IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DAIICHI SANKYO, INC. and GENZYME CORPORATION, Plaintiffs, v. WATSON PHARMACEUTICALS, INC., WATSON PHARMA, INC., and WATSON LABORATORIES, INC. (NV), Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs Daiichi Sankyo, Inc. ("Daiichi Sankyo") and Genzyme Corporation ("Genzyme") (collectively, "Plaintiffs") for their Complaint against Defendants Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals"), Watson Pharma, Inc. ("Watson Pharma"), and Watson Laboratories, Inc. (NV) ("Watson Labs") (collectively, "Watson" or "Defendants") hereby allege as follows:

THE PARTIES

1. Plaintiff Daiichi Sankyo, Inc. 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 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 Watson Pharmaceuticals is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

4. Upon information and belief, Defendant Watson Pharma is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07962.

5. Upon information and belief, Defendant Watson Labs is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

6. Upon information and belief, Watson Pharma and Watson Labs are wholly-owned subsidiaries of Watson Pharmaceuticals.

JURISDICTION AND VENUE

7. 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).

8. This Court has personal jurisdiction over Defendant Watson Pharma by virtue of, *inter alia*, its incorporation in Delaware.

9. This Court has personal jurisdiction over Watson Labs, by virtue of, *inter alia*, this Court's previous determination that Watson Labs "'regularly does or solicits business' in Delaware or engages in a 'persistent course of conduct' in Delaware," and Watson Labs is, therefore, subject to general personal jurisdiction in Delaware.

10. Upon information and belief, Watson Pharmaceuticals organizes its operations by segments — Generic, Brand, and Distribution — and reports its financial results in its Securities and Exchange Commission ("SEC") filing by reference to these segments. Watson

Pharmaceuticals consolidates its financial results with Watson subsidiaries in its SEC filings at least for 2007 to date and does not separate financial reports to the SEC for each Watson subsidiary.

11. Upon information and belief, the Generic segment, which is responsible for developing and submitting Abbreviated New Drug Applications ("ANDAs"), as well as manufacturing and marketing generic pharmaceuticals, relies on contributions from Watson Pharmaceuticals, Watson Labs, and Watson Pharma, each of which works in concert with the others to further the aims of the Generic segment. Upon information and belief, Watson Labs submits ANDAs and manufactures Generic segment products. These and other Generic segment products are marketed and sold by Watson Pharma throughout the United States, including in Delaware.

12. Watson Pharmaceuticals' website states that its Generic segment has a portfolio of 170 pharmaceutical products, including Watson Labs products, and states that the Generic segment filed 36 new ANDAs in 2009. In its 2009 Annual Report, Watson Pharmaceuticals explains that "We sell our generic prescription products primarily under the 'Watson Laboratories' and 'Watson Pharma' labels." Upon information and belief, the ANDAs for the majority of these products in Watson Pharmaceuticals' portfolio are nominally in the name of Watson Labs and another subsidiary, Watson Laboratories, Inc. – Florida.

13. Upon information and belief, Watson Labs also manufactures at least some of the drugs for which it is the nominal ANDA applicant.

14. Upon information and belief, Watson Pharma, a Delaware corporation, is the distributor of drugs for which Watson Labs is the named applicant in the FDA's Approved Drug Product List. Upon information and belief, Watson Pharma, acting as the agent of Watson

Labs and Watson Pharmaceuticals, markets and sells many, if not all, of these drugs in Delaware. Upon information and belief, Watson Labs and Watson Pharma are parties to one or more contractual agreements for distributing drugs made under Watson Labs's ANDAs. Upon information and belief, these agreements are less than arms length.

15. Watson Pharma is licensed to do business in Delaware and, upon information and belief, has sales personnel assigned to cover Delaware for the purpose of marketing and selling Generic segment products of Watson Pharmaceuticals, including Watson Labs products.

16. For example, upon information and belief, various drugs for which Watson Labs is the named ANDA applicant are distributed by Watson Pharma and are available at various retail pharmacies in Delaware, including Walgreens/Happy Harry's and Rite Aid. Upon information and belief, Watson Pharmaceuticals and/or Watson Labs realize revenue from the distribution of Watson Labs drugs by Watson Pharma, where such distributions result in sales of the drugs in Delaware or to persons in Delaware.

17. Watson Pharmaceuticals identifies on its website the address of a Watson Pharma facility (360 Mount Kemble Avenue, Morristown, New Jersey) as one of its locations. Upon information and belief, Watson Pharmaceuticals also issues press releases on behalf of its subsidiaries, including Watson Labs, and on more that one occasion has claimed actions of its subsidiaries as its own.

18. Upon information and belief, Watson Pharmaceuticals, Watson Pharma, and Watson Labs share common employees, officers, and directors.

19. Upon information and belief, Watson Pharmaceuticals and Watson Pharma share common employees, officers, and directors.

20. Upon information and belief, Watson Pharmaceuticals and Watson Labs share common employees, officers, and directors.

21. Upon information and belief, Watson Pharma and Watson Labs share common employees, officers, and directors.

22. Upon information and belief, Watson Pharmaceuticals, through its own actions and the actions of one or more Watson subsidiaries, actively engages in a concerted effort to sell generic products throughout the United States, including in Delaware.

