IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS DEUTSCHLAND GMBH, and SANOFI WINTHROP INDUSTRIE, Plaintiffs, v. MERCK SHARP & DOHME CORP., Defendant.	C.A. No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Sanofi-Aventis U.S. LLC ("Sanofi U.S."), Sanofi-Aventis Deutschland GmbH ("Sanofi GmbH"), and Sanofi Winthrop Industrie ("SWIND") (collectively, "Plaintiffs" or "Sanofi"), by and through their attorneys, for their Complaint against Merck Sharp & Dohme Corp. ("Merck"), hereby allege as follows:

THE PARTIES

1. Plaintiff Sanofi U.S. is a Delaware limited liability corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

2. Plaintiff Sanofi GmbH is a German corporation with its principal place of business located at Industriepark Hoechst, Frankfurt Am Main, Germany D-65926.

3. Plaintiff SWIND is a French corporation with its principal place of business located at 20 avenue Raymond Aron, 92160 Antony, France.

4. On information and belief, Defendant Merck is a New Jersey corporation with its principal place of business located at 2000 Galloping Hill Rd, Kenilworth, NJ 07033.

5. On information and belief, Merck conducts business operations throughout the United States, including in the State of Delaware.

JURISDICTION AND VENUE

5. This is an action for patent infringement and arises under the Patent Laws of the United States, Title 35, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, and 1338(a).

6. This Court has personal jurisdiction over Merck because, *inter alia*, Merck maintains continuous and systematic contacts with this judicial district. Either directly, or through its subsidiaries, agents, and/or affiliates, Merck has conducted and continues to conduct business in this judicial district, including, upon information and belief, by manufacturing, marketing, and selling drug products throughout the United States and in the District of Delaware. In addition, Merck, on information and belief, intends to market the infringing insulin glargine product in this judicial district upon approval of such product by the Federal Food and Drug Administration ("FDA"). This Court also has personal jurisdiction over Merck for the additional reasons set forth below.

7. Merck is registered to do business in the State of Delaware.

8. The Corporation Trust Company, 1209 Orange Street, Corporation Trust Center, New Castle County, Wilmington, Delaware 19801, serves as Merck's Registered Agent in the State of Delaware.

9. Merck has previously elected to avail itself of the benefits of litigating its patent disputes in the District of Delaware. *See, e.g., Merck Sharp & Dohme Corp. v. Royalty Pharma Collection Trust,* C.A. No. 15-00757-GMS; *Merck Sharp & Dohme Corp. v. Amneal Pharms. L.L.C.,* C.A. No. 15-00250-SLR-SRF; *Merck Sharp & Dohme Corp. v. Fresenius Kabi USA,*

L.L.C., C.A. No. 14-01018-UNA; *Merck Sharp Dohme Corp. v. Sandoz Inc.,* C.A. No. 14-00916-RGA.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c), and 1400(b).

PATENTS-IN-SUIT

11. On April 5, 2011, United States Patent No. 7,918,833 ("the '833 Patent"), entitled "Pen-Type Injector," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). A true and correct copy of the '833 Patent is attached as **Exhibit A** to this Complaint.

12. On August 20, 2013, United States Patent No. 8,512,297 ("the '297 Patent"), entitled "Pen-Type Injector," was duly and legally issued by the PTO. A true and correct copy of the '297 Patent is attached as **Exhibit B** to this Complaint.

13. On October 15, 2013, United States Patent No. 8,556,864 ("the '864 Patent"), entitled "Drive Mechanisms Suitable for Use in Drug Delivery Devices," was duly and legally issued by the PTO. A true and correct copy of the '864 Patent is attached as **Exhibit C** to this Complaint.

14. On December 10, 2013, United States Patent No. 8,603,044 ("the '044 Patent"), entitled "Pen-Type Injector," was duly and legally issued by the PTO. A true and correct copy of the '044 Patent is attached as **Exhibit D** to this Complaint.

