IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

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; *Sanofi-Aventis U.S. LLC et al. v. Eli Lilly & Co.*, C.A. No. 14-113-RGA-MPT (D.I. 65).

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

PATENTS-IN-SUIT

11. 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 United States Patent and Trademark Office ("PTO"). A true and correct copy of the '652 Patent is attached as Exhibit A to this Complaint.

12. 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 B to this Complaint.

13. 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 PTO. A true and correct copy of the '833 Patent is attached as Exhibit C to this Complaint.

14. 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 D to this Complaint.

15. 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 E to this Complaint.

16. 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 F to this Complaint.

17. 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 G to this Complaint.

18. The '652 Patent, '930 Patent, '833 Patent, '297 Patent, '864 Patent, '044 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

19. 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.

20. The FDA 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").

21. Insulin glargine [rDNA origin] injection, at a strength of 100 units/mL, in 3 mL and 10 mL dosage units, is identified in the Orange Book as an approved drug product under NDA No. 21-081.

22. Sanofi U.S. timely submitted patent information to FDA for each of the Patents-in-Suit for listing in the Orange Book under NDA No. 21-081.

23. The Patents-in-Suit in the Orange Book cover Lantus® and Lantus® in a disposable insulin device, known as Lantus® SoloSTAR®.

24. On information and belief, Eli Lilly submitted NDA No. 206-609 to FDA, under 21 U.S.C. § 355(b)(2) (§ 505(b)(2) of the FFDCA), seeking FDA approval to commercially

manufacture and sell its proposed product – an insulin glargine [rDNA origin] for injection in 3 mL cartridges, 100 units/mL ("Proposed Product").

25. On information and belief, NDA No. 206-609 is based at least in part on data from bioavailability or bioequivalence studies conducted with insulin glargine [rDNA origin] approved under or related to Sanofi U.S.'s NDA No. 21-081, and based at least in part on prior findings of safety and effectiveness made by FDA for insulin glargine [rDNA origin] under NDA No. 21-081.

26. On information and belief, on May 22, 2014, Eli Lilly sent a "Notice of Paragraph IV Certifications Regarding NDA No. 021081 with Respect to U.S. Patent Nos. 7,918,833, 7,476,652, and 7,713,930 Concerning Eli Lilly and Company's 505(b)(2) Application No. 206,609" ("Notice Letter") pursuant to § 505(b)(2)(A)(iv), (b)(3) of the FFDCA to Plaintiffs. Lilly's Notice Letter states that Lilly's NDA No. 206-609 contained Paragraph IV Certifications to the '833 Patent, '652 Patent, and '930 Patent. In its Notice Letter, Eli Lilly stated that its certification to FDA alleges that, *inter alia*, the '833 Patent, '652 Patent, and '930 Patent 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.

27. Sanofi U.S. received Eli Lilly's Notice Letter on May 23, 2014.

28. Sanofi GmbH received Eli Lilly's Notice Letter on May 27, 2014.

29. Eli Lilly's Notice Letter did not contain notice of Paragraph IV Certifications to the '297 Patent, '864 Patent, '044 Patent, or '069 Patent.

30. On information and belief, Eli Lilly's NDA No. 206-609 did not contain any certifications to the '297 Patent, '864 Patent, '044 Patent, or '069 Patent.

31. Eli Lilly's NDA No. 205-692 for insulin glargine [rDNA origin] for injection in a prefilled insulin delivery device, 100 units/mL, contains Paragraph IV Certifications with respect to the '652 Patent, '930 Patent, '833 Patent, '297 Patent, and '864 Patent dated at least as of December 18, 2013; a Paragraph IV Certification with respect to the '044 Patent dated at least as of January 23, 2014; and a Paragraph IV Certification with respect to the '069 Patent dated at least as of May 14, 2014.

32. Eli Lilly's NDA No. 206-609 should have contained certifications to the '297, '864, '044, and '069 Patents.

33. Eli Lilly's Notice Letter was accompanied by an Offer of Confidential Access.

34. Following a specific proposal made by Sanofi's counsel on June 5, 2014, to simplify the OCA agreement, Eli Lilly and Sanofi executed an Offer of Confidential Access, entitled "Terms of Confidential Access," on June 16, 2014.

