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

# PETITIONER'S UPDATED EXHIBIT LIST

| <u>Exhibit No.</u> | <b>Description</b>  |
|--------------------|---|
| 1001               | U.S. Patent 8,679,069, <i>Pen-Type Injector</i> (issued Mar. 25, 2014)  |
| 1002               | U.S. Patent 8,603,044, Pen-Type Injector (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, Pen-Type Injector (issued Dec. 27, 2016)   |
| 1005               | U.S. Patent 9,604,008, Drive Mechanisms Suitable for Use in Drug<br>Delivery Devices (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<br>for <i>Inter Partes</i> Review of U.S. Patent Nos. 8,679,069; 8,603,044;<br>8,992,486; 9,526,844 and 9,604,008 |
| 1012               | Curriculum Vitae of Karl Leinsing MSME,PE   |
| 1013               | U.S. Patent 6,221,046 - A. Burroughs et al., "Recyclable Medication<br>Dispensing Device" (issued Apr. 24, 2001)  |
| 1014               | U.S. Patent 6,235,004 – S. Steenfeldt-Jensen & S. Hansen, "Injection<br>Syringe" (issued May 22, 2001)  |
| 1015               | U.S. Patent Application US 2002/0053578 A1 – C.S. Møller, "Injection<br>Device" (pub'd May 2, 2002)   |
| 1016               | U.S. Patent 6,932,794 B2 – L. Giambattista & A. Bendek, "Medication<br>Delivery Pen" (issued Aug. 23, 2005)   |

| Exhibit No. | <b>Description</b>   |
|-------------|--|
| 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,           |
|             | Sanofi-Aventis U.S. LLC v. Mylan GmbH, 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)   |
|             | U.S. Patent 6,248,095 B1 – L. Giambattista et al., "Low-cost             |
| 1021        | Medication Delivery Pen" (issued June 19, 2001)                          |
|             | U.S. Patent 6,921,995 B1 – A.A. Bendek et al., "Medication Delivery      |
| 1022        | Pen Having An Improved Clutch Assembly" (issued July 13, 1999)           |
| 1000        | U.S. Patent 5,226,895 – D.C. Harris, "Multiple Dose Injection Pen"       |
| 1023        | (issued July 13, 1993)   |
|             | U.S. Patent 5,851,079 – R.L. Horstman et al., "Simplified                |
| 1024        | 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.)                                |
| 1027        | WO 99/38554 – S.Steenfeldt-Jensen & S.Hansen, "An Injection              |
|             | Syringe" (pub'd Aug. 5, 1999) (Steenfeldt-Jensen PCT)                    |

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| <u>Exhibit No.</u> | <b>Description</b>  |
|--------------------|---|
| 1028               | Mylan GmbH and Biocon's Preliminary Claim Constructions and               |
|                    | Supporting Evidence Pursuant to L. Pat. R. 4.2, Sanofi-Aventis U.S.,      |
|                    | LLC v. Mylan N.V., C.A. No. 17-cv-09105 (filed Sep. 5, 2018)              |
| 1029               | Memorandum Opinion, Sanofi-Aventis U.S. LLC v. Merck Sharp &              |
|                    | Dohme Corp., No. 16-cv-812 (filed Jan. 12, 2018)                          |
| 1030               | Memorandum Opinion, Sanofi -Aventis U.S. LLC v. Eli Lilly and Co.,        |
|                    | No. 14-cv-113 (filed Jan. 20, 2015)                                       |
| 1031               | N. Sclater & N.P. Chironis, Mechanisms & Mechanical Devices               |
|                    | Sourcebook 191-95, "Twenty Screw Devices" (3d ed., July 2, 2001)          |
|                    | EP 0 608 343 B1 – L. Petersen & NA. Hansen, "Large Dose Pen"              |
| 1032               | (pub'd Oct. 18, 1991)   |
|                    | A.G. Erdman & G.N. Sandor, "Mechanical Advantage", §3.7 in                |
| 1033               | 1 Mechanism Design: Analysis and Synthesis (1984)                         |
|                    | WO 01/83008 – S. Hansen & T.D. Miller., "An Injection Device, A           |
|                    | Preassembled Dose Setting And Injection Mechanism For An                  |
| 1034               | Injection Device, And A Method Of Assembling An Injection Device"         |
|                    | (pub'd Nov. 8, 2001)  |
|                    | K.J. Lipska et al., Association of Initiation of Basal Insulin Analogs vs |
|                    | Neutral Protamine Hagedorn Insulin With Hypoglycemia-Related              |
| 1035               | Emergency Department Visits or Hospital Admissions and With               |
|                    | Glycemic Control in Patients With Type 2 Diabetes, 320 J. Am.             |
|                    | Med. Ass'n 53-62 (2018)   |
| 1036               | Transcript, Conference Call (January 15, 2019)                            |
| 1037               | Reserved  |

| Exhibit No. | <b>Description</b>   |
|-------------|--|
| 1038        | Graph showing PTAB Days to Docketing for Review Proceedings filed<br>between 2016-2018                       |
| 1039        | Reserved   |
| 1040        | Declaration of Elham F. Steiner in Support of <i>Petitioner's Motion for</i><br><i>Pro HacVice Admission</i> |
| 1041        | Elham F. Steiner – Attorney Biography  |
| 1042        | Transcript of Telephone Conference on June 19, 2019.   |

Respectfully submitted,

Date: <u>1 July 2019</u>

<u>/ Richard Torczon /</u> Richard Torczon, Lead Counsel Reg. No. 34,448

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