UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, DAIICHI SANKYO CO., LTD., DAIICHI SANKYO, INC., and UBE INDUSTRIES, LTD., Plaintiffs, v. APOTEX CORP. and APOTEX INC., Defendants.	Civil Action No. 1:14-cv-586

COMPLAINT FOR PATENT INFRINGEMENT

Eli Lilly and Company; Daiichi Sankyo Co., Ltd.; Daiichi Sankyo, Inc.; and Ube Industries, Ltd. ("Plaintiffs"), for their Complaint against defendants Apotex Corp. and Apotex Inc. (collectively "Apotex" or "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff Eli Lilly and Company ("Lilly") is a corporation organized and existing under the laws of the State of Indiana and has a principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

2. Plaintiff Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo") is a corporation organized and existing under the laws of Japan and has a principal place of business at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan.

3. Plaintiff Daiichi Sankyo, Inc. ("DSI") is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at Two Hilton Court, Parsippany, New Jersey 07054.

4. DSI is a wholly-owned subsidiary of Daiichi Sankyo U.S. Holdings, Inc., which is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at Two Hilton Court, Parsippany, New Jersey 07054.

5. Daiichi Sankyo U.S. Holdings, Inc. is a wholly-owned subsidiary of Daiichi Sankyo.

6. Plaintiff Ube Industries, Ltd. ("Ube") is a corporation organized and existing under the laws of Japan and has a principal place of business at 1978-96, Kogushi, Ube, Yamaguchi 755-8633, Japan.

7. Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Florida and has a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

8. Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada and has a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

9. Apotex Corp. is a wholly-owned subsidiary of Apotex Inc.

10. The acts of Apotex Inc. complained of herein were done with the cooperation, participation, and assistance of Apotex Corp.

NATURE OF THE ACTION

11. This is a civil action for patent infringement under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, arising out of the filing by Apotex Inc. of an Abbreviated New

Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Lilly's pharmaceutical products, Effient® 5mg and 10mg tablets, prior to the expiration of Daiichi Sankyo's and Ube's United States Patent Nos. 8,404,703 and 8,569,325, which cover methods of using Effient® products and are exclusively licensed to Lilly.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. This Court has personal jurisdiction over Apotex Corp. because Apotex Corp. (1) is registered to do business in this State, (2) intentionally markets and provides pharmaceutical drug products to residents of this State, (3) maintains a broad distributorship network within this State and is licensed as a Wholesale Drug Distributor in this State, and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State. Apotex Corp. has previously submitted to personal jurisdiction in this judicial district.

14. This Court has personal jurisdiction over Apotex Inc. because of Apotex Inc.'s continuous and systematic contacts with this State. Apotex Inc. (1) intentionally markets and provides its generic pharmaceutical drug products to residents of this State, (2) maintains a broad distributorship network within this State, and (3) enjoys substantial income from sales of its generic pharmaceutical products in this State. Apotex Inc. has previously submitted to personal jurisdiction in this judicial district.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

16. On March 26, 2013, the USPTO duly and legally issued United States Patent No. 8,404,703 ("the '703 patent"), entitled "Medicinal Compositions Containing Aspirin." The '703 patent is assigned to Daiichi Sankyo and Ube. A copy of the '703 patent is attached as ***Appendix A***.

17. On October 29, 2013, the USPTO duly and legally issued United States Patent No. 8,569,325 ("the '325 patent"), entitled "Method of Treatment with Coadministration of Aspirin and Prasugrel." The '325 patent is assigned to Daiichi Sankyo and Ube. A copy of the '325 patent is attached as ***Appendix B***.

FACTUAL BACKGROUND

Effient® Products

18. Lilly is an exclusive licensee to the '703 and '325 patents, which cover methods of using Effient® products.

19. Effient® products were approved by the FDA for the reduction of thrombotic cardiovascular events in certain patients with acute coronary syndrome (ACS) who are to be managed with percutaneous coronary intervention (PCI, or angioplasty).

