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").

29. Since receiving the Merck Notice of Certification and the accompanying OCA, Sanofi has negotiated in good faith with Merck to procure a copy of NDA No. 208-722 and related product information under restrictions as would apply had a protective order been issued. Sanofi timely responded to all correspondence with Merck and sought to reach reasonable compromise with Merck regarding its OCA. These negotiations have been unsuccessful.

30. Because of the onerous and unreasonable restrictions on disclosure and use of the information in the OCA insisted upon by Merck, which Sanofi could not reasonably accept, no information in the OCA has been supplied by Merck to Sanofi.

31. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present to the Court evidence that the Proposed Product falls within the scope of one or more claims of the Patents-in-Suit.

32. Each of the Patents-in-Suit was submitted for listing and listed in the Orange Book for Sanofi's NDA No. 21-081 prior to Merck's submission of NDA No. 208-722.

33. Plaintiffs commenced this action within 45 days after receiving Merck's Notice of Certification.

34. FDA's approval of Merck's NDA 208-722 may only be made effective upon a date consistent with 21 U.S.C. § 355(c)(3)(C).

35. On information and belief, Merck'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 one or more claims of each of the Patents-in-Suit, directly or indirectly.

COUNT I

(Infringement of U.S. Patent No. 7,918,833)

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

37. On information and belief, Merck submitted NDA No. 208-722 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 '833 Patent, before the expiration of the '833 Patent. On information and belief, Merck filed NDA No. 208-722 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 Sanofi's NDA No. 21-081 before the expiration of the '833 Patent. Merck's submission of NDA No. 208-722 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

38. On information and belief, Merck was aware of the '833 Patent prior to filing NDA No. 208-722. If Merck's NDA No. 208-722 is approved, Merck'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 '833 Patent under 35 U.S.C. §§ 271(a), (b), and/or (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. 208-722 is stayed, and Merck is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '833 Patent, or any later date of exclusivity to which Plaintiffs and/or the '833 Patent are, or become, entitled.

COUNT II

(Infringement of U.S. Patent No. 8,512,297)

40. Plaintiffs repeat and re-allege paragraphs 1-39 above as if fully set forth herein.

41. On information and belief, Merck submitted NDA No. 208-722 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 '297 Patent, before the expiration of the '297 Patent. On information and belief, Merck filed NDA No. 208-722 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 Sanofi's NDA No. 21-081 before the expiration of the '297 Patent. Merck's submission of NDA No. 208-722 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

42. On information and belief, Merck was aware of the '297 Patent prior to filing NDA No. 208-722. If Merck's NDA No. 208-722 is approved, Merck'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 '297 Patent under 35 U.S.C. §§ 271(a), (b), and/or (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. 208-722 is stayed, and Merck is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '297 Patent, or any later date of exclusivity to which Plaintiffs and/or the '297 Patent are, or become, entitled.

COUNT III

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

44. Plaintiffs repeat and re-allege paragraphs 1-43 above as if fully set forth herein.

45. On information and belief, Merck submitted NDA No. 208-722 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, Merck filed NDA No. 208-722 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 Sanofi's NDA No. 21-081 before the expiration of the '864 Patent. Merck's submission of NDA No. 208-722 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

46. On information and belief, Merck was aware of the '864 Patent prior to filing NDA No. 208-722. If Merck's NDA No. 208-722 is approved, Merck'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/or (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. 208-722 is stayed, and Merck 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 IV

(Infringement of U.S. Patent No. 8,992,486)

48. Plaintiffs repeat and re-allege paragraphs 1-47 above as if fully set forth herein.

49. On information and belief, Merck submitted NDA No. 208-722 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 '486 Patent, before the expiration of the '486 Patent. On information and belief, Merck filed NDA No. 208-722 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 Sanofi's NDA No. 21-081 before the expiration of the '486 Patent. Merck's submission of NDA No. 208-722 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

50. On information and belief, Merck was aware of the '486 Patent prior to filing NDA No. 208-722. If Merck's NDA No. 208-722 is approved, Merck'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 '486 Patent under 35 U.S.C. §§ 271(a), (b), and/or (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 will continue unless FDA's approval of NDA No. 208-722 is stayed, and Merck is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '486 Patent, or any later date of exclusivity to which Plaintiffs and/or the '486 Patent are, or become, entitled.

COUNT V

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

52. Plaintiffs repeat and re-allege paragraphs 1-51 above as if fully set forth herein.

53. On information and belief, Merck submitted NDA No. 208-722 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, Merck filed NDA No. 208-722 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 Sanofi's NDA No. 21-081 before the expiration of the '044 Patent. Merck's submission of NDA No. 208-722 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

54. On information and belief, Merck was aware of the '044 Patent prior to filing NDA No. 208-722. If Merck's NDA No. 208-722 is approved, Merck'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/or (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. 208-722 is stayed, and Merck 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 VI

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

56. Plaintiffs repeat and re-allege paragraphs 1-55 above as if fully set forth herein.

57. On information and belief, Merck submitted NDA No. 208-722 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, Merck filed NDA No. 208-722 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 Sanofi's NDA No. 21-081 before the expiration of the '069 Patent. Merck's submission of NDA No. 208-722 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

58. On information and belief, Merck was aware of the '069 Patent prior to filing NDA No. 208-722. If Merck's NDA No. 208-722 is approved, Merck'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/or (c), literally and/or under the doctrine of equivalents.

