IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SILVERGATE PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
CMP DEVELOPMENT LLC,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendant CMP Development LLC ("CMP" or "Defendant"), Plaintiff Silvergate Pharmaceuticals, Inc. ("Silvergate" or "Plaintiff"), by and through its attorneys, alleges as follows:

The Nature of the Action

1. This is an action for patent infringement of United States Patent Nos. 9,463,183 (the "'183 patent"); 9,616,096 (the "'096 patent"); 9,814,751 (the "'751 patent"); 10,039,800 (the "'800 patent"); 10,265,370 (the "'370 patent"); and 10,406,199 (the "'199 patent") (collectively, the "Lisinopril Patents"), arising under the patent laws of the United States, Title 35, United States Code. This action arises out of the filing by Defendant CMP of Abbreviated New Drug Application ("ANDA") No. 213935 with the U.S. Food and Drug Administration ("FDA") seeking approval of a generic version of Silvergate's oral liquid formulation that is the subject of New Drug Application ("NDA") No. 208401, hereinafter referred to as Silvergate's "QBRELIS® product." 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 Defendant's infringement of the Lisinopril Patents.

The Parties

2. Silvergate is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 6251 Greenwood Plaza Blvd., Suite 101, Greenwood Village, CO 80111.

3. On information and belief, CMP is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 8026 US Highway 264A, Farmville, NC 27828. Upon information and belief, CMP is in the business of, among other things, developing, manufacturing, and selling generic copies of branded pharmaceutical products for the U.S. market.

Jurisdiction and Venue

4. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1, *et seq*. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338(a) (patent infringement). Relief is sought under 35 U.S.C. § 271(e)(2).

5. This Court has personal jurisdiction over CMP because, among other things, on information and belief, CMP is a limited liability company formed under the laws of the State of Delaware.

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

Silvergate's QBRELIS® Product

7. Silvergate's QBRELIS® product is an FDA approved and labeled angiotensin converting enzyme ("ACE") inhibitor indicated for treatment of hypertension in adults and pediatric patients 6 years of age and older. QBRELIS® is also indicated for adjunct therapy for heart failure and treatment of acute myocardial infarction.

8. Silvergate is the holder of approved NDA No. 208401.

Patents-In-Suit

9. The ’183 patent, entitled “Lisinopril Formulations,” was duly and legally issued on October 11, 2016. A true and correct copy of the ’183 patent is attached to this Complaint as Exhibit A.

10. As set forth in Exhibit A, the claims of the ’183 patent (incorporated by reference herein) cover the approved formulation of Silvergate’s QBRELIS® product.

11. The face of the ’183 patent names Gerold L. Mosher and David W. Miles as inventors and Silvergate Pharmaceuticals, Inc. as assignee. Silvergate, as assignee, holds all rights to sue and to recover for infringement of the ’183 patent.

12. Pursuant to 21 U.S.C. § 355, the ’183 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”), in connection with Silvergate’s QBRELIS® product.

13. Silvergate’s QBRELIS® product is covered by at least one claim of the ’183 patent.

14. The ’096 patent, entitled “Lisinopril Formulations,” was duly and legally issued on April 11, 2017. A true and correct copy of the ’096 patent is attached to this Complaint as Exhibit B.

15. As set forth in Exhibit B, the claims of the ’096 patent (incorporated by reference herein) cover one or more approved indications of Silvergate’s QBRELIS® product.

16. The face of the ’096 patent names Gerold L. Mosher and David W. Miles as inventors and Silvergate Pharmaceuticals, Inc. as assignee. Silvergate, as assignee, holds all rights to sue and to recover for infringement of the ’096 patent.

17. Pursuant to 21 U.S.C. § 355, the ’096 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”), in connection with Silvergate’s QBRELIS® product.

18. The use of Silvergate’s QBRELIS® product is covered by at least one claim of the ’096 patent.

19. The ’751 patent, entitled “Lisinopril Formulations,” was duly and legally issued on November 14, 2017. A true and correct copy of the ’751 patent is attached to this Complaint as Exhibit C.

20. As set forth in Exhibit C, the claims of the ’751 patent (incorporated by reference herein) cover the approved formulation of Silvergate’s QBRELIS® product.

21. The face of the ’751 patent names Gerold L. Mosher and David W. Miles as inventors and Silvergate Pharmaceuticals, Inc. as assignee. Silvergate, as assignee, holds all rights to sue and to recover for infringement of the ’751 patent.

22. Pursuant to 21 U.S.C. § 355, the ’751 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”), in connection with Silvergate’s QBRELIS® product.

23. Silvergate’s QBRELIS® product is covered by at least one claim of the ’751 patent.

24. The ’800 patent, entitled “Lisinopril Formulations,” was duly and legally issued on August 7, 2018. A true and correct copy of the ’800 patent is attached to this Complaint as Exhibit D.

