IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DAIICHI SANKYO, INC. and GENZYME CORPORATION,	)	
Plaintiffs,	)	
v.	)	C.A. No _____
LUPIN LTD. AND LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Daiichi Sankyo, Inc. and Genzyme Corporation (collectively, "Plaintiffs") for their Complaint against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. 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, Defendant Lupin Pharmaceuticals, Inc. ("Lupin Pharma") is a Virginia corporation, and a wholly-owned subsidiary and agent of Defendant Lupin Ltd., having a principal place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202. Upon information and belief, Lupin Pharma

manufactures, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Defendant Lupin Ltd. ("Lupin") is a corporation organized and existing under the laws of the India, having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Upon information and belief, Lupin, itself and through its wholly-owned subsidiary and agent Defendant Lupin Pharma, manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

JURISDICTION AND VENUE

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

6. This Court has personal jurisdiction over each of the Defendants by virtue of the facts that, *inter alia*, each Lupin and Lupin Pharma has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

7. Upon information and belief, Lupin Pharma participated in the preparation and filing of Lupin's ANDA No. 201-354 as an agent of Lupin and/or in its own capacity.

8. Upon information and belief, Lupin is in the business of developing, manufacturing, marketing, and selling generic drugs. On information and belief, Lupin established Lupin Pharma for the purpose of distributing, marketing, and selling its generic drug products in the United States. Lupin maintains an Internet website at the URL

www.lupinworld.com at which Lupin represents that it has a representative office at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202, the principal place of business of Lupin Pharma.

9. Upon information and belief, based in part on representations on their websites and Lupin's Annual Reports, Lupin and Lupin Pharma hold themselves out as a unitary entity and have deliberately disregarded corporate formalities by representing to the public that the activities of Lupin and Lupin Pharma are directed, controlled, and carried out by a single entity, namely, Lupin, headquartered in India.

10. Upon information and belief, Lupin maintains and controls a broad distribution network in the United States for Lupin's products that results in the distribution and sale of hundreds of millions of dollars of Lupin's products. The distribution network includes its "direct to market team" and its "structure for marketing generic products," as well as several marketing alliances with other companies in the United States.

11. Upon information and belief, based in part on the representations on Lupin and Lupin Pharma's websites, Lupin and Lupin Pharma sell Lupin drug products directly to Amerisource Bergen, Cardinal Health, and Walgreen's, who then sell Lupin's drug products throughout the United States, including this judicial district.

12. Upon information and belief, based in part on the representation on Lupin and Lupin Pharma's websites, Lupin Pharma has been systematically and continuously selling and shipping Lupin drug products to Happy Harry's Discount Drugs, a Walgreen's Company, which is located in this judicial district.

13. Upon information and belief, Lupin is currently the sole manufacturer of the "Suprax®" drug product in the United States, and Lupin Pharma distributes "Suprax®" for sale throughout the United States including this judicial district.

14. Upon information and belief, Lupin has entered into a multi-year contract with Forest Laboratories, Inc., a Delaware corporation, to promote the "AeroChamber Plus®" drug product, whereby Lupin Pharma has used its "50 person sales force to promote the product to pediatricians." Upon information and belief, Lupin Pharma distributes the "AeroChamber Plus®" drug product for sale throughout the United States including this judicial district.

15. This Court has personal jurisdiction over Defendant Lupin Pharma by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

16. On July 16, 2010, Defendant Lupin consented to jurisdiction in this district for the purpose of this action.

17. This Court also has personal jurisdiction over Defendant Lupin by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

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

FACTUAL BACKGROUND

19. 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®.

20. 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.

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

22. Upon information and belief, Lupin submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 201-354, 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.

23. By letter dated June 18, 2010, Lupin sent a Notice Letter to Daiichi Sankyo and Genzyme in which Lupin represented that it had filed ANDA 201-354 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 Lupin's Notice Letter on June 21, 2010.

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

FIRST COUNT FOR PATENT INFRINGEMENT BY LUPIN AND LUPIN PHARMA

25. Plaintiffs reallege paragraphs 1-24 as if fully set forth herein.

26. By seeking approval of its ANDA 201-354 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, Lupin and Lupin Pharma have infringed the '669 and '675 patents pursuant to 35 U.S.C. § 271(e)(2)(A).

27. The manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Lupin'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.

28. Upon information and belief, the offer to sell and sale of Lupin'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.

29. 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 Lupin's ANDA 201-354 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.

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

SECOND COUNT FOR PATENT INFRINGEMENT BY LUPIN AND LUPIN PHARMA

31. Plaintiffs reallege paragraphs 1-30 as if fully set forth herein.

32. Upon information and belief, Lupin Pharma has actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA 201-354 to the FDA. On information and belief, Lupin Pharma was aware of the '669 and '675 patents when it engaged in these knowing and purposeful activities referred to above.

33. Under 35 U.S.C. §271(b) and 271(e)(2)(A) Lupin Pharma induced the infringement of the '669 and '675 patents by actively and knowingly aiding and abetting the submission to the FDA of ANDA 201-354. The filing of the ANDA by Lupin and Lupin Pharma constitutes a direct act of infringement under 35 U.S.C. §271(e). Lupin Pharma's active and knowing aiding and abetting Lupin in the filing of ANDA 201-354 constitutes induced infringement.

PRAYER FOR RELIEF

Plaintiffs request:

a. An order adjudging and decreeing that Defendants have infringed the '669 and '675 patents by submitting ANDA 201-354 to the FDA;

b. A permanent injunction pursuant to 35 U.S.C. §§ 271(e)(4)(B) restraining and enjoining Defendants and their 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 201-354 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 Defendants commercially manufacture, use, offers for sale, or sell within the United States, or import 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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