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. FIRST TIME US GENERICS LLC, Defendant.	)	CASE NO. 1:14-cv-1168

COMPLAINT FOR PATENT INFRINGEMENT

Eli Lilly and Company, Daiichi Sankyo Co., Ltd., Daiichi Sankyo, Inc., and Ube Industries, Ltd. (collectively, "Plaintiffs"), for their Complaint against defendant First Time US Generics LLC ("FTUG"), 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 FTUG is a corporation organized and existing under the laws of the State of Florida and has a place of business at 505 Park Way, Suite 6, Broomall, PA 19008.

NATURE OF THE ACTION

8. 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 FTUG 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, of which Lilly is an exclusive licensee, which cover methods of using Effient® products.

JURISDICTION AND VENUE

9. This patent infringement action arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(e)(2). This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. This Court has personal jurisdiction over FTUG because, among other reasons, FTUG has directed its intentionally infringing conduct toward Plaintiffs, including Lilly, which has a principal place of business in Indiana. Upon information and belief, following any FDA approval of FTUG's ANDA for generic versions of Effient®, FTUG will market, distribute, and sell its generic product throughout the United States and within Indiana and the Southern District of Indiana, and knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana.

11. Furthermore, upon information and belief, FTUG directly or through its affiliates and partners, markets, sells, and distributes generic drugs throughout the United States, including within the State of Indiana and the Southern District of Indiana, and enjoys substantial income from the sales of those drugs in this State. Upon information and belief, FTUG has engaged in and maintained systematic and continuous business contacts within the State of Indiana and the Southern District of Indiana and has purposefully availed itself of the benefits and protections of the laws of Indiana.

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

THE PATENTS-IN-SUIT

13. 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 *Exhibit A*.

14. 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 *Exhibit B.*

FACTUAL BACKGROUND

Effient® Products

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

16. 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).

17. 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.

18. 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.

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

20. 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.

21. 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").

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

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

24. 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 FTUG

25. FTUG has knowledge of the '703 and '325 patents and has submitted Abbreviated New Drug Application No. 205790 (the "FTUG ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market generic prasugrel hydrochloride tablets for oral administration (the "FTUG Products") in the United States.

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

27. On or about June 10, 2014, FTUG sent Lilly, Daiichi Sankyo, and Ube a letter, dated June 10, 2014, and an attached memorandum (collectively, the "FTUG Notification") stating that FTUG 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 FTUG Products in the United States ("FTUG Paragraph IV Certification").

28. The prasugrel hydrochloride active ingredient in the FTUG 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).

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

30. FTUG will knowingly accompany the FTUG Products with instructions for use that substantially copy the instructions for Effient® products, including instructions for administering the FTUG 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).

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

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

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

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

35. FTUG designed the FTUG Products for use in a way that would infringe the '703 and '325 patents and will instruct users of the FTUG Products to use the FTUG Products in a way that would infringe the '703 and '325 patents.

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

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

38. Plaintiffs commenced this action within 45 days of receiving the FTUG Notification.

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

39. Plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1-38.

40. FTUG's filing of the FTUG ANDA containing the FTUG 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 FTUG 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).

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

42. FTUG 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), if the FTUG ANDA is approved.

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

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

44. Plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1-43.

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

46. FTUG 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), if the FTUG ANDA is approved.

47. Plaintiffs are entitled to a declaration that the commercial manufacture, use, sale and/or offer to sell of either or both of the FTUG Products in the United States, importation of either or both of the FTUG Products into the United States, and/or the inducement of such acts during the term of the '703 patent will induce and/contribute to the infringement of the '703 patent.

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

48. Plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1-47.

49. FTUG's filing of the FTUG ANDA containing the FTUG 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 FTUG 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).

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

51. FTUG 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), if the FTUG ANDA is approved.

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

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

53. Plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1-52.

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

55. FTUG 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), if the FTUG ANDA is approved.

56. Plaintiffs are entitled to a declaration that the commercial manufacture, use, sale and/or offer to sell of either or both of the FTUG Products in the United States, importation of either or both of the FTUG Products into the United States, and/or the inducement of such acts

during the term of the ’325 patent will induce and/contribute to the infringement of the ’325 patent.

PRAYER FOR RELIEF

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

A. That FTUG has infringed the ’703 patent and/or will infringe, actively induce infringement of, and/or contribute to infringement by others of one or more claims of the ’703 patent;

B. That FTUG has infringed the ’325 patent and/or will infringe, actively induce infringement of, and/or contribute to infringement by others of one or more claims of the ’325 patent;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(B), FTUG, 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 FTUG Products within the United States, or importing either or both of the FTUG 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 FTUG 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 FTUG commercially makes, uses, sells or offers to sell either or both of the FTUG Products within the United States, or imports either or both of the FTUG 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 is valid and enforceable;

H. A judgment declaring that the '325 patent is 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: July 14, 2014

/s/ Jan M. Carroll

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