

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 No. IPR2018-01675¹
U.S. Patent No. 8,603,044

**PATENT OWNER'S OBSERVATIONS ON THE
CROSS-EXAMINATION OF MR. KARL LEINSING**

¹ Pfizer Inc., who filed a petition in IPR2019-00977, has been joined as petitioner in this proceeding.

EXHIBIT LIST

Exhibit #	Description
2001	Press Release, “Mylan Enhances Partnership with Biocon through Strategic Collaboration for Insulin Products”, Feb. 13, 2013 (PR Newswire), available at http://newsroom.mylan.com/press-releases?item=122834
2002	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), available at http://newsroom.mylan.com/press-releases?item=123251
2003	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), available at http://newsroom.mylan.com/2017-06-10-Mylan-and-Biocon-Present-Clinical-Data-on-Insulin-Glargine-at-the-American-Diabetes-Associations-77th-Scientific-Sessions
2004	Complaint for Patent Infringement, <i>Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH v. Eli Lilly and Company</i> , C.A. No. 1-14-cv-00113-RGA (D. Del), Dkt. No. 1
2005	Complaint for Patent Infringement, <i>Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH, and Sanofi Winthrop Industrie v. Merck Sharp & Dohme Corp.</i> , C.A. No. 1-16-cv-00812-RGA (D. Del), Dkt. No. 1
2006	Stipulation and Proposed Order, <i>Sanofi-Aventis U.S. LLC v. Mylan, N.V.</i> , Civil Action No. 17-9105-SRC-SLW (D.N.J. Feb 5, 2018), Dkt. No. 45
2007	Complaint for Patent Infringement, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J. Oct. 24, 2017), Dkt. No. 1
2008	Excerpts from Defendants’ Invalidation Contentions, dated Jan. 25, 2018, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2009	Excerpts from Mylan GMBH’s Amended Invalidation Contentions, dated April 25, 2018, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2010	Excerpts from Mylan GMBH’s Exhibit C to Amended Invalidation Contentions, dated April 25, 2018, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)

Exhibit #	Description
2011	Aug. 13, 2018 Service of Sanofi's Responses to Mylan's Amended Contentions, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2012	MP4 file of Sanofi's Patented Pen animation
2013	Excerpts from McGraw Hill Dictionary of Scientific and Technical Terms (Sixth edition, McGraw-Hill 2003), p. 972 and 1873
2014	Excerpts from Merriam-Webster's Collegiate Dictionary (10th edition, Merriam-Webster, Inc. 2001), p. 538
2015	The New Oxford American Dictionary (Oxford University Press 2001), p. 789-90
2016	Defendants' Opposition to Plaintiffs' Motion to Stay dated Nov. 22, 2017, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 1:17-cv-00181-IMK (N.D. Va.), Dkt. No. 44
2017	Joint Proposed Discovery Plan dated Dec. 14, 2017, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2018	Letter from A. Calmann to Judge Waldor dated Apr. 24, 2018, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J.), Dkt. No. 90
2019	Motion to Expedite Defendants' Motion Requesting an Expedited Scheduling Conference dated Nov. 22, 2017, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 1:17-cv-00181-IMK (N.D. Va.), Dkt. No. 46
2020	Initial Planning Meeting Report and Discovery Proposals dated Dec. 22, 2017, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 1:17-cv-00181-IMK (N.D. Va.), Dkt. No. 61
2021	Transcript of Motion / Scheduling Conference dated Jan. 3, 2018, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 1:17-cv-00181-IMK (N.D. Va.), Dkt. No. 64
2022	Excerpts from Transcript, Conference Call dated Aug. 2, 2018, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J.) (confidentiality designation removed)
2023	Report of the Local Patent Rules Committee, Explanatory Notes for 2016 Amendments

