IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DAIICHI SANKYO, INC. and GENZYME CORPORATION,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
IMPAX LABORATORIES, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Daiichi Sankyo, Inc. and Genzyme Corporation (collectively "Plaintiffs") for their Complaint against Defendant Impax Laboratories, Inc. ("Impax") hereby allege as follows:

THE PARTIES

1. Plaintiff Daiichi Sankyo, Inc. ("Daiichi Sankyo") 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.

2. Plaintiff Genzyme Corporation ("Genzyme") is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, having a principal place of business at 500 Kendall Street, Cambridge, Massachusetts 02142.

3. Upon information and belief, Impax is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a).

5. Upon information and belief, Impax markets and sells generic and branded pharmaceutical products to various customers in this judicial district and throughout the United States. Impax engages in a persistent course of conduct in Delaware and derives substantial revenue from products sold in Delaware.

6. Impax is subject to personal jurisdiction in this Court by virtue of, *inter alia*, its incorporation in Delaware and its sales in Delaware.

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

FACTUAL BACKGROUND

8. Plaintiff Daiichi Sankyo holds approved New Drug Application ("NDA") No. 21-176 for which the United States Food and Drug Administration ("FDA") granted approval on May 26, 2000 for 625 mg colesevelam hydrochloride tablets. The colesevelam hydrochloride tablets described in NDA No. 21-176 are currently indicated for the treatment of primary hyperlipidemia and type 2 diabetes mellitus, and are marketed in the United States under the trade name Welchol®.

9. Genzyme owns United States Patent No. 5,607,669 ("'669 patent"), titled "Amine Polymer Sequestrant and Method of Cholesterol Depletion." The '669 patent was duly and legally issued on March 4, 1997, and was originally assigned to GelTex Pharmaceuticals, Inc., which was acquired by, and merged into Genzyme in 2000. A copy of the '669 patent is attached hereto as Exhibit A. Genzyme owns United States Patent No. 5,693,675 ("'675 patent"), titled "Alkylated Amine Polymers." The '675 patent was duly and legally issued on December 2, 1997, and was originally assigned to GelTex Pharmaceuticals, Inc., which was acquired by, and merged into Genzyme in 2000. A copy of the '675 patent is attached hereto as

Exhibit B. Daiichi Sankyo is an exclusive licensee of the '669 and '675 patents in the United States.

10. The '669 and '675 patents are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Welchol®.

11. Upon information and belief, Impax submitted to the FDA Abbreviated New Drug Application ("ANDA"), No. 91-600, including a certification with respect to the '669 and '675 patents under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of 625 mg colesevelam hydrochloride tablets prior to expiration of the '669 and '675 patents.

12. By letter dated December 8, 2009, Impax sent a Notice Letter to Daiichi Sankyo and Genzyme in which Impax represented that it had filed ANDA 91-600 for 625 mg colesevelam hydrochloride tablets, including a certification with respect to the '669 and '675 patents, and that it sought approval of its ANDA prior to the expiration of those patents. Daiichi Sankyo and Genzyme each received Impax's Notice Letter on December 9, 2009.

13. Plaintiffs commenced this action within 45 days of the date of delivery of Impax's Notice Letter.

PATENT INFRINGEMENT BY IMPAX

14. Plaintiffs repeat and re-allege paragraphs 1-13 as if fully set forth herein.

15. By seeking approval of its ANDA No. 91-600 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of 625 mg colesevelam hydrochloride tablets prior to the expiration of the '669

and '675 patents, Impax has infringed the '669 and '675 patents pursuant to 35 U.S.C. § 271(e)(2)(A).

16. The manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Impax's 625 mg colesevelam hydrochloride tablets prior to the expiration of the '669 and '675 patents, if approved by the FDA, would infringe one or more claims of the '669 and '675 patents under 35 U.S.C. § 271.

17. Upon information and belief, the offer to sell and sale of Impax's 625 mg colesevelam hydrochloride tablets, if approved by the FDA, would induce or contribute to the infringement of one or more claims of the '669 and '675 patents under 35 U.S.C. § 271.

18. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Impax's ANDA No. 91-600 be a date that is not earlier than the expiration date of the '669 and '675 patents, or any later expiration of any patent term extension or exclusivity for the '669 and '675 patents to which Plaintiffs are or become entitled to.

19. Plaintiffs will be irreparably harmed by Impax's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

Plaintiffs request:

a. An order adjudging and decreeing that Impax has infringed the '669 and '675 patents by submitting ANDA No. 91-600 to the FDA;

b. A permanent injunction pursuant to 35 U.S.C. §§ 271(e)(4)(B) restraining and enjoining Impax and its directors, officers, agents, attorneys, affiliates, divisions,

successors and employees, and those acting in privity or concert with them, from infringing the '669 and '675 patents by the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product claimed in the '669 and '675 patents;

c. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 91-600 be a date that is not earlier than the expiration date of the '669 and '675 patents, or any later expiration of any patent term extension or exclusivity for the '669 and '675 patents to which Plaintiffs are or become entitled;

d. That Plaintiffs be awarded monetary relief to the extent Impax commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States any product that infringes or induces or contributes to the infringement of the '669 and '675 patents, within the United States prior to the expiration of the '669 and '675 patents, including any later expiration of any patent term extension or exclusivity for the patents to which Plaintiffs are or become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest; and

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

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