25. As set forth in Exhibit D, the claims of the ’800 patent (incorporated by reference herein) cover one or more approved indications of Silvergate’s QBRELIS® product.

26. The face of the ’800 patent names Gerold L. Mosher and David W. Miles as inventors and Silvergate Pharmaceuticals, Inc. as assignee. Silvergate, as assignee, holds all rights to sue and to recover for infringement of the ’800 patent.

27. Pursuant to 21 U.S.C. § 355, the ’800 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”), in connection with Silvergate’s QBRELIS® product.

28. The use of Silvergate’s QBRELIS® product is covered by at least one claim of the ’800 patent.

29. The ’370 patent, entitled “Lisinopril Formulations,” was duly and legally issued on April 23, 2019. A true and correct copy of the ’370 patent is attached to this Complaint as Exhibit E.

30. As set forth in Exhibit E, the claims of the ’370 patent (incorporated by reference herein) cover the approved formulation of Silvergate’s QBRELIS® product.

31. The face of the ’370 patent names Gerold L. Mosher and David W. Miles as inventors and Silvergate Pharmaceuticals, Inc. as assignee. Silvergate, as assignee, holds all rights to sue and to recover for infringement of the ’370 patent.

32. Pursuant to 21 U.S.C. § 355, the ’370 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”), in connection with Silvergate’s QBRELIS® product.

33. Silvergate’s QBRELIS® product is covered by at least one claim of the ’370 patent.

34. The ’199 patent, entitled “Lisinopril Formulations,” was duly and legally issued on September 10, 2019. A true and correct copy of the ’199 patent is attached to this Complaint as Exhibit F.

35. As set forth in Exhibit F, the claims of the ’199 patent (incorporated by reference herein) cover one or more approved indications of Silvergate’s QBRELIS® product.

36. The face of the ’199 patent names Gerold L. Mosher and David W. Miles as inventors and Silvergate Pharmaceuticals, Inc. as assignee. Silvergate, as assignee, holds all rights to sue and to recover for infringement of the ’199 patent.

37. Pursuant to 21 U.S.C. § 355, the ’199 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”), in connection with Silvergate’s QBRELIS® product.

38. The use of Silvergate’s QBRELIS® product is covered by at least one claim of the ’199 patent.

Infringement by CMP

39. By letter dated December 19, 2019 (the “Notice Letter”), CMP notified Silvergate that it had submitted ANDA No. 213935 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)(iv)(I) and 21 C.F.R. §314.95(c)(1)) seeking approval to engage in the commercial manufacture, use, and sale of a generic version of Silvergate’s QBRELIS® product (the CMP “ANDA Product” or “Proposed Product”) before the expiration of the Lisinopril Patents. Upon information and belief, CMP intends to engage in commercial manufacture, use, and sale of the CMP ANDA Product promptly upon receiving FDA approval to do so.

40. By filing ANDA No. 213935, CMP has necessarily represented to FDA that the CMP ANDA Product has the same active ingredients as Silvergate's QBRELIS® product, has the same route of administration, dosage form, use, and strength as Silvergate's QBRELIS® product, and is bioequivalent to Silvergate's QBRELIS® product.

CLAIM 1 FOR RELIEF

Infringement of the '183 Patent Under 35 U.S.C. § 271 (e)(2)(A)

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

42. CMP submitted ANDA No. 213935 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the CMP ANDA Product throughout the United States. By submitting the ANDA, CMP has committed an act of infringement of the '183 patent under 35 U.S.C. § 271 (e)(2)(A).

43. If CMP'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 CMP ANDA Product will constitute acts of infringement of the '183 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

44. Upon information and belief, CMP had actual and constructive knowledge of the '183 patent prior to filing ANDA No. 213935 and was aware that filing this ANDA with FDA constituted an act of infringement of the '183 patent. In addition, upon information and belief, CMP had specific intent to infringe the '183 patent when it filed ANDA No. 213935. Moreover, there are no substantial non-infringing uses for the CMP ANDA Product other than as the pharmaceutical claimed in the '183 patent.

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

CLAIM 2 FOR RELIEF

Infringement of the '096 Patent Under 35 U.S.C. § 271 (e)(2)(A)

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

47. CMP submitted ANDA No. 213935 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the CMP ANDA Product throughout the United States. By submitting the ANDA, CMP has committed an act of infringement of the '096 patent under 35 U.S.C. § 271 (e)(2)(A).

48. If CMP'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 CMP ANDA Product will constitute acts of infringement of the '096 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

49. Upon information and belief, CMP had actual and constructive knowledge of the '096 patent prior to filing ANDA No. 213935 and was aware that filing this ANDA with FDA constituted an act of infringement of the '096 patent. In addition, upon information and belief, CMP had specific intent to infringe the '096 patent when it filed ANDA No. 213935. Moreover, there are no substantial non-infringing uses for the CMP ANDA Product other than as the pharmaceutical claimed in the '096 patent.

