IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SILVERGATE PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 19-2100 (LPS)
	)	
ALKEM LABORATORIES LTD.,	)	
	)	
Defendant.	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Silvergate Pharmaceuticals, Inc. ("Silvergate"), by and through its attorneys, brings this First Amended Complaint against Defendant Alkem Laboratories Ltd. ("Alkem"), and alleges as follows:

THE NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent Nos. 9,669,008 ("'008 patent"), 9,808,442 ("'442 patent"), 10,039,745 ("'745 patent"), 10,154,987 ("'987 patent"), 10,772,868 ("'868 patent"), 10,786,482 ("'482 patent"), and 10,918,621 (the "'621 patent") (collectively, the "Patents-in-Suit") under the patent laws of the United States of America, Title 35, United States Code, arising out of the submission by Alkem of Abbreviated New Drug Application ("ANDA") No. 213714 to the United States Food and Drug Administration ("FDA") seeking approval of a generic version of Silvergate's oral solution formulation that is the subject of New Drug Application ("NDA") No. 208686, hereinafter referred to as Silvergate's "Epaned® Product" or "Epaned®." Silvergate seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and other applicable laws for Alkem's infringement of the Patents-in-Suit.

2. This is also an action under 35 U.S.C. §§ 2201-2202 for a declaratory judgment of infringement of the '621 patent under 35 U.S.C. §§ 271 (a)-(c).

THE PARTIES

3. Silvergate is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 8 Cabot Road, Suite 2000, Woburn, MA 01801.

4. Silvergate is a wholly-owned subsidiary of Azurity Pharmaceuticals, Inc. ("Azurity").

5. On information and belief, Alkem is an Indian corporation, having a principal place of business at Devashish Building, Alkem House, Senapti Bapat Road, Lower Parel, Mumbai – 400 013, India.

6. On information and belief, Alkem is in the business of, among other things, developing, manufacturing, marketing, importing, and selling generic copies of branded pharmaceutical products for the United States market.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1 *et seq*., and from Alkem's submission of ANDA No. 213714 ("Alkem's ANDA").

8. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a). Relief is sought under 35 U.S.C. § 271(e)(2).

9. On information and belief, this Court has personal jurisdiction over Alkem because of, among other things, Alkem's persistent and continuous contacts with Delaware. Alkem has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Alkem regularly and continuously transacts business in Delaware, including by directly or indirectly developing, manufacturing, marketing, and selling generic pharmaceutical products in

Delaware. On information and belief, Alkem derives substantial revenue from the sale of those products in Delaware, and has availed itself of the privilege of conducting business within Delaware. Alkem regularly engaged in patent litigation concerning FDA-approved products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Boehringer Ingelheim Pharms. Inc. et al. v. Alkem Laboratories Ltd.*, C.A. No. 18-1738-CFC, D.I. 15 (D. Del. Jan. 11, 2019); *H. Lundbeck A/S et al. v. Alkem Labs. Ltd. et al.*, C.A. No. 18-89-LPS, D.I. 13 (D. Del. 2018 Apr. 2, 2018); *Biogen International GmbH et al. v. Alkem Labs. Ltd. et al.*, C.A. No. 17-850-LPS, D.I. 12 (D. Del. Oct. 16, 2017).

10. On information and belief, this judicial district is a likely destination of the product that is the subject of Alkem's ANDA.

11. Alternatively, this Court has personal jurisdiction over Alkem pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Silvergate's claims arise under federal law; (b) Alkem is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Alkem has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDA No. 213714 to FDA and/or manufacturing, importing, offering to sell, and/or selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Alkem satisfies due process.

12. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

SILVERGATE'S EPANED® PRODUCT

13. Silvergate's Epaned® Product is the only FDA approved and labeled ace inhibitor treatment that is a ready-to-use oral solution for hypertension in children. Epaned® is also

indicated to treat hypertension in adults, heart failure, and asymptomatic left ventricular dysfunction.

14. Azurity is the holder of approved NDA No. 208686.

PATENTS-IN-SUIT

15. The ’008 patent, entitled “Enalapril Formulations,” issued to Gerold Mosher and David Miles on June 6, 2017 from United States Patent Application No. 15/081,603. A true and correct copy of the ’008 patent is attached to this First Amended Complaint as Exhibit A.

16. The ’008 patent was duly and legally issued to Silvergate as the assignee and Silvergate owns all rights, title, and interest in the ’008 patent.

17. Pursuant to 21 U.S.C. § 355, the ’008 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) in connection with NDA No. 208686 and Silvergate’s Epaned® Product.

18. Silvergate’s Epaned® Product is covered by at least one claim of the ’008 patent.

19. The ’442 patent, entitled “Enalapril Formulations,” issued to Gerold Mosher and David Miles on November 7, 2017 from United States Patent Application No. 15/613,622. A true and correct copy of the ’442 patent is attached to this First Amended Complaint as Exhibit B.