35. On June 24, 2014, Sanofi received approximately 20 pages of Eli Lilly's 505(b)(2) application. Those pages were provided subject to the Terms of Confidential Access.

36. On June 26, 2014, Sanofi requested from Eli Lilly additional material from the NDA No. 206-609, as well as schematics of the injector pen delivery device(s) to be used, if approved by FDA, to administer Lilly's Proposed Product ("Lilly's NDA Pens" or "Lilly NDA Pens").

37. On information and belief, on June 27, 2014, Eli Lilly sent Sanofi, via UPS Overnight Mail, an additional 28 pages from its NDA No. 206-609.

38. Eli Lilly did not provide the other requested materials about its Proposed Product.

39. Lilly has refused to timely provide Plaintiffs with sufficient information about its Proposed Product concerning whether it infringes, either directly or indirectly, the Patents-in-Suit.

40. 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 directly and/or indirectly infringe each of the Patents-in-Suit, literally and/or under the Doctrine of Equivalents.

41. Each of the '652 Patent, '930 Patent, and '833 Patent was submitted for listing in the Orange Book for NDA No. 21-081 on or before May 5, 2011.

42. On information and belief, Eli Lilly submitted NDA No. 206-609 to FDA after May 5, 2011.

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

44. FDA's approval of NDA No. 206-609 may only be made effective upon a date consistent with 21 U.S.C. § 355(c)(3)(C).

45. To the extent Sanofi submitted the '297 Patent, '864 Patent, '044 Patent, and '069 Patent for listing in the Orange Book prior to Lilly's submission of NDA No. 206-609, FDA approval of NDA No. 206-609 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. 7,476,652 Under § 271(e)(2))

46. Plaintiffs repeat and re-allege paragraphs 1-45 above as if fully set forth herein.

47. On information and belief, Eli Lilly submitted NDA No. 206-609 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. 206-609 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 relation to insulin glargine [rDNA origin] approved under or related to NDA No. 21-081 before the expiration of the ’652 Patent, and relying at least in part on prior findings of safety and effectiveness made by FDA for insulin glargine [rDNA origin] under NDA No. 21-081.

48. Eli Lilly’s submission of NDA No. 206-609 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

49. If Eli Lilly’s NDA No. 206-609 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), literally and/or under the Doctrine of Equivalents.

50. On information and belief, Eli Lilly was aware of the ’652 Patent prior to filing NDA No. 206-609.

51. On information and belief, Eli Lilly seeks FDA approval to commercially sell its Proposed Product to the public for use in or with the Lilly NDA Pens.

52. If Eli Lilly’s NDA No. 206-609 is approved, the use of Eli Lilly’s Proposed Product would directly infringe the ’652 Patent literally and/or under the Doctrine of Equivalents.

53. Eli Lilly was aware of the ’652 Patent prior to filing NDA No. 206-609, and it knew, or willfully blinded itself to the fact, that such use would constitute patent infringement.

54. If Eli Lilly's NDA No. 206-609 is approved, Eli Lilly's manufacture, 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(b), 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. 206-609 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 II
(Infringement of U.S. Patent No. 7,713,930 Under § 271(e)(2))

56. Plaintiffs repeat and re-allege paragraphs 1-45 above as if fully set forth herein.

57. On information and belief, Eli Lilly submitted NDA No. 206-609 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. 206-609 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 relation to insulin glargine [rDNA origin] approved under or related to NDA No. 21-081 before the expiration of the '930 Patent, and relying at least in part on prior findings of safety and effectiveness made by FDA for insulin glargine [rDNA origin] under NDA No. 21-081.

58. Eli Lilly's submission of NDA No. 206-609 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

59. If Eli Lilly's NDA No. 206-609 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), literally and/or under the Doctrine of Equivalents.

60. On information and belief, Eli Lilly was aware of the '930 Patent prior to filing NDA No. 206-609.

61. On information and belief, Eli Lilly seeks FDA approval to commercially sell its Proposed Product to the public for use in or with the Lilly NDA Pens.

62. If Eli Lilly's NDA No. 206-609 is approved, the use of Eli Lilly's Proposed Product would directly infringe the '930 Patent literally and/or under the Doctrine of Equivalents.

