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. 1:15-cv-00792
HEC PHARM USA, INC. and HEC PHARM CO., LTD.,	)	
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 USA Inc. ("HEC Pharm US") and HEC Pharm Co., Ltd. ("HEC Pharm") (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 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.

8. 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.

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

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 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 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.

13. 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.

14. In the alternative, this Court has personal jurisdiction over HEC Pharm under Fed. R. Civ. P. 4(k)(2) because this action arises under federal law, HEC Pharm is not subject to

jurisdiction in any state's courts of general jurisdiction, and the exercise of jurisdiction over HEC Pharm is consistent with the Constitution and the laws of the United States.

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 *Exhibit 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 *Exhibit 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 HEC

28. HEC has knowledge of the '703 and '325 patents 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 and '325 patents.

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 "First HEC Notification") stating that HEC had included within its ANDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) for the '325 patent and 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '703 patent stating 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 ("First Paragraph IV Certification").

31. On July 7, 2014, Plaintiffs filed a complaint for patent infringement of the '703 patent in the Southern District of Indiana against HEC. *Eli Lilly and Company, et al. v. HEC Pharm Co., Ltd., and HEC Pharm USA Inc.*, Case No. 1:14-cv-1135-SEB-DKL (filed July 7, 2014). Plaintiffs commenced the action within 45 days of receiving the First HEC Notification.

32. On July 11, 2014, counsel for HEC notified counsel for Plaintiffs that HEC had amended its First Paragraph IV Certification to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III Certification").

33. On July 21, 2014, as a result of HEC's conversion of their First Paragraph IV Certification to a Paragraph III Certification, Plaintiffs dismissed their lawsuit against HEC without prejudice. *Id.*, Notice of Dismissal, Dkt. Nos. 8 & 9 (filed July 21, 2014; acknowledged July 22, 2014).

34. On or about April 16, 2015, HEC Pharm US sent Lilly, Daiichi Sankyo, DSI, and Ube a Supplemental Notification letter, dated April 16, 2015, and an attached memorandum (collectively, the "Second HEC Notification") stating that the HEC ANDA had been amended to include 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 HEC Products in the United States ("Second Paragraph IV Certifications").

35. 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).

36. 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).

37. 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 and '325 patents. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4), and (8).

38. 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.

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

40. 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 and '325 patents. HEC therefore will actively induce and/or contribute to infringement of the '703 and '325 patents.

41. 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 and ’325 patents.

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

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

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

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

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

46. Plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1-45.

47. HEC’s amendment of the HEC ANDA containing the Second Paragraph IV Certifications 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).

48. 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.

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. HEC lacked a good faith basis for alleging invalidity of the '703 patent when it amended the HEC ANDA and made the Second Paragraph IV Certifications. Accordingly, the Second Paragraph IV Certifications were wholly unjustified as to this patent.

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

51. Plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1-50.

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

53. 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.

54. 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.

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

55. Plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1-54.

56. HEC's amendment of the HEC ANDA containing the Second Paragraph IV Certifications 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 '325 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

57. 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 '325 patent.

58. HEC 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 HEC ANDA is approved.

59. HEC lacked a good faith basis for alleging invalidity of the '325 patent when it amended the HEC ANDA and made the Second Paragraph IV Certifications. Accordingly, the Second Paragraph IV Certifications were wholly unjustified as to this patent.

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

60. Plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1-59.

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

62. HEC 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 HEC ANDA is approved.

63. 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 ’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 HEC 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 HEC 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), 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 and ’325 patents;

D. 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 latest of the expiration dates of the '703 and '325 patents, including any extensions.

E. 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 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: May 20, 2015

/s/ Jan M. Carroll

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

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

Of counsel:

Bruce R. Genderson
Adam L. Perlman
Ellen E. Oberwetter
Dov P. Grossman
Andrew V. Trask
Elise M. Baumgarten
Carol J. Pruski
Sara K. Creighton
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000 (telephone)
bgenderson@wc.com
aperlman@wc.com
eoberwetter@wc.com
dgrossman@wc.com
atrask@wc.com
ebaumgarten@wc.com
cpruski@wc.com
screighton@wc.com