20. The ’442 patent was duly and legally issued to Silvergate as the assignee and Silvergate owns all rights, title, and interest in the ’442 patent.

21. Pursuant to 21 U.S.C. § 355, the ’442 patent is listed in the Orange Book in connection with NDA No. 208686 and Silvergate’s Epaned® Product.

22. The use of Silvergate’s Epaned® Product is covered by at least one claim of the ’442 patent.

23. The approved indications for Silvergate's Epaned® Product are covered by at least one claim of the '442 patent.

24. The '745 patent, entitled "Enalapril Formulations," issued to Gerold Mosher and David Miles on August 7, 2018 from United States Patent Application No. 15/802,341. A true and correct copy of the '745 patent is attached to this First Amended Complaint as Exhibit C.

25. The '745 patent was duly and legally issued to Silvergate as the assignee and Silvergate owns all rights, title, and interest in the '745 patent.

26. Pursuant to 21 U.S.C. § 355, the '745 patent is listed in the Orange Book in connection with NDA No. 208686 and Silvergate's Epaned® Product.

27. Silvergate's Epaned® Product is covered by at least one claim of the '745 patent.

28. The '987 patent, entitled "Enalapril Formulations," issued to Gerold Mosher and David Miles on December 18, 2018 from United States Patent Application No. 16/003,994. A true and correct copy of the '987 patent is attached to this First Amended Complaint as Exhibit D.

29. The '987 patent was duly and legally issued to Silvergate as the assignee and Silvergate owns all rights, title, and interest in the '987 patent.

30. Pursuant to 21 U.S.C. § 355, the '987 patent is listed in the Orange Book in connection with Silvergate's Epaned® Product.

31. The use of Silvergate's Epaned® Product is covered by at least one claim of the '987 patent.

32. The approved indications for Silvergate's Epaned® Product are covered by at least one claim of the '987 patent.

33. The ’868 patent, entitled “Enalapril Formulations,” issued to Gerold Mosher and David Miles on September 15, 2020 from United States Patent Application No. 16/242,898. A true and correct copy of the ’868 patent is attached to this First Amended Complaint as Exhibit E.

34. The ’868 patent was duly and legally issued to Silvergate as the assignee and Silvergate owns all rights, title, and interest in the ’868 patent.

35. Pursuant to 21 U.S.C. § 355, the ’868 patent is listed in the Orange Book in connection with NDA No. 208686 and Silvergate’s Epaned® Product.

36. Silvergate’s Epaned® Product is covered by at least one claim of the ’868 patent.

37. The ’482 patent, entitled “Enalapril Formulations,” issued to Gerold Mosher and David Miles on September 29, 2020 from United States Patent Application No. 16/177,159. A true and correct copy of the ’482 patent is attached to this First Amended Complaint as Exhibit F.

38. The ’482 patent was duly and legally issued to Silvergate as the assignee and Silvergate owns all rights, title, and interest in the ’482 patent.

39. Pursuant to 21 U.S.C. § 355, the ’482 patent is listed in the Orange Book in connection with NDA No. 208686 and Silvergate’s Epaned® Product.

40. Silvergate’s Epaned® Product is covered by at least one claim of the ’482 patent.

41. The ’621 patent, entitled “Enalapril Formulations,” issued to Gerold Mosher and David Miles on February 16, 2021 from United States Patent Application No. 16/991,575 (“’575 application”). A true and correct copy of the ’621 patent is attached to this First Amended Complaint as Exhibit G.

42. The ’621 patent was duly and legally issued to Silvergate as the assignee and Silvergate owns all rights, title, and interest in the ’621 patent.

INFRINGEMENT BY ALKEM

43. By a Notice Letter dated September 23, 2019, and received by Silvergate on September 25, 2019, Alkem notified Silvergate that it had submitted ANDA No. 213714 to FDA under Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) (21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95) seeking approval to engage in the commercial manufacture, use, and sale of a generic version of Silvergate’s Epaned® Product (“Alkem ANDA Product”) before the expiration of the ’008, ’442, ’745, and ’987 patents.

44. By a Notice Letter dated February 2, 2021, and received by Silvergate on February 3, 2021, Alkem notified Silvergate that it had submitted ANDA No. 213714 to FDA under Section 505(j)(2)(B) of the FDCA (21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95) seeking approval to engage in the commercial manufacture, use, and sale of the Alkem ANDA Product before the expiration of the ’868 and ’482 patents.

45. Each of the ’008, ’442, ’745, ’987, ’868, ’482, and ’621 patents expire on March 25, 2036.

46. On information and belief, Alkem intends to engage in commercial manufacture, use, and sale of the Alkem ANDA Product promptly upon receiving FDA approval to do so.