59. 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. 208-722 is stayed, and Merck 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.

COUNT VII

(Infringement of U.S. Patent No. 9,011,391)

60. Plaintiffs repeat and re-allege paragraphs 1-59 above as if fully set forth herein.

61. On information and belief, Merck submitted NDA No. 208-722 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 '391 Patent, before the expiration of the '391 Patent. On information and belief, Merck filed NDA No. 208-722 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 Sanofi's NDA No. 21-081 before the expiration of the '391 Patent. Merck's submission of NDA No. 208-722 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

62. On information and belief, Merck was aware of the '391 Patent prior to filing NDA No. 208-722. If Merck's NDA No. 208-722 is approved, Merck'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 '391 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

63. 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. 208-722 is stayed, and Merck is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '391 Patent, or any later date of exclusivity to which Plaintiffs and/or the '391 Patent are, or become, entitled.

COUNT VIII

(Infringement of U.S. Patent No. 9,233,211)

64. Plaintiffs repeat and re-allege paragraphs 1-63 above as if fully set forth herein.

65. On information and belief, Merck submitted NDA No. 208-722 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 '211 Patent, before the expiration of the '211 Patent. On information and belief, Merck filed NDA No. 208-722 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 Sanofi's NDA No. 21-081 before the expiration of the '211 Patent. Merck's submission of NDA No. 208-722 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

66. On information and belief, Merck was aware of the '211 Patent prior to filing NDA No. 208-722. If Merck's NDA No. 208-722 is approved, Merck'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 '211 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

67. 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. 208-722 is stayed, and Merck is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '211 Patent, or any later date of exclusivity to which Plaintiffs and/or the '211 Patent are, or become, entitled.

COUNT IX

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

68. Plaintiffs repeat and re-allege paragraphs 1-67 above as if fully set forth herein.

69. On information and belief, Merck submitted NDA No. 208-722 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, Merck filed NDA No. 208-722 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 Sanofi's NDA No. 21-081 before the expiration of the '652 Patent. Merck's submission of NDA No. 208-722 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

70. On information and belief, Merck was aware of the '652 Patent prior to filing NDA No. 208-722. If Merck's NDA No. 208-722 is approved, Merck'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/or (c), literally and/or under the doctrine of equivalents.

71. 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. 208-722 is stayed, and Merck 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 X

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

72. Plaintiffs repeat and re-allege paragraphs 1-71 above as if fully set forth herein.

73. On information and belief, Merck submitted NDA No. 208-722 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, Merck filed NDA No. 208-722 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 Sanofi's NDA No. 21-081 before the expiration of the '930 Patent. Merck's submission of NDA No. 208-722 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

74. On information and belief, Merck was aware of the '930 Patent prior to filing NDA No. 208-722. If Merck's NDA No. 208-722 is approved, Merck'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/or (c), literally and/or under the doctrine of equivalents.

75. 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. 208-722 is stayed, and Merck 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.

REQUESTED RELIEF

Plaintiffs respectfully seek the following relief:

a) The entry of judgment holding that Merck has infringed each of the ’833, ’297, ’864, ’044, ’486, ’069, ’391, ’211, ’652 and ’930 Patents;

b) The entry of an order pursuant to 35 U.S.C. § 271(e)(4)(A), declaring that the effective date of any approval of Merck’s NDA No. 208-722 shall be a date that is not earlier than the last date of expiration of any of the ’833, ’297, ’864, ’044, ’486, ’069, ’391, ’211, ’652 and ’930 Patents or any additional period of exclusivity to which Plaintiffs and/or said Patents are, or become, entitled;

c) The entry of a preliminary injunction, enjoining Merck, its officers, agents, attorneys, and employees, and those acting in 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 insulin glargine [rDNA origin] injection in 3 mL cartridges, 100 units/mL as claimed by the Patents-in-Suit for the full terms thereof (and any additional period of exclusivity to which Sanofi and/or the Patents-in-Suit are, or become, entitled), and from inducing or contributing to such activities.

d) The entry of a permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) enjoining Merck, its officers, agents, attorneys, and employees, and those acting or attempting to act in active concert with them or acting on their behalf, from infringing any of the ’833, ’297, ’864, ’044, ’486, ’069, ’391, ’211, ’652 and ’930 Patents by engaging in any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any product covered by the ’833, ’297, ’864, ’044, ’486, ’069, ’391, ’211, ’652 and

'930 Patents for the full terms thereof or any additional period of exclusivity to which Plaintiffs and/or such Patents are, or become, entitled, and from inducing or contributing to such activities;

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

f) The taxation of all allowable costs against Merck; and

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

Dated: September 16, 2016

FISH & RICHARDSON P.C.

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