IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., WYETH LLC, PFIZER PHARMACEUTICALS LLC, PF PRISM C.V., and PFIZER MANUFACTURING HOLDINGS LLC,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Pfizer Inc., Wyeth LLC, Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer Manufacturing Holdings LLC (collectively, "Pfizer"), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendant Apotex Inc. (collectively with Apotex Corp., "Apotex") of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Pfizer's TYGACIL® tigecycline injectable IV infusion, ("TYGACIL®") prior to the expiration of U.S. Patent No. 8,372,995 ("the '995 patent").

PARTIES

2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017.

3. Plaintiff Wyeth LLC is a limited liability company organized and existing under the laws of Delaware and having a place of business at 5 Giralda Farms, Madison, New Jersey 07940. Wyeth LLC's sole member is Pfizer Inc.

4. Plaintiff Pfizer Pharmaceuticals LLC is a limited liability company organized and existing under the laws of Delaware and having a place of business at Bo. Carmelitas, Road 689, Km 1.9, Vega Baja, Puerto Rico 00693. Pfizer Pharmaceuticals LLC is a wholly-owned subsidiary of PF PRISM C.V.

5. Plaintiff PF PRISM C.V. is a limited partnership (*commanditaire vennootschap*) organized and existing under the laws of the Netherlands, and registered at the trade register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456, with offices at Blaak 40 basement, 3011 TA, Rotterdam, Netherlands. PF PRISM C.V. is the holder of New Drug Application No. 21821, which has been approved by the FDA.

6. Plaintiff Pfizer Manufacturing Holdings LLC is a limited liability company organized and existing under the laws of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Manufacturing Holdings LLC is a general partner of PF PRISM C.V.

7. Upon information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

8. Upon information and belief, defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

9. Upon information and belief, Apotex Inc. is in the business of manufacturing, marketing and selling generic drug products. As a part of this business, upon information and belief, Apotex Inc., directly or through agents (including but not limited to Apotex Corp.), regularly files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. Upon information and belief, as a part of these ANDAs, Apotex Inc., directly or through agents (including but not limited to Apotex Corp.), regularly files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of U.S. patents that cover them. Upon information and belief, Apotex Inc.'s ordinary business operations include litigating and filing claims in the courts of the United States, including the United States District Court for the District of Delaware, regarding the infringement, validity, and/or enforceability of United States patents that cover or are alleged to cover generic drug products that are the subject of ANDAs filed by Apotex.

10. Upon information and belief, Apotex Inc. manufactures drug products for the purpose of sale within the United States, including in Delaware, by Apotex Corp.

11. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc. that serves as Apotex Inc.'s United States sales agent and distributor and sells and offers for sale Apotex Inc.'s drug products throughout the United States, including in Delaware. Upon information and belief, Apotex Inc. derives substantial revenue from services or things used or consumed in the state of Delaware. Apotex Inc. has stated on its website that "Apotex

Inc. serves a marketplace of over 115 countries, and is committed to growth on a global basis through affiliates such as Apotex Corp. in the United States of America."

12. Upon information and belief, Apotex Inc. and Apotex Corp. are two arms of the same business group, operate in concert with each other, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, employees of Apotex Inc., including Apotex Inc. CEO Dr. Bernard Sherman, frequently speak on behalf of Apotex Corp. Apotex Inc. has also stated on its website that Apotex is "a vertically integrated company" with a "preference . . . to develop, manufacture and market our own products—from API to finished dosage form to marketing and distribution."

13. The Notice Letter listed Kiran Krishnan, the "VP, US Regulatory Affairs" of "Apotex Corp" as the agent in the United States authorized to accept service of process for Apotex.