47. On information and belief, Alkem is seeking approval to engage in the commercial manufacture, use, and sale of the Alkem ANDA Product before the expiration of the ’008, ’442, ’745, ’987, ’868, ’482, and ’621 patents.

48. By submitting ANDA No. 213714, Alkem has represented to FDA that the Alkem ANDA Product has the same active ingredients as Silvergate’s Epaned® Product; has the same

route of administration, dosage form, use, and strength as Silvergate's Epaned® Product; and is bioequivalent to Silvergate's Epaned® Product.

CLAIMS FOR RELIEF

Count I—Infringement of the '008 Patent

49. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

50. Alkem submitted ANDA No. 213714 to FDA under Section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product throughout the United States before the expiration of the '008 patent. By submitting the ANDA, Alkem has committed an act of infringement of one or more claims of the '008 patent under 35 U.S.C. § 271(e).

51. If Alkem's ANDA is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Alkem ANDA Product will constitute acts of infringement of the '008 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

52. On information and belief, Alkem had actual and constructive knowledge of the '008 patent, and is aware that submission of ANDA No. 213714 to FDA constituted an act of infringement of the '008 patent. In addition, on information and belief, Alkem had specific intent to infringe the '008 patent when it filed ANDA No. 213714. Moreover, there are no substantial non-infringing uses for the Alkem ANDA Product other than as the pharmaceutical claimed in the '008 patent.

53. The commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Silvergate's patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

Count II—Infringement of the ’442 Patent

54. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

55. Alkem submitted ANDA No. 213714 to FDA under Section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product throughout the United States before the expiration of the ’442 patent. By submitting the ANDA, Alkem has committed an act of infringement of one or more claims of the ’442 patent under 35 U.S.C. § 271(e).

56. If Alkem’s ANDA is approved by FDA, the commercial use, offer to sell, or sale within the United States, and/or importation into the United States of the Alkem ANDA Product will constitute acts of infringement of the ’442 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

57. On information and belief, Alkem had actual and constructive knowledge of the ’442 patent prior to submitting ANDA No. 213714 and was aware that submission of Alkem’s ANDA to FDA constituted an act of infringement of the ’442 patent. In addition, on information and belief, Alkem had specific intent to infringe the ’442 patent when it filed ANDA No. 213714. Moreover, there are no substantial non-infringing uses for the Alkem ANDA Product other than the methods claimed in the ’442 patent.

58. The commercial use, offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Silvergate’s patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

Count III—Infringement of the ’745 Patent

59. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

60. Alkem submitted ANDA No. 213714 to FDA under Section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product throughout the United States before the expiration of the '745 patent. By submitting the ANDA, Alkem has committed an act of infringement of one or more claims of the '745 patent under 35 U.S.C. § 271(e).

61. If Alkem's ANDA is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Alkem ANDA Product will constitute acts of infringement of the '745 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

62. On information and belief, Alkem had actual and constructive knowledge of the '745 patent prior to submitting ANDA No. 213714 and was aware that submission of Alkem's ANDA to FDA constituted an act of infringement of the '745 patent. In addition, on information and belief, Alkem had specific intent to infringe the '745 patent when it filed ANDA No. 213714. Moreover, there are no substantial non-infringing uses for the Alkem ANDA Product other than as the pharmaceutical claimed in the '745 patent.

63. The commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Silvergate's patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

Count IV—Infringement of the '987 Patent

64. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

65. Alkem submitted ANDA No. 213714 to FDA under Section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product throughout the United States before the expiration of

the ’987 patent. By submitting the ANDA, Alkem has committed an act of infringement of one or more claims of the ’987 patent under 35 U.S.C. § 271(e).

66. If Alkem’s ANDA is approved by FDA, the commercial use, offer to sell, or sale within the United States, and/or importation into the United States of the Alkem ANDA Product will constitute acts of infringement of the ’987 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

67. On information and belief, Alkem had actual and constructive knowledge of the ’987 patent prior to submitting ANDA No. 213714 and was aware that submission of Alkem’s ANDA to FDA constituted an act of infringement of the ’987 patent. In addition, on information and belief, Alkem had specific intent to infringe the ’987 patent when it filed ANDA No. 213714. Moreover, there are no substantial non-infringing uses for the Alkem ANDA Product other than the methods claimed in the ’987 patent.

68. The commercial use, offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Silvergate’s patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

Count V—Infringement of the ’868 Patent

69. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

70. Alkem submitted ANDA No. 213714 to FDA under Section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product throughout the United States before the expiration of the ’868 patent. By submitting the ANDA, Alkem has committed an act of infringement of one or more claims of the ’868 patent under 35 U.S.C. § 271(e).