20. Effient® products contain prasugrel hydrochloride, which is known as 5-[(1RS)-2-cyclopropyl-1-(2-fluorophenyl)-2-oxoethyl]-4,5,6,7-tetrahydrothieno[3,2-c]pyridin-2-yl acetate hydrochloride or 2-acetoxy-5-(α-cyclopropylcarbonyl-2-fluorobenzy1)-4,5,6,7-tetrahydrothieno[3,2-c]pyridine hydrochloride.

21. Effient® products are formulated in two strengths, EQ 5 mg or EQ 10 mg base of prasugrel hydrochloride, where the EQ 10 mg base dose is the reference listed drug.

22. The instructions accompanying Effient® products state that patients taking Effient® products should also take aspirin.

23. The use of Effient® products in combination with aspirin for the reduction of thrombotic cardiovascular events in patients with ACS who are to be managed with PCI is covered by the claims of the '703 and '325 patents.

24. Lilly holds an approved New Drug Application, No. 22-307, for the manufacture and sale of Effient® products, 5 mg and 10 mg prasugrel hydrochloride tablets, in the United States (the "Effient® NDA").

25. Lilly currently markets Effient® products in the United States.

26. DSI currently co-promotes Effient® products in the United States with Lilly.

27. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '703 and '325 patents are listed in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), as covering Effient® products.

Infringement by Apotex

28. Apotex Inc. has knowledge of the '703 and '325 patents and has submitted Abbreviated New Drug Application No. 205978 (the "Apotex ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market prasugrel hydrochloride tablets for oral administration (the "Apotex Products") in the United States.

29. The active ingredient and strength of the Apotex Products is 5 mg and 10 mg EQ base of prasugrel hydrochloride.

30. On or about March 7, 2014, Apotex Inc. sent Lilly, Daiichi Sankyo, and Ube a letter, dated March 7, 2014, and an attached memorandum (collectively, the "Apotex Notification") stating that Apotex Inc. had included within its ANDA a certification pursuant to

21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '703 and '325 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Apotex Products in the United States ("Apotex Paragraph IV Certification").

31. The prasugrel hydrochloride active ingredient in the Apotex Products is the same as the prasugrel hydrochloride active ingredient in Effient® products. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(5).

32. The Apotex ANDA refers to and relies upon the Effient® NDA and contains data that, according to Apotex Inc., demonstrates that the Apotex Products and Effient® products are bioequivalent. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

33. Apotex Inc. will knowingly accompany the Apotex Products with instructions for use that substantially copy the instructions for Effient® products, including instructions for administering the Apotex Products with aspirin as claimed in the '703 and '325 patents. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4), and (8).

34. Apotex Inc. knows that the instructions that will accompany the Apotex Products will induce and/or contribute to others using the Apotex Products in the manner set forth in the instructions.

35. Physicians, health care providers, and/or patients will directly infringe one or more claims of the '703 and '325 patents by using the Apotex Products in accordance with the instructions provided by Apotex Inc., after the FDA approves the Apotex ANDA.

36. Apotex Inc. specifically intends that physicians, health care providers, and/or patients will use the Apotex Products in accordance with the instructions provided by Apotex Inc. to directly infringe one or more claims of the '703 and '325 patents. Apotex Inc. therefore will actively induce and/or contribute to infringement of the '703 and '325 patents.

37. Apotex Inc. knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the Apotex Products in a manner that directly infringes at least one claim of the ’703 and ’325 patents.

38. Apotex Inc. designed the Apotex Products for use in a way that would infringe the ’703 and ’325 patents and will instruct users of the Apotex Products to use the Apotex Products in a way that would infringe the ’703 and ’325 patents.

39. Apotex Corp. was actively involved in the preparation and/or submission of the Apotex ANDA including the Apotex Paragraph IV Certification against the ’703 and ’325 patents.

40. Apotex Corp. actively and knowingly provided Apotex Inc. with material information and support in preparing and submitting the Apotex ANDA and has therefore aided and/or abetted in the filing of the Apotex ANDA.

41. The Apotex Products are not a staple article or commodity of commerce suitable for substantial non-infringing use.

42. Unless Apotex is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Apotex’s infringement of the ’703 and ’325 patents. Plaintiffs do not have an adequate remedy at law.

