

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

DAIICHI SANKYO CO., LTD. and )  
DAIICHI SANKYO, INC., )  
 )  
Plaintiffs, )  
 ) C.A. No. \_\_\_\_\_  
v. )  
 )  
APOTEX INC. AND APOTEX CORP., )  
 )  
 )  
Defendants. )

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Daiichi Sankyo Co., Ltd. and Daiichi Sankyo, Inc. (hereinafter “Plaintiffs”), for their Complaint against Defendants Apotex Inc. and Apotex Corp. (hereinafter “Defendants”), allege as follows:

**NATURE OF ACTION**

1. This is an action for patent infringement.

**PARTIES**

2. Plaintiff Daiichi Sankyo Co., Ltd. (“Daiichi Sankyo Japan”) is a corporation organized and existing under the laws of Japan, having a place of business at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan.

3. Plaintiff Daiichi Sankyo, Inc. (“Daiichi Sankyo U.S.”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Two Hilton Court, Parsippany, New Jersey 07054.

4. Daiichi Sankyo Co., Ltd. and Daiichi Sankyo, Inc. are hereinafter collectively referred to as “Daiichi Sankyo”.

5. On information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

6. On information and belief, Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

7. On information and belief, Apotex Corp. is a corporation organized under the laws of the State of Delaware, having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

8. On information and belief, Apotex Corp. sells generic drug products manufactured by Apotex Inc. throughout the United States, including this judicial district.

9. Apotex Inc. and Apotex Corp. are hereinafter collectively referred to as “Apotex”.

#### **JURISDICTION AND VENUE**

10. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

11. Based on the facts and causes alleged herein, this Court has personal jurisdiction over Apotex.

12. Upon information and belief, Apotex has admitted personal jurisdiction of the United States District Court for the District of Delaware.

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

## **CLAIM FOR RELIEF - PATENT INFRINGEMENT**

14. Plaintiff Daiichi Sankyo Japan holds an approved new drug application (“NDA”) No. 20-989 for Evoxac<sup>®</sup> Capsules (30 mg), which capsules contain the active ingredient cevimeline hydrochloride. Evoxac<sup>®</sup> Capsules were approved by the United States Food and Drug Administration (“FDA”) on January 11, 2000, for the treatment of symptoms of dry mouth in patients with Sjögren’s Syndrome.

15. Daiichi Sankyo Japan is the assignee of United States Patent No. 5,340,821 (hereinafter referred to as “the ‘821 patent”). The ‘821 patent issued on August 23, 1994. A true copy of the ‘821 patent is attached hereto as Exhibit A.

16. The ‘821 patent claims various methods including a method for treating the symptoms of Sjögren Syndrome by administering cevimeline hydrochloride.

17. The ‘821 patent was assigned by the inventors to Snow Brand Milk Products Co., Ltd., Japan. As Snow Brand Milk Products Co., Ltd., Japan was merged into Daiichi Pharmaceutical Co., Ltd., which was subsequently merged into Daiichi Sankyo Japan, its rights in the ‘821 patent were succeeded by Daiichi Sankyo Japan.

18. Daiichi Sankyo U.S. is an exclusive licensee under the ‘821 patent and is marketing and selling in the United States the Evoxac<sup>®</sup> capsules.

19. Apotex submitted to the FDA an abbreviated new drug application (“ANDA”), ANDA No. 91-260, under the provisions of 21 U.S.C. §355(j), seeking approval to engage in the commercial manufacture, use, offer to sell, or sell generic cevimeline hydrochloride 30 mg capsules (hereinafter referred to as “Apotex’s ANDA Product”) for the treatment of symptoms of dry mouth in patients with Sjögren’s Syndrome within the United States, and/or import into the United States Apotex’s ANDA Product.

20. Apotex submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sell within the United States and/or import into the United States, of Apotex's ANDA Product before the expiration of the '821 patent.

21. By filing the ANDA under 21 U.S.C. §355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sell within the United States and/or import into the United States, of Apotex's ANDA Product before the expiration of the '821 patent, Apotex has committed an act of infringement under 35 U.S.C. §271(e)(2)(A). Further, the commercial manufacture, use, offer to sell, or sell within the United States and/or import into the United States, of Apotex's ANDA Product for which Apotex seeks approval in its ANDA will also infringe one or more claims of the '821 patent.

22. Plaintiffs, Daiichi Sankyo, are entitled to the relief provided by 35 U.S.C. §271(e)(4), including an Order of this Court that the effective date of any approval of the aforementioned ANDA relating to Apotex's ANDA Product be a date which is not earlier than July 7, 2013, the expiration of the '821 patent, or any later date of exclusivity to which Plaintiffs become entitled. Further, Plaintiffs are entitled to an award of damages for any commercial manufacture, use, offer to sell, or sell within the United States and/or import into the United States, of Apotex's ANDA Product, and any act committed by Apotex with respect to the subject matter claimed in the '821 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs respectfully request the following relief:

A. Judgment that Apotex has infringed one or more claims of the '821 patent by filing the aforesaid ANDA relating to Apotex's ANDA Product;

B. Judgment that manufacture, use, sell, or offer to sell within the United States, and/or import into the United States, of Apotex's ANDA Product will infringe the '821 patent;

C. A permanent injunction restraining and enjoining Apotex and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sell within the United States, and/or import into the United States, of Apotex's ANDA Product as claimed in the '821 patent;

D. An Order that the effective date of any approval of the aforementioned ANDA relating to Apotex's ANDA Product be a date which is not earlier than the expiration of the right of exclusivity under the '821 patent, or any later date of exclusivity to which Plaintiffs become entitled; and

E. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Jack B. Blumenfeld*

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