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.	)	CASE NO. 1:14-cv-1135
HEC PHARM CO., LTD., and HEC PHARM USA INC., Defendants.	)	

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 defendants HEC Pharm Co., Ltd. ("HEC Pharm") and HEC Pharm USA Inc. ("HEC Pharm US") (collectively, "HEC"), 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 HEC Pharm is a corporation organized and existing under the laws of China and has a principal place of business at Binjiang Road 62, Yidu, Yichang, 443300, China.

8. Defendant HEC Pharm US is a corporation organized and existing under the laws of Delaware and has a principal place of business at 116 Village Blvd., Suite 200, Princeton, NJ 08540.

9. Upon information and belief, the acts of HEC Pharm complained of herein were done with the cooperation, participation, and assistance of HEC Pharm US.

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 HEC 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 No. 8,404,703, of which Lilly is an exclusive licensee, which covers 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 HEC Pharm because, among other reasons, HEC Pharm 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 HEC's ANDA for generic versions of Effient®, HEC Pharm 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, HEC Pharm markets, sells, and distributes generic drugs throughout the United States, either directly or through HEC Pharm US, 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, HEC Pharm 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 HEC Pharm US because, among other reasons, HEC Pharm US 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 HEC's ANDA for generic versions of Effient®, HEC Pharm US intends to market, sell, and distribute these 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, HEC Pharm US 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, HEC Pharm US 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 PATENT-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.

FACTUAL BACKGROUND

Effient® Products

18. Lilly is an exclusive licensee to the '703 patent, which covers 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 patent.

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 patent is listed in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”), as covering Effient® products.

Infringement by HEC

28. HEC has knowledge of the ’703 patent and has submitted Abbreviated New Drug Application No. 206021 (the “HEC ANDA”) to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market prasugrel hydrochloride tablets for oral administration (the “HEC Products”) in the United States prior to the expiration of the ’703 patent.

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

30. On or about May 24, 2014, HEC Pharm sent Lilly and Daiichi Sankyo a letter, dated May 24, 2014, and an attached memorandum (collectively, the "HEC Notification") stating that HEC had included within its ANDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '703 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the HEC Products in the United States ("HEC Paragraph IV Certification").

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

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

34. HEC knows that the instructions that will accompany the HEC Products will induce and/or contribute to others using the HEC 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 patent by using the HEC Products in accordance with the instructions provided by HEC, after the FDA approves the HEC ANDA.

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

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

38. HEC designed the HEC Products for use in a way that would infringe the ’703 patent and will instruct users of the HEC Products to use the HEC Products in a way that would infringe the ’703 patent.

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

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

41. Plaintiffs commenced this action within 45 days of receiving the HEC Notification.

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

42. Plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1-41.

43. HEC’s filing of the HEC ANDA containing the HEC 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 HEC 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).

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

45. HEC 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 HEC ANDA is approved.

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

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

47. Plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1-46.

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

49. HEC 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 HEC ANDA is approved.

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

PRAYER FOR RELIEF

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

A. That HEC, either individually or collectively, 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, pursuant to 35 U.S.C. § 271(e)(4)(B), HEC, 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 HEC Products within the United States, or importing either or both of the HEC Products into the United States prior to the expiration of the ’703 patent;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the HEC ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the ’703 patent, including any extensions.

D. If HEC commercially makes, uses, sells or offers to sell either or both of the HEC Products within the United States, or imports either or both of the HEC Products into the United States, prior to the expiration of the ’703 patent, 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;

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

F. A judgment declaring that the ’703 patent is valid and enforceable;

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

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

Dated: July 7, 2014

/s/ Jan M. Carroll

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