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 Patent No. 8,778,366 (the "'366 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. 209375 with the U.S. Food and Drug Administration ("FDA") seeking approval of a generic version of Silvergate's liquid formulation that is the subject of New Drug Application ("NDA") No. 204308, 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 '366 Patent.

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 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 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. §§ 1391(c) and 1400(b).

SILVERGATE'S EPANED® PRODUCT

7. Silvergate's EPANED® product is the only FDA approved and labeled ace inhibitor treatment for hypertension in children. EPANED® is also indicated to treat hypertension in adults, heart failure, and asymptomatic left ventricular dysfunction.

8. Silvergate is the holder of approved NDA No. 204308.

PATENT-IN-SUIT

9. The ’366 Patent, entitled “Enalapril Compositions,” issued to Lian G. Rajewski, Roger A. Rajewski, John L. Haslam, Kathleen Heppert, Michael C. Beckloff, Frank Segrave, Robert Mauro, and Peter Colabuono on July 15, 2014. A true and correct copy of the ’366 Patent is attached to this Complaint as Exhibit 1.

10. As set forth in the ’366 Patent, the claims of the ’366 Patent (incorporated by reference herein) cover one of the approved indications of Silvergate’s EPANED® product.

11. The ’366 Patent was duly and legally issued to Silvergate and the University of Kansas as co-assignees. In addition, Silvergate is the exclusive licensee of the ’366 Patent with the sole right to sue and recover for the infringement thereof.

12. Pursuant to 21 U.S.C. § 355, the ’366 Patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with Silvergate’s EPANED® product.

13. The approved indications of Silvergate’s EPANED® product are covered by at least one claim of the ’366 Patent.

INFRINGEMENT BY BIONPHARMA

14. By letter dated November 23, 2016 (“the Notice Letter”), Bionpharma notified Silvergate that it had submitted ANDA No. 209375 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 ’366 Patent. 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.

15. By filing ANDA No. 209375, Bionpharma has necessarily 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, use, and strength as Silvergate's EPANED® product, and is bioequivalent to Silvergate's EPANED® product.

CLAIM FOR RELIEF
(Infringement of the '366 Patent Under 35 U.S.C. § 271 (e)(2)(A))

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

17. Bionpharma submitted ANDA No. 209375 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. By submitting the ANDA, Bionpharma has committed an act of infringement of the '366 Patent under 35 U.S.C. § 271 (e)(2)(A).

18. 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 constitute acts of infringement of the '366 Patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

19. Upon information and belief, Bionpharma had actual and constructive knowledge of the '366 Patent prior to filing ANDA No. 209375 and was aware that filing this ANDA with FDA constituted an act of infringement of the '366 Patent. In addition, upon information and belief, Bionpharma had specific intent to infringe the '366 Patent when it filed ANDA No.

209375. Moreover, there are no substantial non-infringing uses for the Bionpharma ANDA Product other than as the pharmaceutical claimed in the ’366 Patent.

20. 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 the following relief:

a) A judgment that Bionpharma has infringed the ’366 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 209375 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 ’366 Patent;

b) A finding that the ’366 Patent is 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. 209375 shall be a date which is not earlier than the latest expiration date of the ’366 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, or importation into the United States, of any drug product the use of which is covered by the ’366 Patent, including the Bionpharma 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

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