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,	)	**C.A. NO. 1:14-cv-109-_____**
v.	)	
PAR PHARMACEUTICAL COMPANIES, INC., and PAR PHARMACEUTICAL, INC.,	)	
Defendants.	)	

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 Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively "Par Pharmaceutical"), 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 Par Pharmaceutical Companies, Inc. ("Par Pharmaceutical Companies") is a corporation organized and existing under the laws of Delaware and has a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

8. Defendant Par Pharmaceutical, Inc. ("Par") is a corporation organized and existing under the laws of Delaware and has a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

9. Par is a wholly-owned subsidiary of Par Pharmaceutical Companies.

10. Par Pharmaceutical Companies operates primarily through its wholly-owned subsidiary Par.

11. The acts of Par complained of herein were done with the cooperation, participation, and assistance of Par Pharmaceutical Companies.

NATURE OF THE ACTION

12. 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 Defendant Par 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

13. 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.

14. This Court has personal jurisdiction over Par because of Par's continuous and systematic contacts with this State. Par (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.

15. This Court has personal jurisdiction over Par Pharmaceutical Companies because Par Pharmaceutical Companies is (1) the parent company of Par, (2) operates primarily through its wholly owned subsidiary Par, and (3) shares common headquarters and officers and directors with Par.

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 United States Patent and Trademark Office ("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.

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 Appendix 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 chemically designated as 5-[(1RS)-2-cyclopropyl-1-(2-fluorophenyl)-2-oxoethyl]-4,5,6,7-tetrahydrothieno[3,2-c]pyridin-2-yl acetate 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 Par Pharmaceutical

29. Par has knowledge of the '703 and '325 patents and has submitted Abbreviated New Drug Application No. 20-5700 (the "Par ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market prasugrel hydrochloride tablets for oral administration (the "Par Products") in the United States.

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

31. On or about December 9, 2013, Par sent Lilly, Daiichi Sankyo, and Ube a letter, dated December 9, 2013, and an attached memorandum (collectively, the "Par Notification") stating that Par 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 Par Products in the United States ("Paragraph IV Certification").

32. The prasugrel hydrochloride active ingredient in the Par 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).

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

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

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

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

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

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

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

40. Par Pharmaceutical Companies was actively involved in the preparation and/or submission of the Par ANDA including the Paragraph IV Certification against the ’703 and ’325 patents.

41. Par Pharmaceutical Companies actively and knowingly provided Par with material information and support in preparing and submitting the Par ANDA and has therefore aided and/or abetted in the filing of the Par ANDA.

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

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

44. Plaintiffs commenced this action within 45 days of the date of the Par Notification.

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

45. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 12-44 of this Complaint.

46. Par’s filing of the Par ANDA containing the 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 Par 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).

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

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

49. Par 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 Par ANDA is approved.

50. Par Pharmaceutical Companies 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).

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

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

52. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 12-51 of this Complaint.

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

54. Par 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 Par ANDA is approved.

55. Par Pharmaceutical Companies 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

56. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 12-55 of this Complaint.

57. Par's filing of the Par 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 Par 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).

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

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

60. Par 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 Par ANDA is approved.

61. Par Pharmaceutical Companies 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).

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

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

63. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 12-62 of this Complaint.

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

65. Par 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 Par ANDA is approved.

66. Par Pharmaceutical Companies 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 Par Pharmaceutical Companies and Par as follows:

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

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

C. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Par and Par Pharmaceutical Companies, their 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 Par Products within the United States, or importing either or both of the Par 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 Par 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. A judgment declaring that the '703 patent remains valid and enforceable;

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

G. If either Par or Par Pharmaceutical Companies commercially makes, uses, sells or offers to sell either or both of the Par Products within the United States, or imports either or both of the Par 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;

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

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: January 23, 2014

Respectfully submitted,

By: */s/ Jan M. Carroll*

Jan M. Carroll, No. 4187-49
BARNES & THORNBURG LLP
11 South Meridian Street
Indianapolis, Indiana 46204-3535
jan.carroll@btlaw.com
(317) 236-1313

Attorney for Plaintiffs,
Eli Lilly and Company, Daiichi Sankyo Co., Ltd., Daiichi Sankyo, Inc., and Ube Industries, Ltd.

OF COUNSEL:

Lisa B. Pensabene, Esq.
FITZPATRICK, CELLA,
HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104