15. On March 31, 2015, United States Patent No. 8,992,486 ("the '486 Patent"), entitled "Pen-Type Injector," was duly and legally issued by the PTO. A true and correct copy of the '486 Patent is attached as **Exhibit E** to this Complaint.

16. On March 25, 2014, United States Patent No. 8,679,069 ("the '069 Patent"), entitled "Pen-Type Injector," was duly and legally issued by the PTO. A true and correct copy of the '069 Patent is attached as **Exhibit F** to this Complaint.

17. On April 21, 2015, United States Patent No. 9,011,391 ("the '391 Patent"), entitled "Pen-Type Injector," was duly and legally issued by the PTO. A true and correct copy of the '391 Patent is attached as **Exhibit G** to this Complaint.

18. On January 12, 2016, United States Patent No. 9,233,211 ("the '211 Patent"), entitled "Relating to a Pen-Type Injector," was duly and legally issued by the PTO. A true and correct copy of the '211 Patent is attached as **Exhibit H** to this Complaint.

19. On January 13, 2009, United States Patent No. 7,476,652 ("the '652 Patent"), entitled "Acidic Insulin Preparations Having Improved Stability," was duly and legally issued by the PTO. A true and correct copy of the '652 Patent is attached as **Exhibit I** to this Complaint.

20. On May 11, 2010, United States Patent No. 7,713,930 ("the '930 Patent"), entitled "Acidic Insulin Preparations Having Improved Stability," was duly and legally issued by the PTO. A true and correct copy of the '930 Patent is attached as **Exhibit J** to this Complaint.

21. The '833, '297, '864, '044, '486, '069, '391, '211, '652 and '930 Patents are collectively referred to herein as the "Patents-in-Suit." By assignment, Sanofi GmbH owns all right, title, and interest in and to the Patents-in-Suit. Sanofi U.S. and SWIND are the exclusive licensees of certain rights in or to the Patents-in-Suit. Plaintiffs have the right to sue and recover damages for the infringement of the Patents-in-Suit.

BACKGROUND

22. Sanofi U.S. is the holder of approved New Drug Application ("NDA") No. 21-081 for insulin glargine [rDNA origin] for injection, which is prescribed and sold in the United

States under the trademarks Lantus® and Lantus® SoloSTAR®. Currently, there are no generic or follow-on versions of Lantus® or Lantus® SoloSTAR® on the market in the United States.

23. The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by FDA under the Federal Food, Drug, and Cosmetic Act ("FFDCA"). Sanofi U.S. has listed each of the Patents-In-Suit in the Orange Book as covering its Lantus® and/or Lantus® SoloSTAR® products.

24. On information and belief, Merck submitted NDA No. 208-722 to the FDA under 21 U.S.C. § 355(b)(2) (§ 505(b)(2) of the FFDCA) seeking FDA's approval to manufacture commercially and sell its proposed product—an insulin glargine [rDNA origin] for subcutaneous injection in a prefilled insulin delivery device, 100 units/mL ("Proposed Product")—that contains data from bioavailability or bioequivalence studies conducted in connection with Sanofi U.S.'s NDA No. 21-081.

25. On information and belief, on August 4, 2016, Merck sent a "Notice of Certification" pursuant to § 505(b)(2)(A)(iv) of the FFDCA to Sanofi U.S. and Sanofi GmbH, which discloses that Merck's NDA No. 208-722 contained Paragraph IV certifications for the Patents-in-Suit. In its Notice, Merck stated that its certifications to the FDA allege that each of the Patents-In-Suit is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Merck's Proposed Product before their respective expirations.

26. Sanofi U.S. received Merck's Notice of Certification on August 9, 2016.

27. Sanofi GmbH received Merck's Notice of Certification on August 8, 2016.

28. Merck's Notice of Certification was accompanied by an Offer of Confidential Access ("OCA").

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