23. This Court has personal jurisdiction over Defendants Watson Pharmaceuticals, Watson Labs, and Watson Pharma because, *inter alia*, they, either directly or through an agent, including each other, regularly do or solicit business in Delaware, engage in other persistent courses of conduct in Delaware, and/or derive substantial revenue from services or things used or consumed in Delaware. These activities further demonstrate that Watson Pharmaceuticals, Watson Labs, and Watson Pharma have continuous and systematic contacts in Delaware.

24. Upon information and belief, Watson Pharmaceuticals, Watson Labs, and Watson Pharma are agents of each other and/or work in concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including Watson's 625 mg colesevelam hydrochloride tablet drug product described in ANDA No. 200-830.

25. Upon information and belief, each of Watson Pharmaceuticals, Watson Labs, and Watson Pharma, as part of Watson Pharmaceuticals Generic segment, will manufacture, market, and/or sell within the United States Watson's 625 mg colesevelam hydrochloride tablet drug product in ANDA No. 200-830 if FDA approval is granted.

26. Upon information and belief, if ANDA No. 200-830 is approved, Watson's 625 mg colesevelam hydrochloride tablet drug product would be marketed and distributed in Delaware, prescribed by physicians practicing and dispensed by pharmacies located within Delaware, and/or used by persons in Delaware, all of which would have a substantial effect on Delaware.

27. Upon information and belief, Watson Labs sent a letter to Plaintiffs dated March 24, 2011 ("Watson's Notice Letter"), which was on letterhead bearing at the top Watson Pharmaceutical's logo. It was signed by Joyce Delgaudio, with the title of Executive Director, Regulatory Affairs, Watson Laboratories, Inc. Upon information and belief, Ms. Delgaudio also holds the position of Executive Director, Regulatory Affairs, Watson Pharmaceuticals. Watson Labs directed Plaintiffs to send any correspondence or requests for confidential access regarding ANDA No. 200-830 to Mr. Matthew O. Brady at "Watson, 311 Bonnie Circle, Corona, CA 92880." Upon information and belief, Mr. Brady holds the position of Senior Intellectual Property Counsel at Watson Pharmaceuticals.

28. On April 5, 2011, Mr. Brady confirmed that the Watson Laboratories, Inc. entity that submitted ANDA No. 200-830, is Watson Laboratories, Inc. (NV) — Watson Labs.

29. Upon information and belief, Watson Pharmaceuticals, at least through its Legal Department, has contributed to ANDA No. 200-830.

30. This Court has personal jurisdiction over Defendants Watson Pharmaceuticals, Watson Labs, and Watson Pharma, by virtue of the fact that, *inter alia*, they have committed, aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement, or actively induced another to do so, that has led to

foreseeable harm and injury to Plaintiff Daiichi Sankyo, a Delaware corporation, and Plaintiff Genzyme.

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

FACTUAL BACKGROUND

32. 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®.

33. 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.

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

35. Upon information and belief, Watson submitted to the FDA ANDA No. 200-830, 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 the expiration of the '669 and '675 patents.

36. In Watson's Notice Letter, Watson represented that it had filed ANDA No. 200-830 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.

37. Upon information and belief, the acts of Watson Labs subject to this complaint were done at the direction of, with the authorization of and with the cooperation, assistance and participation of Watson Pharma and Watson Pharmaceuticals.

38. Upon information and belief, the acts of Watson Labs subject to this complaint were done, at least in part, for the benefit of Watson Pharma and Watson Pharmaceuticals.

39. Upon information and belief, Watson Pharma and Watson Pharmaceuticals caused, actively encouraged and/or directed Watson Labs to file ANDA No. 200-830.

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

FIRST COUNT FOR PATENT INFRINGEMENT BY WATSON

41. Plaintiffs reallege paragraphs 1-40 as if fully set forth herein.

42. By seeking approval of its ANDA No. 200-830 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, Watson has infringed the '669 and '675 patents pursuant to 35 U.S.C. § 271(e)(2)(A).

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

44. Upon information and belief, the offer to sell and sale of Watson'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.

45. 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 Watson's ANDA No. 200-830 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.

46. Plaintiffs will be irreparably harmed by Watson'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 WATSON

47. Plaintiffs reallege paragraphs 1-46 as if fully set forth herein.

48. Upon information and belief, Watson Pharma and Watson Pharmaceuticals actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 200-830 to the FDA. On

information and belief, Watson Pharma and Watson Pharmaceuticals were aware of the '669 and '675 patents when they engaged in these knowing and purposeful activities referred to above.

49. Under 35 U.S.C. § 271(b) and 271(e)(2)(A) Watson Pharma and Watson Pharmaceuticals induced the infringement of the '669 and '675 patents by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 200-830. The filing of the ANDA by Watson Labs constitutes a direct act of infringement under 35 U.S.C. § 271(e). Watson Pharma and Watson Pharmaceuticals' active and knowing aiding and abetting Watson Labs in the filing of ANDA No. 200-830 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 No. 200-830 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 No. 200-830 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, offer 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 '669 and '675 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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