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. ACCORD HEALTHCARE, INC., USA, et al., Defendants.	)	CASE NO. 1:14-cv-00389-SEB-TAB **CONSOLIDATED** (Formerly CASE NO. 1:15-cv-00673-LJM-TAB)

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT AGAINST THE LUPIN DEFENDANTS

On April 27, 2015, Eli Lilly and Company, Daiichi Sankyo Co., Ltd., Daiichi Sankyo, Inc., and Ube Industries, Ltd. (collectively, "Plaintiffs"), filed a Complaint for Patent Infringement against defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"), and that case was assigned case number 1:15-cv-00673-LJM-TAB. Case number 1:15-cv-00673-LJM-TAB was subsequently consolidated with the action referenced above. Plaintiffs now amend their Complaint against Lupin by filing this First Amended Complaint and 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 Lupin Ltd. is a corporation organized and existing under the laws of India and has a principal place of business at Laxmi Towers, 'B' Wing, Bandra Kurla Complex, Bandra (East), Mumbai, 400 051, India.

8. Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Virginia and has a principal place of business at 111 South Calvert Street, 21st Floor, Baltimore, MD 21202. Upon information and belief, Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Lupin Ltd.

9. Upon information and belief, the acts of Lupin Ltd. complained of herein were done with the cooperation, participation, and assistance of Lupin Pharmaceuticals, Inc.

NATURE OF THE ACTION

10. 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 Lupin 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

11. 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.

12. This Court has personal jurisdiction over Lupin Ltd. because, among other reasons, Lupin Ltd. 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 Lupin's ANDA for generic versions of Effient®, Lupin Ltd. knows and intends that its generic products will be marketed, distributed, and sold 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.

13. Furthermore, upon information and belief, Lupin Ltd., markets, sells, and distributes generic drugs throughout the United States, directly or through Lupin Pharmaceuticals, Inc., 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, Lupin Ltd. 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.

14. This Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. because, among other reasons, Lupin Pharmaceuticals, Inc. 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 Lupin's ANDA for generic versions of Effient®, Lupin Pharmaceuticals, Inc. will market, distribute, and sell its generic products 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.

15. Furthermore, upon information and belief, Lupin Pharmaceuticals, Inc. markets, sells, and distributes generic drugs throughout the United States, either directly or through its affiliates, 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, Lupin Pharmaceuticals, Inc. 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.

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

THE PATENTS-IN-SUIT

17. 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.

18. 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

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

20. 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).

21. 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.

22. 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.

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

24. 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.

25. 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").

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

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

28. 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 Lupin

29. Lupin has knowledge of the '703 and '325 patents and has submitted Abbreviated New Drug Application No. 205930 (the "Lupin ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market generic prasugrel hydrochloride tablets for oral administration (the "Lupin Products") in the United States.

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

31. On or about April 6, 2015, Lupin sent Lilly, Daiichi Sankyo, and Ube a letter, dated April 6, 2015, and an attached memorandum (collectively, the "Lupin Notification") stating that Lupin 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 Lupin Products in the United States ("Lupin Paragraph IV Certification").

32. On or about September 30, 2015, Lupin sent Lilly, Daiichi Sankyo, DSI, Daiichi Sankyo U.S. Holdings, Inc., and Ube a letter, dated September 30, 2015, and an attached memorandum stating that Lupin revised the formulation of its generic product that is the subject of the Lupin ANDA and, in connection with this revised formulation, resubmitted certifications 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 Lupin Products in the United States ("Second Lupin Paragraph IV Certification").

33. The prasugrel hydrochloride active ingredient in the Lupin 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).

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

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

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

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

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

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

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

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

42. Unless Lupin is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Lupin 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 Lupin Notification.

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

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

45. Lupin's filing of the Lupin ANDA containing the Lupin Paragraph IV Certification and the Second Lupin 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 Lupin 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).

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

47. Lupin 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 Lupin ANDA is approved.

48. Lupin lacked a good faith basis for alleging invalidity of the '703 patent when it filed the Lupin ANDA and made the Lupin Paragraph IV Certification and the Second Lupin Paragraph IV Certification. Accordingly, the Lupin Paragraph IV Certification and the Second Lupin Paragraph IV Certification were wholly unjustified.

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

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

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

51. Lupin 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 Lupin ANDA is approved.

52. Plaintiffs are entitled to a declaration that the commercial manufacture, use, sale and/or offer to sell of either or both of the Lupin Products in the United States, importation of either or both of the Lupin 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

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

54. Lupin's filing of the Lupin ANDA containing the Lupin Paragraph IV Certification and the Second Lupin 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 Lupin 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).

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

56. Lupin 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 Lupin ANDA is approved.

57. Lupin lacked a good faith basis for alleging invalidity of the '325 patent when it filed the Lupin ANDA and made the Lupin Paragraph IV Certification and the Second Lupin Paragraph IV Certification. Accordingly, the Lupin Paragraph IV Certification and the Second Lupin Paragraph IV Certification were wholly unjustified.

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

58. Plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1-57.

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

60. Lupin 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 Lupin ANDA is approved.

61. Plaintiffs are entitled to a declaration that the commercial manufacture, use, sale and/or offer to sell of either or both of the Lupin Products in the United States, importation of either or both of the Lupin 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 Lupin 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 Lupin 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), Lupin, 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 Lupin Products within the United States, or importing either or both of the Lupin 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 Lupin 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 Lupin commercially makes, uses, sells or offers to sell either or both of the Lupin Products within the United States, or imports either or both of the Lupin 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: November 20, 2015

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CERTIFICATE OF SERVICE

I hereby certify that on November 20, 2015, a copy of the foregoing document was filed electronically. Notice of this filing will be sent to all counsel of record by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ Carol J. Pruski

Carol J. Pruski