63. Eli Lilly was aware of the '930 Patent prior to filing NDA No. 206-609, and it knew, or willfully blinded itself to the fact, that such use would constitute patent infringement.

64. If Eli Lilly's NDA No. 206-609 is approved, Eli Lilly's manufacture, 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(b), literally and/or under the Doctrine of Equivalents.

65. 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. 206-609 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 III
(Infringement of U.S. Patent No. 7,918,833 Under § 271(e)(2))

66. Plaintiffs repeat and re-allege paragraphs 1-45 above as if fully set forth herein.

67. On information and belief, Eli Lilly submitted NDA No. 206-609 to obtain approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of its Proposed Product, before the expiration of the '833 Patent. On information and belief, Eli Lilly filed NDA No. 206-609 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 relation to insulin glargine [rDNA origin] approved under or related to NDA No. 21-081 before the expiration of the '833 Patent, and relying at least in part on prior findings of safety and effectiveness made by FDA for insulin glargine [rDNA origin] under NDA No. 21-081.

68. Eli Lilly's submission of NDA No. 206-609 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

69. On information and belief, Eli Lilly was aware of the '833 Patent prior to filing NDA No. 206-609.

70. On information and belief, Eli Lilly seeks FDA approval to administer Lilly's Proposed Product in or with Lilly's NDA Pens.

71. On information and belief, Eli Lilly seeks FDA approval to commercially sell its Proposed Product to the public for use in or with the Lilly NDA Pens.

72. If Eli Lilly's NDA No. 206-609 is approved, the use of Eli Lilly's Proposed Product in or with the Lilly NDA Pens would directly infringe the '833 Patent literally and/or under the Doctrine of Equivalents.

73. Eli Lilly was aware of the ’833 Patent prior to filing NDA No. 206-609, and it knew, or willfully blinded itself to the fact, that such use would constitute patent infringement.

74. If Eli Lilly’s NDA No. 206-609 is approved, Eli Lilly’s manufacture, 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(b), literally and/or under the Doctrine of Equivalents.

75. If Eli Lilly’s NDA No. 206-609 is approved, Eli Lilly’s use in the United States of its Proposed Product in and with the Lilly NDA Pens would infringe the ’833 Patent under 35 U.S.C. § 271(a), literally and/or under the Doctrine of Equivalents.

76. 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. 206-609 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 ’833 Patent, or any later date of exclusivity to which Plaintiffs and/or the ’833 Patent are, or become, entitled.

COUNT IV
(Infringement of U.S. Patent No. 8,512,297 Under § 271(e)(2))

77. Plaintiffs repeat and re-allege paragraphs 1-45 above as if fully set forth herein.

78. On information and belief, Eli Lilly submitted NDA No. 206-609 to obtain approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of its Proposed Product, before the expiration of the ’297 Patent. On information and belief, Eli Lilly filed NDA No. 206-609 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 relation to insulin glargine [rDNA origin]

approved under or related to NDA No. 21-081 before the expiration of the ’297 Patent, and relying at least in part on prior findings of safety and effectiveness made by FDA for insulin glargine [rDNA origin] under NDA No. 21-081.

79. Eli Lilly’s submission of NDA No. 206-609 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

80. On information and belief, Eli Lilly was aware of the ’297 Patent prior to filing NDA No. 206-609.

81. On information and belief, Eli Lilly seeks FDA approval to administer Lilly’s Proposed Product in or with Lilly’s NDA Pens.

82. On information and belief, Eli Lilly seeks FDA approval to commercially sell its Proposed Product to the public for use in or with the Lilly NDA Pens.

83. If Eli Lilly’s NDA No. 206-609 is approved, the use of Eli Lilly’s Proposed Product in or with the Lilly NDA Pens would directly infringe the ’297 Patent literally and/or under the Doctrine of Equivalents.

84. Eli Lilly was aware of the ’297 Patent prior to filing NDA No. 206-609, and it knew, or willfully blinded itself to the fact, that such use would constitute patent infringement.

85. Eli Lilly’s Proposed Product, when used in or with the Lilly NDA Pens, is a component, and material part, of the patented invention claimed in the ’297 Patent.

86. Eli Lilly’s Proposed Product is designed for and adapted for use in and with the infringing Lilly NDA Pens, and has no substantial non-infringing uses.