43. Plaintiffs commenced this action within 45 days of receiving the Apotex Notification.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 8,404,703

44. Apotex Inc.’s filing of the Apotex ANDA containing the Apotex Paragraph IV Certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of

the Apotex Products in the United States before the expiration of the '703 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

45. Apotex Corp. actively and knowingly aided, abetted, and induced Apotex Inc. to submit the Apotex ANDA containing the Apotex Paragraph IV Certification before the expiration of the '703 patent, which is an act of infringement under 35 U.S.C. § 271(b).

46. After the FDA approves the Apotex ANDA, Apotex Inc. plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Apotex Products in the United States, import either or both of the Apotex Products into the United States, and/or induce such acts during the term of the '703 patent.

47. Apotex Inc. has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Apotex ANDA is approved.

48. Apotex Corp. has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

49. Apotex Inc. lacked a good faith basis for alleging invalidity of the '703 patent when it filed the Apotex ANDA and made the Apotex Paragraph IV Certification. Accordingly, the Apotex Paragraph IV Certification was wholly unjustified.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,404,703

50. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

51. Apotex Inc. has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Apotex ANDA is approved.

52. Apotex Corp. has taken and intends to take active steps to induce, or contribute to, the infringement of the '703 patent under 35 U.S.C. § 271(b) and/or § 271(c).

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 8,569,325

53. Apotex Inc.'s filing of the Apotex ANDA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer to sell and/or sale or inducement thereof of either or both of the Apotex Products in the United States before the expiration of the '325 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

54. Apotex Corp. actively and knowingly aided, abetted, and induced Apotex Inc. to submit the Apotex ANDA before the expiration of the '325 patent, which is an act of infringement under 35 U.S.C. § 271(b).

55. If the FDA approves the Apotex ANDA, Apotex Inc. plans to, intends to, and will commercially manufacture, use, sell and/or offer to sell either or both of the Apotex Products in the United States, import either or both of the Apotex Products into the United States, and/or induce such acts during the term of the '325 patent.

56. Apotex Inc. has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Apotex ANDA is approved.

57. Apotex Corp. has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

58. Apotex Inc. lacked a good faith basis for alleging invalidity of the '325 patent when it filed the Apotex ANDA and made the Apotex Paragraph IV Certification. Accordingly, the Apotex Paragraph IV Certification was wholly unjustified.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,569,325

59. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

60. Apotex Inc. has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Apotex ANDA is approved.

61. Apotex Corp. has taken and intends to take active steps to induce, or contribute to, the infringement of the '325 patent under 35 U.S.C. § 271(b) and/or § 271(c).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor against Defendants as follows:

A. That Apotex, either individually or collectively, has infringed or will infringe, after the Apotex ANDA is approved, one or more claims of the '703 patent;

B. That Apotex, either individually or collectively, has infringed or will infringe, after the Apotex ANDA is approved, one or more claims of the '325 patent;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Apotex, its officers, agents, servants, and employees, and those persons in active concert or privity with any of them are permanently enjoined from making, using, selling or offering to sell either or both of the Apotex Products within the United States, or importing either or both of the Apotex Products into the United States prior to the expiration of the '703 and '325 patents;

D. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Apotex ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C.

§ 355(j)) shall not be earlier than the latest of the expiration dates of the '703 and '325 patents, including any extensions;

E. If Apotex commercially makes, uses, sells or offers to sell either or both of the Apotex Products within the United States, or imports either or both of the Apotex Products into the United States, prior to the expiration of either of the '703 and '325 patents, including any extensions, that Plaintiffs will be awarded monetary damages for those infringing acts to the fullest extent allowed by law and be awarded prejudgment interest based on those monetary damages;

F. That this case be deemed exceptional under 35 U.S.C. § 285;

G. A judgment declaring that the '703 patent remains valid and enforceable;

H. A judgment declaring that the '325 patent remains valid and enforceable;

I. That Plaintiffs be awarded reasonable attorney's fees, costs, and expenses; and

J. That Plaintiffs be awarded such other relief as the Court deems just and proper.

Dated: April 16, 2014

Respectfully submitted,

By: /s/ *Jan M. Carroll*

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