Exhibit #	Description
2024	Transcript, Conference Call for Case IPR2018-01675, -01676, -01678, -01680 (P.T.A.B. Feb. 5, 2019)
2025	Redline of Amended Patent Owner Preliminary Response (filed February 20, 2019)
2026-2099	<i>Reserved</i>
2100	Leinsing Deposition Exhibit 2100: Thomas van der Burg, <i>Injection Force of SoloSTAR® Compared with Other Disposable Insulin Pen Devices at Constant Volume Flow Rates</i> , J. of Diabetes Sci. and Tech., Vol. 5, Issue 1, 150-155 (Jan. 2001)
2101	Leinsing Deposition Exhibit 2101: Estelle Davis, et. al., <i>An evaluation of prefilled insulin pens: a focus on the Next Generation FlexPen®</i> , Med. Devices: Evidence & Research, 41-50 (2010:3)
2102	Leinsing Deposition Exhibit 2102: Hand drawings
2103	Leinsing Deposition Exhibit 2103: Annotations of Figures 6-15 of Burroughs
2104	Leinsing Deposition Exhibit 2104: Annotations of Figures 5-8 of the 486 Patent
2105	Leinsing Deposition Exhibit 2105: Hand drawings
2106	Leinsing Deposition exhibit 2106: Annotations of Figures 11 and 12 of Giambattista
2107	Declaration of Alexander Slocum, Ph.D.
2108	Curriculum Vitae of Alexander Slocum, Ph.D.
2109	<i>Reserved</i>
2110	<i>Reserved</i>
2111	Declaration of Dr. Robin S. Goland
2112	Curriculum Vitae of Dr. Robin S. Goland
2113	Bradley M. Wright et al., <i>A Review Of Insulin Pen Devices And Use In The Elderly Diabetic Population</i> , 3 Clinical Medicine Insights: Endocrinology & Diabetes 54-63 (2010)
2114	Teresa L. Pearson, <i>A-Practical-Review-of-Insulin-Pen-Devices</i> , EMJ Diabet., 58-64 (2014:2)

Exhibit #	Description
2115	Arthritis & Diabetes, <i>What do diabetes and arthritis have in common? Plenty.</i> , https://www.arthritis.org/living-with-arthritis/comorbidities/diabetes-and-arthritis/
2116	Andreas Bode, <i>Development of the SoloSTAR insulin pen device design verification and validation</i> , 6 Expert Opinion on Drug Delivery 103-112 (2008)
2117	Sanofi's Patented Pen animation
2118	John Carter, <i>Usability, Participant Acceptance, and Safety of a Prefilled Insulin Injection Device in a 3-Month Observational Survey in Everyday Clinical Practice in Australia</i> , <i>J. Diabetes Sci & Tech.</i> , Vol. 3, Issue 6, 1425-1438 (Nov. 2009)
2119	Sherwyn Schwartz, <i>Correct Use of a New Reusable Insulin Injection Pen by Patients with Diabetes: A Design Validation Study</i> , 4 <i>J. Diabetes Sci. and Tech.</i> 1229-1235 (2010)
2120	<i>Reserved</i>
2121	DBA Design Effectiveness Awards 2009
2122	SoloSTAR Disposable Pen Injector (The Grand Prix Oct. 22, 2009)
2123	Arnd Friedrichs et al., <i>Dose Accuracy and Injection Force of Different Insulin Glargine Pens</i> , 7 <i>J. Diabetes Sci. and Tech.</i> 1346-1353 (2013)
2124	Stacey A. Seggelke et al., <i>Effect of Glargine Insulin Delivery Method (Pen Device Versus Vial/Syringe) on Glycemic Control and Patient Preferences in Patients with Type 1 and Type 2 Diabetes</i> , 20 <i>ENDOCRINE PRACTICE</i> , 536, 536, 538-539 (2014)
2125	Julia Pfutzner et al., <i>Evaluation of Dexterity in Insulin-Treated Patients with Type 1 and Type 2 Diabetes Mellitus</i> , 5 <i>J. Diabetes Sci. and Tech.</i> 158-165 (2011)
2126	Jerome S. Fischer et al., <i>United States Patient Preference and Usability for the New Disposable Insulin Device Solostar® versus Other Disposable Pens</i> , 2 <i>JOURNAL OF DIABETES SCIENCE AND TECHNOLOGY</i> 1157-1160 (2008)
2127	U.S. Provisional Patent Application 60/073820

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