87. If Eli Lilly’s NDA No. 206-609 is approved, Eli Lilly’s manufacture, sale, and/or offer to sell in the United States, and/or importation into the United States would infringe the ’297 Patent under 35 U.S.C. § 271(b) and (c), literally and/or under the Doctrine of Equivalents.

88. If Eli Lilly's NDA No. 206-609 is approved, Eli Lilly's use in the United States of its Proposed Product in and with the Lilly NDA Pens would infringe the '297 Patent under 35 U.S.C. § 271(a), literally and/or under the Doctrine of Equivalents.

89. 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. 206-609 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 '297 Patent, or any later date of exclusivity to which Plaintiffs and/or the '297 Patent are, or become, entitled.

COUNT V
(Declaratory Judgment of Infringement of U.S. Patent No. 8,512,297)

90. Plaintiffs repeat and re-allege paragraphs 1-45 above as if fully set forth herein.

91. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

92. There is a substantial controversy between the parties with respect to the '297 Patent, in connection with which they have adverse legal interests, and said controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment by this Court.

93. Eli Lilly has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Lilly's Proposed Product prior to the expiration of the '297 Patent.

94. Eli Lilly's actions, including but not limited to, the filing of NDA No. 205-692 and NDA No. 206-609 prior to the expiration of the '297 Patent, indicate a refusal to change the course of its action in the face of the acts by Plaintiffs.

95. On information and belief, Eli Lilly was aware of the ’297 Patent prior to filing NDA No. 206-609.

96. On information and belief, Eli Lilly seeks FDA approval to administer Lilly’s Proposed Product in or with Lilly’s NDA Pens.

97. On information and belief, Eli Lilly seeks FDA approval to commercially sell its Proposed Product to the public for use in or with the Lilly NDA Pens.

98. The use of Eli Lilly’s Proposed Product in or with the Lilly NDA Pens would directly infringe the ’297 Patent literally and/or under the Doctrine of Equivalents.

99. Eli Lilly was aware of the ’297 Patent prior to filing NDA No. 206-609, and it knew, or willfully blinded itself to the fact, that such use would constitute patent infringement.

100. Eli Lilly’s Proposed Product, when used in or with the Lilly NDA Pens, is a component, and material part, of the patented invention claimed in the ’297 Patent.

101. Eli Lilly’s Proposed Product is designed for and adapted for use in and with the infringing Lilly NDA Pens, and has no substantial non-infringing uses.

102. If Eli Lilly’s NDA No. 206-609 is approved, Eli Lilly’s use in the United States of its Proposed Product in and with the Lilly NDA Pens would infringe the ’297 Patent under 35 U.S.C. § 271(a), literally and/or under the Doctrine of Equivalents.

103. Plaintiffs are entitled to a declaratory judgment that the future commercial manufacture, use, sale, and/or offer to sell in the United States, and/or importation into the United States of Lilly’s Proposed Product will infringe the ’297 Patent under 35 U.S.C. § 271(a), (b) and (c), literally and/or under the Doctrine of Equivalents.

104. 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. 206-609 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 '297 Patent, or any later date of exclusivity to which Plaintiffs and/or the '297 Patent are, or become, entitled.

COUNT VI
(Infringement of U.S. Patent No. 8,556,864 Under § 271(e)(2))

105. Plaintiffs repeat and re-allege paragraphs 1-45 above as if fully set forth herein.

106. On information and belief, Eli Lilly submitted NDA No. 206-609 to obtain approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of its Proposed Product, before the expiration of the '864 Patent. On information and belief, Eli Lilly filed NDA No. 206-609 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 relation to insulin glargine [rDNA origin] approved under or related to NDA No. 21-081 before the expiration of the '864 Patent, and relying at least in part on prior findings of safety and effectiveness made by FDA for insulin glargine [rDNA origin] under NDA No. 21-081.

107. Eli Lilly's submission of NDA No. 206-609 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

108. On information and belief, Eli Lilly was aware of the '864 Patent prior to filing NDA No. 206-609.

109. On information and belief, Eli Lilly seeks FDA approval to administer Lilly's Proposed Product in or with Lilly's NDA Pens.