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

CLAIM 3 FOR RELIEF

Infringement of the '751 Patent Under 35 U.S.C. § 271 (e)(2)(A)

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

52. CMP submitted ANDA No. 213935 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the CMP ANDA Product throughout the United States. By submitting the ANDA, CMP has committed an act of infringement of the '751 patent under 35 U.S.C. § 271 (e)(2)(A).

53. If CMP'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 CMP ANDA Product will constitute acts of infringement of the '751 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

54. Upon information and belief, CMP had actual and constructive knowledge of the '751 patent prior to filing ANDA No. 213935 and was aware that filing this ANDA with FDA constituted an act of infringement of the '751 patent. In addition, upon information and belief, CMP had specific intent to infringe the '751 patent when it filed ANDA No. 213935. Moreover, there are no substantial non-infringing uses for the CMP ANDA Product other than as the pharmaceutical claimed in the '751 patent.

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

CLAIM 4 FOR RELIEF

Infringement of the '800 Patent Under 35 U.S.C. § 271 (e)(2)(A)

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

57. CMP submitted ANDA No. 213935 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the CMP ANDA Product throughout the United States. By submitting the ANDA, CMP has committed an act of infringement of the '800 patent under 35 U.S.C. § 271 (e)(2)(A).

58. If CMP'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 CMP ANDA Product will constitute acts of infringement of the '800 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

59. Upon information and belief, CMP had actual and constructive knowledge of the '800 patent prior to filing ANDA No. 213935 and was aware that filing this ANDA with FDA constituted an act of infringement of the '800 patent. In addition, upon information and belief, CMP had specific intent to infringe the '800 patent when it filed ANDA No. 213935. Moreover, there are no substantial non-infringing uses for the CMP ANDA Product other than as the pharmaceutical claimed in the '800 patent.

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

CLAIM 5 FOR RELIEF

Infringement of the '370 Patent Under 35 U.S.C. § 271 (e)(2)(A)

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

62. CMP submitted ANDA No. 213935 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the CMP ANDA Product throughout the United States. By submitting the ANDA, CMP has committed an act of infringement of the '370 patent under 35 U.S.C. § 271 (e)(2)(A).

63. If CMP'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 CMP ANDA Product will constitute acts of infringement of the '370 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

64. Upon information and belief, CMP had actual and constructive knowledge of the '370 patent prior to filing ANDA No. 213935 and was aware that filing this ANDA with FDA constituted an act of infringement of the '370 patent. In addition, upon information and belief, CMP had specific intent to infringe the '370 patent when it filed ANDA No. 213935. Moreover, there are no substantial non-infringing uses for the CMP ANDA Product other than as the pharmaceutical claimed in the '370 patent.

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

CLAIM 6 FOR RELIEF

Infringement of the '199 Patent Under 35 U.S.C. § 271 (e)(2)(A)

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

67. CMP submitted ANDA No. 213935 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the CMP ANDA Product throughout the United States. By submitting the ANDA, CMP has committed an act of infringement of the '199 patent under 35 U.S.C. § 271 (e)(2)(A).

68. If CMP'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 CMP ANDA Product will constitute acts of infringement of the '199 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

69. Upon information and belief, CMP had actual and constructive knowledge of the '199 patent prior to filing ANDA No. 213935 and was aware that filing this ANDA with FDA constituted an act of infringement of the '199 patent. In addition, upon information and belief, CMP had specific intent to infringe the '199 patent when it filed ANDA No. 213935. Moreover, there are no substantial non-infringing uses for the CMP ANDA Product other than as the pharmaceutical claimed in the '199 patent.

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

Prayer for Relief

Silvergate respectfully requests the following relief:

a) A judgment that CMP has infringed the '183, '096, '751, '800, '370, and '199 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 213935 under Section 505(j) of the FDCA, and that CMP's making, using, offering to sell, or selling in the United States, or importing into the United States of the CMP ANDA Product will infringe one or more claims of the '183, '096, '751, '800, '370, and '199 patents;

b) A finding that the '183, '096, '751, '800, '370, and '199 patents are valid and enforceable;

c) An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 213935 shall be a date which is not earlier than the latest expiration date of the '183, '096, '751, '800, '370, or '199 patent, as extended by any applicable periods of exclusivity;

d) An order under 35 U.S.C. § 27l(e)(4)(B) permanently enjoining CMP, 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, or importation into the United States, of any drug product covered by, or any drug product for which the use of the drug product is covered by the '183, '096, '751, '800, '370, or '199 patent, including the CMP ANDA Product;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

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January 31, 2020