IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS DEUTSCHLAND GMBH,	)	
Plaintiffs,	)	
	)	C.A. No. 14-113-RGA-MPT
v.	)	
ELI LILLY AND COMPANY,	)	
Defendant.	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi-Aventis U.S. LLC ("Sanofi U.S.") and Sanofi-Aventis Deutschland GmbH ("Sanofi GmbH") (collectively, "Plaintiffs" or "Sanofi"), by and through their attorneys, for their complaint against Eli Lilly and Company ("Eli Lilly"), 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, Bldg. K607, Frankfurt Am Main, Germany D-65926.

3. On information and belief, Defendant Eli Lilly is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

4. On information and belief, Eli Lilly conducts business operations in the United States, including in the State of Delaware.

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JURISDICTION AND VENUE

5. This is an action for patent infringement 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, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Eli Lilly because, *inter alia*, Eli Lilly maintains continuous and systematic contacts with this judicial district. Either directly, or through its subsidiaries, agents, and/or affiliates, Eli Lilly 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. This Court has personal jurisdiction over Eli Lilly for the additional reasons set forth below.

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

8. National Registered Agents, Inc., 160 Greentree Drive, Suite 101, Dover, Delaware 19904 serves as Eli Lilly's Registered Agent in the State of Delaware.

9. Eli Lilly has previously elected to avail itself of the benefits of litigating its patent disputes in the District of Delaware. *See, e.g., Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, C.A. No. 08-335-GMS. Eli Lilly also filed counterclaims in this lawsuit.

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

PATENTS-IN-SUIT

11. 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 United States Patent and Trademark Office ("PTO"). A true and correct copy of the '864 Patent is attached as Exhibit A to this Complaint.

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12. 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 B to this Complaint.

13. 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 C to this Complaint.

14. 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 D to this Complaint.

15. 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 E to this Complaint.

16. The '864 Patent, '044 Patent, '652 Patent, '930 Patent, and '069 Patent 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. is an exclusive licensee of the Patents-in-Suit with exclusive rights, including the rights to sell and offer to sell in the United States the technologies, products, or services claimed by the Patents-in-Suit. Plaintiffs have the right to sue and recover for the infringement of the Patents-in-Suit.

BACKGROUND

17. 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

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or follow-on versions of Lantus® or of Lantus® SoloSTAR® approved by the United States Food and Drug Administration ("FDA") for sale in the United States.

18. 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 '864, '044, '652, '930, and '069 Patents in the Orange Book as covering its Lantus® and/or Lantus® SoloSTAR® products.

19. On information and belief, Eli Lilly submitted NDA No. 205-692 to 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 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.

20. On information and belief, on December 18, 2013, Eli Lilly sent a "Notice of Paragraph IV Certifications" pursuant to § 505(b)(2)(A)(iv), (b)(3) of the FFDCA to Plaintiffs, which discloses that its NDA No. 205-692 contained Paragraph IV certifications for, *inter alia*, the '864, '652, and '930 Patents. In its letter, Eli Lilly stated that its certification to FDA alleges that, *inter alia*, the '864, '652, and '930 Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Eli Lilly's Proposed Product, before their respective expirations.

21. Sanofi U.S. received Eli Lilly's Notice of Paragraph IV Certifications on December 19, 2013.

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22. Sanofi GmbH received Eli Lilly's Notice of Paragraph IV Certifications on December 20, 2013.

23. On information and belief, on January 23, 2014, Eli Lilly sent an amendment to its "Notice of Paragraph IV Certifications" pursuant to § 505(b)(2)(A)(iv), (b)(3) of the FFDCA to Plaintiffs, disclosing that Eli Lilly amended its Paragraph IV certifications contained in NDA No. 205-692 to include the '044 Patent. In its letter dated January 23, 2014, Eli Lilly stated that its certification to FDA alleges, *inter alia*, that each of the Patents-in-Suit is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Eli Lilly's Proposed Product, before their respective expirations.

24. Sanofi U.S. received Eli Lilly's amendment to its Notice of Paragraph IV Certifications on January 24, 2014.

25. Sanofi GmbH received Eli Lilly's amendment to its Notice of Paragraph IV Certifications on or about January 27, 2014.

26. On information and belief, on May 14, 2014, Eli Lilly sent a "Notice of Paragraph IV Certification Regarding NDA No. 012081 with Respect to U.S. Patent No. 8,679,069" (the "'069 Patent Notice of Paragraph IV Certification") pursuant to § 505(b)(2)(A)(iv), (b)(3) of the FFDCA to Plaintiffs, disclosing that Eli Lilly amended its Paragraph IV certifications contained in NDA No. 205-692 to include the '069 Patent. In its letter dated May 14, 2014, Eli Lilly stated that its certification to FDA alleges, *inter alia*, that the '069 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Eli Lilly's Proposed Product, before its expiration.

27. Sanofi U.S. received Eli Lilly's '069 Patent Notice of Paragraph IV Certification on May 15, 2014.

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