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.

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.

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

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.

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.

28. Eli Lilly's Notice of Paragraph IV Certifications dated December 18, 2013, was accompanied by an Offer of Confidential Access.

29. Eli Lilly and Sanofi executed an Offer of Confidential Access, entitled "Terms of Confidential Access," on January 23, 2014.

30. On January 25, 2014, Sanofi received approximately 66 pages of Eli Lilly's 505(b)(2) application. Those pages were provided subject to the Terms of Confidential Access. No other portions of the 505(b)(2) application were provided before the Original Complaint for Patent Infringement (D.I. 1) was filed.

31. On information and belief, Eli Lilly's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States, of its Proposed Product would infringe each of the Patents-in-Suit, literally and/or under the Doctrine of Equivalents.

32. Each of the '652 Patent, '930 Patent, and '864 Patent were submitted for listing in the Orange Book for NDA No. 21-081 on or before October 25, 2013.

33. On information and belief, Eli Lilly submitted NDA No. 205-692 to FDA after October 25, 2013.

34. Plaintiffs commenced this action within 45 days after receiving Eli Lilly's Notice of Paragraph IV Certifications.

35. FDA's approval of NDA 205-692 may only be made effective upon a date consistent with 21 U.S.C. § 355(c)(3)(C).

COUNT I
(Infringement of U.S. Patent No. 8,556,864)

36. Plaintiffs repeat and re-allege paragraphs 1-35 above as if fully set forth herein.

37. On information and belief, Eli Lilly submitted NDA No. 205-692 to obtain approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of its

Proposed Product, which is claimed in the '864 Patent, before the expiration of the '864 Patent. On information and belief, Eli Lilly filed NDA No. 205-692 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Product using data from bioavailability or bioequivalence studies conducted in connection with NDA No. 21-081 before the expiration of the '864 Patent. Eli Lilly's submission of NDA No. 205-692 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

38. On information and belief, Eli Lilly was aware of the '864 Patent prior to filing NDA No. 205-692. If Eli Lilly's NDA No. 205-692 is approved, Eli Lilly's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States, of its Proposed Product would infringe the '864 Patent under 35 U.S.C. § 271(a), (b), and (c), literally and/or under the Doctrine of Equivalents.

39. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 205-692 is stayed, and Eli Lilly is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '864 Patent, or any later date of exclusivity to which Plaintiffs and/or the '864 Patent are, or become, entitled.

COUNT II
(Infringement of U.S. Patent No. 8,603,044)

40. Plaintiffs repeat and re-allege paragraphs 1-35 above as if fully set forth herein.

41. On information and belief, Eli Lilly submitted NDA No. 205-692 to obtain approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of its Proposed Product, which is claimed in the '044 Patent, before the expiration of the '044 Patent. On information and belief, Eli Lilly filed NDA No. 205-692 pursuant to § 505(b)(2) of the

FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Product using data from bioavailability or bioequivalence studies conducted in connection with NDA No. 21-081 before the expiration of the ’044 Patent. Eli Lilly’s submission of NDA No. 205-692 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

42. On information and belief, Eli Lilly is aware of the ’044 Patent. If Eli Lilly’s NDA No. 205-692 is approved, Eli Lilly’s manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States, of its Proposed Product would infringe the ’044 Patent under 35 U.S.C. § 271(a), (b), and (c), literally and/or under the Doctrine of Equivalents.

43. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA’s approval of NDA No. 205-692 is stayed, and Eli Lilly is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the ’044 Patent, or any later date of exclusivity to which Plaintiffs and/or the ’044 Patent are, or become, entitled.

COUNT III
(Infringement of U.S. Patent No. 7,476,652)

44. Plaintiffs repeat and re-allege paragraphs 1-35 above as if fully set forth herein.

45. On information and belief, Eli Lilly submitted NDA No. 205-692 to obtain approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of its Proposed Product, which is claimed in the ’652 Patent, before the expiration of the ’652 Patent. On information and belief, Eli Lilly filed NDA No. 205-692 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Product using data from bioavailability or bioequivalence studies conducted in

connection with NDA No. 21-081 before the expiration of the ’652 Patent. Eli Lilly’s submission of NDA No. 205-692 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

46. On information and belief, Eli Lilly was aware of the ’652 Patent prior to filing NDA No. 205-692. If Eli Lilly’s NDA No. 205-692 is approved, Eli Lilly’s manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States, of its Proposed Product would infringe the ’652 Patent under 35 U.S.C. § 271(a), (b), and (c), literally and/or under the Doctrine of Equivalents.

47. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA’s approval of NDA No. 205-692 is stayed, and Eli Lilly is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the ’652 Patent, or any later date of exclusivity to which Plaintiffs and/or the ’652 Patent are, or become, entitled.

COUNT IV
(Infringement of U.S. Patent No. 7,713,930)

48. Plaintiffs repeat and re-allege paragraphs 1-35 above as if fully set forth herein.

49. On information and belief, Eli Lilly submitted NDA No. 205-692 to obtain approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of its Proposed Product, which is claimed in the ’930 Patent, before the expiration of the ’930 Patent. On information and belief, Eli Lilly filed NDA No. 205-692 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Product using data from bioavailability or bioequivalence studies conducted in connection with NDA No. 21-081 before the expiration of the ’930 Patent. Eli Lilly’s submission of NDA No. 205-692 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

50. On information and belief, Eli Lilly was aware of the ’930 Patent prior to filing NDA No. 205-692. If Eli Lilly’s NDA No. 205-692 is approved, Eli Lilly’s manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States, of its Proposed Product would infringe the ’930 Patent under 35 U.S.C. § 271(a), (b), and (c), literally and/or under the Doctrine of Equivalents.

51. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm continue unless FDA’s approval of NDA No. 205-692 is stayed, and Eli Lilly is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the ’930 Patent, or any later date of exclusivity to which Plaintiffs and/or the ’930 Patent are, or become, entitled.

COUNT V
(Infringement of U.S. Patent No. 8,679,069)

52. Plaintiffs repeat and re-allege paragraphs 1-35 above as if fully set forth herein.

53. On information and belief, Eli Lilly submitted NDA No. 205-692 to obtain approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of its Proposed Product, which is claimed in the ’069 Patent, before the expiration of the ’069 Patent. On information and belief, Eli Lilly filed NDA No. 205-692 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Product using data from bioavailability or bioequivalence studies conducted in connection with NDA No. 21-081 before the expiration of the ’069 Patent. Eli Lilly’s submission of NDA No. 205-692 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

54. On information and belief, Eli Lilly is aware of the ’069 Patent. If Eli Lilly’s NDA No. 205-692 is approved, Eli Lilly’s manufacture, use, sale and/or offer to sell in the

United States, and/or importation into the United States, of its Proposed Product would infringe the ’069 Patent under 35 U.S.C. § 271(a), (b), and (c), literally and/or under the Doctrine of Equivalents.

55. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA’s approval of NDA No. 205-692 is stayed, and Eli Lilly is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the ’069 Patent, or any later date of exclusivity to which Plaintiffs and/or the ’069 Patent are, or become, entitled.

REQUESTED RELIEF

Plaintiffs respectfully seek the following relief:

a) The entry of judgment declaring that Eli Lilly has infringed each of the Patents-in-Suit;

b) The entry of a permanent injunction, enjoining Eli Lilly, its officers, agents, attorneys, and employees, and those acting in active concert with them, from infringing any of the Patents-in-Suit, from engaging in any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the insulin glargine [rDNA origin] injection in a prefilled insulin delivery device, 100 units/mL as claimed by the Patents-in-Suit for the full terms thereof (and any additional period of exclusivity to which Plaintiffs and/or the Patents-in-Suit are, or become, entitled), and from inducing or contributing to such activities;

c) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), declaring that the effective date of any approval of NDA No. 205-692 shall be a date that is not earlier than the last

date of expiration of any of the Patents-in-Suit, or any later date of exclusivity to which Plaintiffs and/or the Patents-in-Suit are, or become, entitled;

d) The entry of an order declaring that this is an exceptional case and awarding Sanofi its costs, expenses, and reasonable attorney fees under 35 U.S.C. § 285 and all other applicable statutes, rules, and common law;

e) The taxation of all allowable costs against Eli Lilly;

f) The award to Plaintiffs of any other relief that the Court deems just and proper under the circumstances.

ASHBY & GEDDES

/s/ Steven J. Balick

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