IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SILVERGATE PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No.
	)	
BIONPHARMA INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendant Bionpharma Inc. ("Bionpharma" 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 Patents Nos. 9,669,008 (the "'008 Patent"), 9,808,442 (the "'442 Patent"), and 10,039,745 (the "'745 Patent") arising under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Defendant Bionpharma of Abbreviated New Drug Application ("ANDA") No. 212408 with the U.S. Food and Drug Administration ("FDA") seeking approval of a generic version of Silvergate's enalapril maleate oral solution that is the subject of New Drug Application ("NDA") No. 208686, hereinafter referred to as Silvergate's "EPANED® 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 '008, '442, and '745 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, Bionpharma is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 600 Alexander Rd #2-4B, Princeton, NJ 08540. Upon information and belief, Bionpharma 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, 35 U.S.C. § 1, *et seq*. 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).

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

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

Silvergate's Epaned® Product

7. 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.

8. Silvergate holds approved NDA No. 208686.

Patents-In-Suit

9. The ’008 Patent, entitled “Enalapril Formulations,” issued to Gerold L. Mosher and David W. Miles on June 6, 2017. A true and correct copy of the ’008 Patent is attached to this Complaint as Exhibit A.

10. 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.

11. 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 Silvergate’s EPANED ® product.

12. The ’442 Patent, entitled “Enalapril Formulations,” issued to Gerold L. Mosher and David W. Miles on November 7, 2017. A true and correct copy of the ’442 Patent is attached to this Complaint as Exhibit B.

13. 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.

14. The use of Silvergate’s EPANED® product is covered by at least one claim of the ’442 Patent.

15. Pursuant to 21 U.S.C. § 355, the ’442 Patent is listed in the Orange Book in connection with Silvergate’s EPANED® product.

16. The ’745 Patent, entitled “Enalapril Formulations,” issued to Gerold L. Mosher and David W. Miles on August 7, 2018. A true and correct copy of the ’745 Patent is attached to this Complaint as Exhibit C.

17. 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.

18. Silvergate's EPANED® product is covered by at least one claim of the '745 Patent.

19. Pursuant to 21 U.S.C. § 355, the '745 Patent is listed in the Orange Book in connection with Silvergate's EPANED® product.

Infringement by Bionpharma

20. By letter dated October 30, 2018 ("the Notice Letter"), Bionpharma notified Silvergate that it had submitted ANDA No. 212408 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 ("the Bionpharma ANDA Product") before the expiration of the '008, '442, and '745 Patents. Upon information and belief, Bionpharma intends to engage in commercial manufacture, use, and sale of the Bionpharma ANDA Product promptly upon receiving FDA approval to do so.

21. By filing ANDA No. 212408, Bionpharma has represented to FDA that the Bionpharma ANDA Product has the same active ingredients as Silvergate's EPANED® product, has the same route of administration, dosage form, and strength as Silvergate's EPANED® product, and is bioequivalent to Silvergate's EPANED® product.

22. This action is being filed within forty-five (45) days of Silvergate's receipt of the Notice Letter.

CLAIM 1 FOR RELIEF
Infringement of the '008 Patent Under 35 U.S.C. § 271 (e)(2)(A)

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

24. Bionpharma submitted ANDA No. 212408 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 Bionpharma ANDA Product throughout the United States before the expiration of the '008 Patent. By submitting the ANDA, Bionpharma has committed an act of infringement of the '008 Patent under 35 U.S.C. § 271(e)(2)(A).

25. If Bionpharma'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 Bionpharma ANDA Product will infringe the '008 Patent under 35 U.S.C. § 271(a)-(c).

26. Upon information and belief, Bionpharma had actual knowledge of the '008 Patent prior to filing ANDA No. 212408 and was aware that filing this ANDA with FDA constituted an act of infringement of the '008 Patent. In addition, upon information and belief, Bionpharma had specific intent to infringe the '008 Patent when it filed ANDA No. 212408. Moreover, there are no substantial non-infringing uses for the Bionpharma ANDA Product other than as the pharmaceutical claimed in the '008 Patent.

27. The commercial manufacture, use, offer for sale, sale, and/or importation of the Bionpharma 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 '442 Patent Under 35 U.S.C. § 271 (e)(2)(A)

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

29. Bionpharma submitted ANDA No. 212408 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 Bionpharma ANDA Product throughout the United States before the

expiration of the ‘442 Patent. By submitting the ANDA, Bionpharma has committed an act of infringement of the ’442 Patent under 35 U.S.C. § 271(e)(2)(A).

30. If Bionpharma’s ANDA is approved by FDA, the commercial use, offer to sell, or sale within the United States of the Bionpharma ANDA Product will infringe the ’442 Patent under 35 U.S.C. § 271(a)-(c).

31. Upon information and belief, Bionpharma had actual knowledge of the ’442 Patent prior to filing ANDA No. 212408 and was aware that filing this ANDA with FDA constituted an act of infringement of the ’442 Patent. In addition, upon information and belief, Bionpharma had specific intent to infringe the ’442 Patent when it filed ANDA No. 212408. Moreover, there are no substantial non-infringing uses for the Bionpharma ANDA Product other than as the pharmaceutical claimed in the ’442 Patent.

32. The commercial use, offer for sale, and/or sale of the Bionpharma 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 ’745 Patent Under 35 U.S.C. § 271 (e)(2)(A)

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

34. Bionpharma submitted ANDA No. 212408 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 Bionpharma ANDA Product throughout the United States before the expiration of the ‘745 Patent. By submitting the ANDA, Bionpharma has committed an act of infringement of the ’745 Patent under 35 U.S.C. § 271(e)(2)(A).

35. If Bionpharma'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 Bionpharma ANDA Product will infringe the '745 Patent under 35 U.S.C. § 271(a)-(c).

36. Upon information and belief, Bionpharma had actual knowledge of the '745 Patent prior to filing ANDA No. 212408 and was aware that filing this ANDA with FDA constituted an act of infringement of the '745 Patent. In addition, upon information and belief, Bionpharma had specific intent to infringe the '745 Patent when it filed ANDA No. 212408. Moreover, there are no substantial non-infringing uses for the Bionpharma ANDA Product other than as the pharmaceutical claimed in the '745 Patent.

37. The commercial manufacture, use, offer for sale, sale, and/or importation of the Bionpharma 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 that the Court grant the following relief:

a) A judgment that Bionpharma has infringed the '008, '442, and '745 Patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 212408 under Section 505(j) of the FDCA, and that Bionpharma's making, using, offering to sell, or selling in the United States, or importing into the United States, of the Bionpharma ANDA Product will infringe one or more claims of the '008, '442, and '745 Patents;

b) A finding that the '008, '442, and '745 Patents are valid and enforceable;

c) An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of FDA approval of ANDA No. 212408 shall be a date which is not earlier than the latest expiration date of the '008, '442, or '745 Patent, as extended by any applicable periods of exclusivity;

d) An order under 35 U.S.C. § 27l(e)(4)(B) permanently enjoining Bionpharma, 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 sale in the United States, or importation into the United States, of any drug product covered by the '008, '442, or '745 Patent, including the Bionpharma ANDA Product;

e) 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

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

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