110. On information and belief, Eli Lilly seeks FDA approval to commercially sell its Proposed Product to the public for use in or with the Lilly NDA Pens.

111. If Eli Lilly's NDA No. 206-609 is approved, the use of Eli Lilly's Proposed Product in or with the Lilly NDA Pens would directly infringe the '864 Patent literally and/or under the Doctrine of Equivalents.

112. Eli Lilly was aware of the '864 Patent prior to filing NDA No. 206-609, and it knew, or willfully blinded itself to the fact, that such use would constitute patent infringement.

113. If Eli Lilly's NDA No. 206-609 is approved, Eli Lilly's manufacture, 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(b), literally and/or under the Doctrine of Equivalents.

114. If Eli Lilly's NDA No. 206-609 is approved, Eli Lilly's use in the United States of its Proposed Product in and with the Lilly NDA Pens would infringe the '864 Patent under 35 U.S.C. § 271(a), literally and/or under the Doctrine of Equivalents.

115. 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. 206-609 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 VII
(Declaratory Judgment of Infringement of U.S. Patent No. 8,556,864)

116. Plaintiffs repeat and re-allege paragraphs 1-45 above as if fully set forth herein.

117. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

118. There is a substantial controversy between the parties with respect to the ’864 Patent, in connection with which they have adverse legal interests, and said controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment by this Court.

119. Eli Lilly has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Lilly’s Proposed Product prior to the expiration of the ’864 Patent.

120. Eli Lilly’s actions, including but not limited to, the filing of NDA No. 205-692 and NDA No. 206-609 prior to the expiration of the ’864 Patent, indicate a refusal to change the course of its action in the face of the acts by Plaintiffs.

121. On information and belief, Eli Lilly was aware of the ’864 Patent prior to filing NDA No. 206-609.

122. On information and belief, Eli Lilly seeks FDA approval to administer Lilly’s Proposed Product in or with Lilly’s NDA Pens.

123. On information and belief, Eli Lilly seeks FDA approval to commercially sell its Proposed Product to the public for use in or with the Lilly NDA Pens.

124. The use of Eli Lilly’s Proposed Product in or with the Lilly NDA Pens would directly infringe the ’864 Patent literally and/or under the Doctrine of Equivalents.

125. Eli Lilly was aware of the ’864 Patent prior to filing NDA No. 206-609, and it knew, or willfully blinded itself to the fact, that such use would constitute patent infringement.

126. If Eli Lilly’s NDA No. 206-609 is approved, Eli Lilly’s use in the United States of its Proposed Product in and with the Lilly NDA Pens would infringe the ’864 Patent under 35 U.S.C. § 271(a), literally and/or under the Doctrine of Equivalents.

127. Plaintiffs are entitled to a declaratory judgment that the future commercial manufacture, sale, and/or offer to sell in the United States, and/or importation into the United States of Lilly's Proposed Product will infringe the '864 Patent under 35 U.S.C. § 271(a) and (b), literally and/or under the Doctrine of Equivalents.

128. 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. 206-609 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 VIII
(Infringement of U.S. Patent No. 8,603,044 Under § 271(e)(2))

129. Plaintiffs repeat and re-allege paragraphs 1-45 above as if fully set forth herein.

130. On information and belief, Eli Lilly submitted NDA No. 206-609 to obtain approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of its Proposed Product, before the expiration of the '044 Patent. On information and belief, Eli Lilly filed NDA No. 206-609 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 relation to insulin glargine [rDNA origin] approved under or related to NDA No. 21-081 before the expiration of the '044 Patent, and relying at least in part on prior findings of safety and effectiveness made by FDA for insulin glargine [rDNA origin] under NDA No. 21-081.

131. Eli Lilly's submission of NDA No. 206-609 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

132. On information and belief, Eli Lilly was aware of the ’044 Patent prior to filing NDA No. 206-609.

133. On information and belief, Eli Lilly seeks FDA approval to administer Lilly’s Proposed Product in or with Lilly’s NDA Pens.

134. On information and belief, Eli Lilly seeks FDA approval to commercially sell its Proposed Product to the public for use in or with the Lilly NDA Pens.

135. If Eli Lilly’s NDA No. 206-609 is approved, the use of Eli Lilly’s Proposed Product in or with the Lilly NDA Pens would directly infringe the ’044 Patent literally and/or under the Doctrine of Equivalents.