71. If Alkem's ANDA is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Alkem ANDA Product will constitute acts of infringement of the '868 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

72. On information and belief, Alkem has actual and constructive knowledge of the '868 patent, and is aware that submission of ANDA No. 213714 to FDA constituted an act of infringement of the '868 patent. In addition, upon information and belief, Alkem has specific intent to infringe the '868 patent. Moreover, there are no substantial non-infringing uses for the Alkem ANDA Product other than as the pharmaceutical claimed in the '868 patent.

73. The commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Silvergate's patent rights will cause irreparable harm to Silvergate for which damages are inadequate.

Count VI—Infringement of the '482 Patent

74. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

75. Alkem submitted ANDA No. 213714 to FDA under Section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product throughout the United States before the expiration of the '482 patent. By submitting the ANDA, Alkem has committed an act of infringement of one or more claims of the '482 patent under 35 U.S.C. § 271(e).

76. If Alkem's ANDA is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Alkem ANDA Product will constitute acts of infringement, either literally or under the doctrine of equivalents, of the '482 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

77. On information and belief, Alkem has actual and constructive knowledge of the '482 patent, and is aware that submission of ANDA No. 213714 to FDA constituted an act of infringement of the '482 patent. In addition, upon information and belief, Alkem has specific intent to infringe the '482 patent. Moreover, there are no substantial non-infringing uses for the Alkem ANDA Product other than as the pharmaceutical claimed in the '482 patent.

78. The commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Silvergate's patent rights will cause irreparable harm to Silvergate for which damages are inadequate.

Count VII—Infringement of the '621 Patent

79. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

80. Alkem submitted ANDA No. 213714 to FDA under Section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product throughout the United States before the expiration of the '621 patent. By submitting the ANDA, Alkem has committed an act of infringement of the '621 patent under 35 U.S.C. § 271(e).

81. There is an immediate and justiciable controversy between Silvergate and Alkem as to the infringement of the '621 patent.

82. If Alkem's ANDA is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Alkem ANDA Product will constitute acts of infringement of the '621 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

83. On information and belief, Alkem has actual and constructive knowledge of the '621 patent and the '575 application, and is aware that submission of ANDA No. 213714 to FDA

constituted an act of infringement of the '621 patent. In addition, upon information and belief, Alkem has specific intent to infringe the '621 patent. Moreover, there are no substantial non-infringing uses for the Alkem ANDA Product other than as the pharmaceutical claimed in the '621 patent.

84. The commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Silvergate's patent rights will cause irreparable harm to Silvergate for which damages are inadequate.

Count VIII—Declaratory Judgment of Infringement of the '621 Patent Under 35 U.S.C. § 271(a)-(c)

85. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

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

87. There is an actual case or controversy such that the Court may entertain Silvergate's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

88. Alkem has refused to provide Silvergate with any advanced notice of launch of the product that is the subject of Alkem's ANDA No. 213714.

89. On information and belief, Alkem will engage in and/or induce another to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Alkem's ANDA No. 213714 immediately and imminently upon approval of ANDA No. 213714.

90. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Alkem's ANDA No. 213714 will constitute acts of infringement of the '621 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

91. The foregoing actions by Alkem will constitute infringement of the '621 patent.

92. Alkem will commit those acts of infringement without license or authorization.

93. Silvergate is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Alkem's ANDA No. 213714 by Alkem will infringe the '621 patent.

94. Silvergate does not have an adequate remedy at law.

95. The commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Silvergate's patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

PRAYER FOR RELIEF

Silvergate respectfully requests the following relief:

a) A judgment that Alkem has infringed the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 213714 under Section 505(j) of the FDCA, and that Alkem's making, using, offering to sell, or selling in the United States or importing into the United States of the Alkem ANDA Product will infringe one or more claims of the Patents-in-Suit;

b) That a declaration be issued under 28 U.S.C. § 2201 that if Alkem, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale and/or importation of the product

that is the subject of Alkem ANDA No. 213714, it will constitute an act of infringement of the '621 patent under one or more of 35 U.S.C. § 271(a), (b), and/or (c);

c) A finding that the Patents-in-Suit are valid and enforceable;

d) An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 213714 shall be a date which is not earlier than the latest expiration date of the Patents-in-Suit, as extended by any applicable periods of exclusivity;

e) An order under 35 U.S.C. § 27l(e)(4)(B) permanently enjoining Alkem, its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, sale, and/or importation into the United States, of any drug product the use of which is covered by the Patents-in-Suit, including the Alkem ANDA Product;

f) An order under 35 U.S.C. § 283 permanently enjoining Alkem, its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, and/or importation into the United States, of any drug product covered by the '621 patent, including the Alkem ANDA Product;

g) A finding that this is an exceptional case under 35 U.S.C. § 285, and that Silvergate be awarded reasonable attorneys' fees and costs; and

h) An award of any such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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