. Lipska et al., <i>Association of Initiation of Basal Insulin Analogs vs Neutral Protamine Hagedorn Insulin With Hypoglycemia-Related Emergency Department Visits or Hospital Admissions and With</i>

<u>Exhibit No.</u>	<u>Description</u>
	<i>Glycemic Control in Patients With Type 2 Diabetes</i> , 320 J. Am. Med. Ass'n 53-62 (2018)
1036	Transcript, Conference Call (January 15, 2019)
1037	Reserved
1038	Graph showing PTAB Days to Docketing for Review Proceedings filed between 2016-2018
1039	Reserved
1040	Declaration of Elham F. Steiner in Support of <i>Petitioner's Motion for Pro Hac Vice Admission</i>
1041	Elham F. Steiner – Attorney Biography
1042	Transcript of Telephone Conference on June 19, 2019.
1043	Transcript of Telephone Conference on July 25, 2019.
1044	Nat'l. Diabetes Statistic Report 2017, "Estimates of Diabetes and Its Burden in the United States, CDC, p.1-20
1045	Teresa L. Pearson, "Practical Aspects of Insulin Pen Devices", <i>Journal of Diabetes Science and Technology</i> , Vol. 4, Issue 3, May 2010, p.522-531
1046	Nancy J.V. Bohannon, "Insulin Delivery Using Pen Devices", <i>Postgraduate Medicine</i> , 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
1047	Marilyn R. Graff, RN, CDE et al., "Assessment by Patients with Diabetes Mellitus of Two Insulin Pen Delivery Systems Versus a

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