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., GLENMARK GENERICS INC., USA, GLENMARK GENERICS LTD. and GLENMARK PHARMACEUTICALS, LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Daiichi Sankyo, Inc. and Genzyme Corporation (collectively "Plaintiffs") for their Complaint against Defendants Impax Laboratories, Inc. ("Impax"), Glenmark Generics Inc., USA ("Glenmark USA"), Glenmark Generics Ltd. ("Glenmark Ltd."), and Glenmark Pharmaceuticals, Ltd. ("Glenmark Pharma"), 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.

4. Upon information and belief, Glenmark USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Corporate Dr., Mahwah, NJ 07430, and is a wholly-owned subsidiary, division, and agent of Glenmark Ltd.

5. Upon information and belief, Glenmark Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Glenmark House, B. D. Sawant Marg, Chakala, Off Western Express Highway, Andheri (East), Mumbai – 400099, India, and is a wholly-owned subsidiary of Glenmark Pharma.

6. Upon information and belief, Glenmark Pharma is a corporation organized and existing under the laws of India, having its principal place of business at Glenmark House, B. D. Sawant Marg, Chakala, Off Western Express Highway, Andheri (East), Mumbai – 400099, India.

7. Glenmark USA, Glenmark Ltd., and Glenmark Pharma are collectively referred to as "Glenmark."

JURISDICTION AND VENUE

8. 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).

9. Upon information and belief, Impax markets and sells pharmaceuticals and 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.

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

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

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

13. Upon information and belief, Glenmark Ltd. manufactures pharmaceuticals and pharmaceutical products that are sold and used throughout the United States, including within Delaware and has acted in concert with Glenmark USA, which is incorporated in Delaware.

14. Glenmark Ltd. is subject to jurisdiction in Delaware because it conducts business in this district as alleged in paragraph 13. In the alternative, Glenmark Ltd. is subject to jurisdiction in the United States under principles of general jurisdiction, and specifically in Delaware pursuant to Fed. R. Civ. P. 4(k)(2).

15. Upon Information and belief, Glenmark Pharma manufactures pharmaceuticals and pharmaceutical products that are sold and used throughout the United States, including within Delaware and has acted in concert with Glenmark USA, which is incorporated in Delaware.

16. Glenmark Pharma is subject to jurisdiction in Delaware because it conducts business in this district as alleged in paragraph 15. In the alternative, Glenmark Pharma is subject to jurisdiction in the United States under principles of general jurisdiction, and specifically in Delaware pursuant to Fed. R. Civ. P. 4(k)(2).

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

FACTUAL BACKGROUND

18. Plaintiff Daiichi Sankyo holds approved New Drug Application ("NDA") No. 22-362 for which the United States Food and Drug Administration ("FDA") granted approval on October 2, 2009 for 1.875 gm/packet and 3.75 gm/packet colesevelam hydrochloride for oral suspension. The colesevelam hydrochloride for oral suspension products described in NDA No. 22-362 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®.

19. 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.

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

21. Upon information and belief, Impax submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 201975, 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 1.875 gm/packet and 3.75

gm/packet colesevelam hydrochloride for oral suspension prior to expiration of the '669 and '675 patents.

22. By letters dated October 13, 2010 and October 14, 2010, Impax sent Notice Letters to Daiichi Sankyo and Genzyme in which Impax represented that it had filed ANDA No. 201975 for 1.875 gm/packet and 3.75 gm/packet colesevelam hydrochloride for oral suspension, 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 Letters on October 15, 2010.

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

24. Upon information and belief, Glenmark submitted to the FDA ANDA No. 202190, 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 1.875 gm/packet and 3.75 gm/packet colesevelam hydrochloride for oral suspension prior to expiration of the '669 and '675 patents.

25. By letter dated November 5, 2010, Glenmark sent a Notice Letter to Daiichi Sankyo and Genzyme in which Glenmark represented that it had filed ANDA No. 202190 for 1.875 gm/packet and 3.75 gm/packet colesevelam hydrochloride for oral suspension, 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 received Glenmark's Notice Letter on November 9, 2010 and Genzyme received Glenmark's Notice Letter on November 10, 2010.

26. Upon information and belief, the acts of Glenmark USA subject to this complaint were done at the direction of, with the authorization of and with the cooperation, assistance and participation of Glenmark Ltd. and Glenmark Pharma.

27. Upon information and belief, the acts of Glenmark USA subject to this complaint were done, at least in part, for the benefit of Glenmark Ltd. and Glenmark Pharma.

28. Upon information and belief, Glenmark Ltd. and Glenmark Pharma, caused, actively encouraged and/or directed Glenmark USA to file ANDA No. 202190.

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

FIRST COUNT FOR PATENT INFRINGEMENT BY IMPAX

30. Plaintiffs repeat and re-allege paragraphs 1-29 as if fully set forth herein.

31. By seeking approval of its ANDA No. 201975 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of 1.875 gm/packet and 3.75 gm/packet colesevelam hydrochloride for oral suspension 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).

32. The manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Impax's 1.875 gm/packet and 3.75 gm/packet colesevelam hydrochloride for oral suspension 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.

33. Upon information and belief, the offer to sell and sale of Impax's 1.875 gm/packet and 3.75 gm/packet colesevelam hydrochloride for oral suspension, 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.

34. 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. 201975 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.

35. 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.

SECOND COUNT FOR PATENT INFRINGEMENT BY GLENMARK

36. Plaintiffs repeat and re-allege paragraphs 1-29 as if fully set forth herein.

37. By seeking approval of its ANDA No. 202190 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of 1.875 gm/packet and 3.75 gm/packet colesevelam hydrochloride for oral suspension prior to the expiration of the '669 and '675 patents, Glenmark has infringed the '669 and '675 patents pursuant to 35 U.S.C. § 271(e)(2)(A).

38. The manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Glenmark's 1.875 gm/packet and 3.75 gm/packet colesevelam hydrochloride for oral suspension 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.

39. Upon information and belief, the offer to sell and sale of Glenmark's 1.875 gm/packet and 3.75 gm/packet colesevelam hydrochloride for oral suspension, 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.

40. 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 Glenmark's ANDA No. 202190 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.

41. Upon information and belief, Glenmark Ltd. and Glenmark Pharma have actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 202190 to the FDA. On information and belief, Glenmark Ltd. and Glenmark Pharma were aware of the '669 and '675 patents when they engaged in these knowing and purposeful activities referred to above.

42. Under 35 U.S.C. §271(b) and 271(e)(2)(A) Glenmark Ltd. and Glenmark Pharma induced the infringement of the '669 and '675 patents by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 202190. The filing of the ANDA by Glenmark constitutes a direct act of infringement under 35 U.S.C. §271(e). Glenmark Ltd. and Glenmark Pharma's active and knowing aiding and abetting Glenmark USA in the filing of ANDA No. 202190 constitutes induced infringement.

43. Plaintiffs will be irreparably harmed by Glenmark'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 and Glenmark have infringed the '669 and '675 patents by submitting ANDA Nos. 201975 and 202190, respectively, to the FDA;

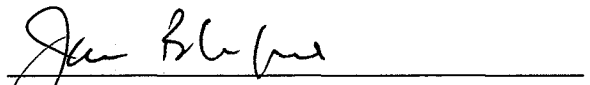
b. A permanent injunction pursuant to 35 U.S.C. §§ 271(e)(4)(B) restraining and enjoining Impax and Glenmark and their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from infringing the '669 and '675 patents by 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 Nos. 201975 and 202190 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 and/or Glenmark 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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