136. Eli Lilly was aware of the ’044 Patent prior to filing NDA No. 206-609, and it knew, or willfully blinded itself to the fact, that such use would constitute patent infringement.

137. Eli Lilly’s Proposed Product, when used in or with the Lilly NDA Pens, is a component, and material part, of the patented invention claimed in the ’044 Patent.

138. Eli Lilly’s Proposed Product is designed for and adapted for use in and with the infringing Lilly NDA Pens, and has no substantial non-infringing uses.

139. If Eli Lilly’s NDA No. 206-609 is approved, Eli Lilly’s manufacture, 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(b) and (c), literally and/or under the Doctrine of Equivalents.

140. If Eli Lilly’s NDA No. 206-609 is approved, Eli Lilly’s use in the United States of its Proposed Product in and with the Lilly NDA Pens would infringe the ’044 Patent under 35 U.S.C. § 271(a), literally and/or under the Doctrine of Equivalents.

141. 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. 206-609 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 IX
(Declaratory Judgment of Infringement of U.S. Patent No. 8,603,044)

142. Plaintiffs repeat and re-allege paragraphs 1-45 above as if fully set forth herein.

143. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

144. There is a substantial controversy between the parties with respect to the '044 Patent, in connection with which they have adverse legal interests, and said controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment by this Court.

145. Eli Lilly has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Lilly's Proposed Product prior to the expiration of the '044 Patent.

146. Eli Lilly's actions, including but not limited to, the filing of NDA No. 205-692 and NDA No. 206-609 prior to the expiration of the '044 Patent, indicate a refusal to change the course of its action in the face of the acts by Plaintiffs.

147. On information and belief, Eli Lilly was aware of the '044 Patent prior to filing NDA No. 206-609.

148. On information and belief, Eli Lilly seeks FDA approval to administer Lilly's Proposed Product in or with Lilly's NDA Pens.

149. On information and belief, Eli Lilly seeks FDA approval to commercially sell its Proposed Product to the public for use in or with the Lilly NDA Pens.

150. The use of Eli Lilly's Proposed Product in or with the Lilly NDA Pens would directly infringe the '044 Patent literally and/or under the Doctrine of Equivalents.

151. Eli Lilly was aware of the '044 Patent prior to filing NDA No. 206-609, and it knew, or willfully blinded itself to the fact, that such use would constitute patent infringement.

152. Eli Lilly's Proposed Product, when used in or with the Lilly NDA Pens, is a component, and material part, of the patented invention claimed in the '044 Patent.

153. Eli Lilly's Proposed Product is designed for and adapted for use in and with the infringing Lilly NDA Pens, and has no substantial non-infringing uses.

154. If Eli Lilly's NDA No. 206-609 is approved, Eli Lilly's use in the United States of its Proposed Product in and with the Lilly NDA Pens would infringe the '044 Patent under 35 U.S.C. § 271(a), literally and/or under the Doctrine of Equivalents.

155. Plaintiffs are entitled to a declaratory judgment that the future commercial manufacture, sale, and/or offer to sell in the United States, and/or importation into the United States of Lilly's Proposed Product will infringe the '044 Patent under 35 U.S.C. § 271(a), (b) and (c), literally and/or under the Doctrine of Equivalents.

156. 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. 206-609 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 X
(Infringement of U.S. Patent No. 8,679,069 Under § 271(e)(2))

157. Plaintiffs repeat and re-allege paragraphs 1-45 above as if fully set forth herein.

158. On information and belief, Eli Lilly submitted NDA No. 206-609 to obtain approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of its Proposed Product, before the expiration of the '069 Patent. On information and belief, Eli Lilly filed NDA No. 206-609 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 relation to insulin glargine [rDNA origin] approved under or related to NDA No. 21-081 before the expiration of the '069 Patent, and relying at least in part on prior findings of safety and effectiveness made by FDA for insulin glargine [rDNA origin] under NDA No. 21-081.

159. Eli Lilly's submission of NDA No. 206-609 is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

160. On information and belief, Eli Lilly was aware of the '069 Patent prior to filing NDA No. 206-609.

161. On information and belief, Eli Lilly seeks FDA approval to administer Lilly's Proposed Product in or with Lilly's NDA Pens.

