IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DAIICHI SANKYO CO., LTD. and DAIICHI SANKYO, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No.
SANDOZ INC.	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Daiichi Sankyo Co., Ltd. and Daiichi Sankyo, Inc. (hereinafter "Plaintiffs"), for their Complaint against Defendant Sandoz Inc. (hereinafter "Sandoz"), 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 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, NJ 07054.

4. Daiichi Sankyo Japan and Daiichi Sankyo U.S. are hereinafter collectively referred to as "Daiichi Sankyo".

12. 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.

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

14. The '821 patent was assigned by the inventors to Snow Brand Milk Products Co., Ltd., Japan. Snow Brand Milk Products Co., Ltd., Japan merged into Daiichi Pharmaceutical Co., Ltd., which was subsequently merged into Daiichi Sankyo Japan. Thus, the '821 patent is now owned by Daiichi Sankyo Japan.

15. Daiichi Sankyo U.S. is an exclusive licensee under the '821 patent and is marketing and selling in the United States Evoxac® capsules.

16. Sandoz submitted to the FDA an abbreviated new drug application ("ANDA"), ANDA No. 91-545, under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of generic cevimeline hydrochloride 30 mg capsules (hereinafter referred to as "Sandoz's ANDA product") for the treatment of symptoms of dry mouth in patients with Sjögren's Syndrome within the United States.

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

18. 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 sale within the United

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

19. 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 Sandoz'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 Sandoz's ANDA Product, and any act committed by Sandoz with respect to the subject matter claimed in the '821 patent, which 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 Sandoz has infringed one or more claims of the '821 patent by filing the aforesaid ANDA relating to Sandoz's ANDA Product;

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

C. A permanent injunction restraining and enjoining Sandoz 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 Sandoz'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 Sandoz'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 to; and

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

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