162. On information and belief, Eli Lilly seeks FDA approval to commercially sell its Proposed Product to the public for use in or with the Lilly NDA Pens.

163. If Eli Lilly's NDA No. 206-609 is approved, the use of Eli Lilly's Proposed Product in or with the Lilly NDA Pens would directly infringe the '069 Patent literally and/or under the Doctrine of Equivalents.

164. Eli Lilly was aware of the ’069 Patent prior to filing NDA No. 206-609, and it knew, or willfully blinded itself to the fact, that such use would constitute patent infringement.

165. Eli Lilly’s Proposed Product, when used in or with the Lilly NDA Pens, is a component, and material part, of the patented invention claimed in the ’069 Patent.

166. Eli Lilly’s Proposed Product is designed for and adapted for use in and with the infringing Lilly NDA Pens, and has no substantial non-infringing uses.

167. If Eli Lilly’s NDA No. 206-609 is approved, Eli Lilly’s manufacture, 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(b) and (c), literally and/or under the Doctrine of Equivalents.

168. If Eli Lilly’s NDA No. 206-609 is approved, Eli Lilly’s use in the United States of its Proposed Product in and with the Lilly NDA Pens would infringe the ’069 Patent under 35 U.S.C. § 271(a), literally and/or under the Doctrine of Equivalents.

169. 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. 206-609 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.

COUNT XI
(Declaratory Judgment of Infringement of U.S. Patent No. 8,679,069)

170. Plaintiffs repeat and re-allege paragraphs 1-45 above as if fully set forth herein.

171. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

172. There is a substantial controversy between the parties with respect to the ’069 Patent, in connection with which they have adverse legal interests, and said controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment by this Court.

173. Eli Lilly has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Lilly’s Proposed Product prior to the expiration of the ’069 Patent.

174. Eli Lilly’s actions, including but not limited to, the filing of NDA No. 205-692 and NDA No. 206-609 prior to the expiration of the ’069 Patent, indicate a refusal to change the course of its action in the face of the acts by Plaintiffs.

175. On information and belief, Eli Lilly was aware of the ’069 Patent prior to filing NDA No. 206-609.

176. On information and belief, Eli Lilly seeks FDA approval to administer Lilly’s Proposed Product in or with Lilly’s NDA Pens.

177. On information and belief, Eli Lilly seeks FDA approval to commercially sell its Proposed Product to the public for use in and with the Lilly NDA Pens.

178. The use of Eli Lilly’s Proposed Product in or with the Lilly NDA Pens would directly infringe the ’069 Patent literally and/or under the Doctrine of Equivalents.

179. Eli Lilly was aware of the ’069 Patent prior to filing NDA No. 206-609, and it knew, or willfully blinded itself to the fact, that such use would constitute patent infringement.

180. Eli Lilly’s Proposed Product, when used in or with the Lilly NDA Pens, is a component, and material part, of the patented invention claimed in the ’069 Patent.

181. Eli Lilly’s Proposed Product is designed for and adapted for use in and with the infringing Lilly NDA Pens, and has no substantial non-infringing uses.

182. If Eli Lilly's NDA No. 206-609 is approved, Eli Lilly's use in the United States of its Proposed Product in and with the Lilly NDA Pens would infringe the '069 Patent under 35 U.S.C. § 271(a), literally and/or under the Doctrine of Equivalents.

183. Plaintiffs are entitled to a declaratory judgment that the future commercial manufacture, sale, and/or offer to sell in the United States, and/or importation into the United States of Lilly's Proposed Product will infringe the '069 Patent under 35 U.S.C. § 271(a), (b) and (c), literally and/or under the Doctrine of Equivalents.

184. 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. 206-609 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 preliminary injunction, enjoining Eli Lilly, 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 Plaintiffs and/or the Patents-in-Suit are, or become, entitled), and from inducing or contributing to such activities;

c) The entry of a permanent injunction, enjoining Eli Lilly, 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 Plaintiffs and/or the Patents-in-Suit are, or become, entitled), and from inducing or contributing to such activities;

d) 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. 206-609 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;

e) 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;

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

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

ASHBY & GEDDES

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