14. Upon information and belief, the website of Apotex Corp. is http://www.apotexcorp.com. Upon information and belief, apotexcorp.com is registered to "Apotex" at the Ontario address of Apotex Inc., and the administrative and technical contact listed by the Internet domain registrar for apotexcorp.com is an employee of Apotex Inc. Upon information and belief, visitors to http://www.apotexcorp.com are redirected to a web page on the website of Apotex Inc., http://www.apotex.com, that is directed towards and is accessible to residents of the United States, including Delaware, and that makes available a product catalog describing and marketing products sold, through Apotex Corp., in the United States, including Delaware.

JURISDICTION AND VENUE

15. Jurisdiction and venue are proper in this District pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 1391, and 1400(b).

16. Apotex Corp. is subject to personal jurisdiction in Delaware because, among other things, upon information and belief, Apotex Corp. is a Delaware corporation with a registered agent in Delaware (The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801); it is registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer CSR" and "Pharmacy - Wholesale" pursuant to 24 Del. C. § 2540; it is in the business of marketing drug products, which it distributes and sells throughout the United States, including in Delaware; it derives substantial revenue from services or things used or consumed in Delaware; it transacts business with companies located and/or headquartered in Delaware; and, upon receiving FDA approval, it intends to offer to sell and sell the generic product described in ANDA No. 204439 in the United States, including in Delaware.

17. Apotex Inc. is subject to personal jurisdiction in Delaware because, among other things, upon information and belief, Apotex Inc. is in the business of manufacturing drug products which it manufactures, distributes, and sells or offers to sell, primarily through Apotex Corp., throughout the United States, including in Delaware; it derives substantial revenue from services or things used or consumed in the state of Delaware; it transacts business with companies located and/or headquartered in Delaware; as part of its ordinary business practice of engaging in U.S. patent litigation, it has regularly and routinely litigated ANDA cases without contesting jurisdiction in this District, including by availing itself of this forum by filing counterclaims; it has, directly or through an agent, filed an ANDA, and/or been actively involved in the preparation and submission of an ANDA, for the purpose of seeking approval to engage in

the commercial manufacture, use, offer for sale, sale, and/or importation of the generic product described in ANDA No. 204439 in the United States, including in Delaware; upon receiving FDA approval, it intends to offer to sell and sell, primarily through Apotex Corp., the generic product described in ANDA No. 204439 throughout the United States, including in Delaware; and Apotex Corp., acting as Apotex Inc.'s agent and/or alter ego, regularly does and solicits business in Delaware and is engaged in a persistent, continuous and systematic course of conduct in Delaware in which it distributes, sells, and offers to sell Apotex Inc.'s drug products in Delaware and derives substantial revenue from services or things used or consumed in the state of Delaware on behalf of Apotex Inc.

18. Upon information and belief, both Apotex Corp. and Apotex Inc. have on multiple occasions consented to personal jurisdiction in patent infringement actions in this District, including in *Forest Laboratories, Inc., et al. v. Cobalt Laboratories Inc., et al.*, No. 08-cv-00021-LPS (D. Del.); *Boehringer Ingelheim Pharmaceuticals, Inc. v. Apotex Inc. and Apotex Corp.*, No. 08-cv-00065-SLR (D. Del.); *Sanofi-Aventis and Sanofi-Aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, No. 08-cv-00347 (D. Del.); *Aventis Pharma S.A. and Sanofi-Aventis U.S., LLC v. Apotex Inc. and Apotex Corp.*, No. 08-cv-00496 (D. Del.); *The Procter & Gamble Company and Hoffmann-La Roche, Inc. v. Apotex, Inc. and Apotex Corp.*, No. 09-cv-00143-LPS (D. Del.); *Pronova Biopharma Norge AS v. Apotex Corp. and Apotex Inc.*, No. 09-00304-SLR-MPT (D. Del.); *Daiichi Sankyo Co., Ltd. and Daiichi Sankyo, Inc. v. Apotex Inc. and Apotex Corp.*, No. 09-cv-00470 (D. Del.); *Cephalon, Inc. and Cephalon France v. Apotex Corp. and Apotex Inc.*, No. 10-cv-01078-GMS (D. Del.); *Alcon Research Ltd. v. Apotex Corp. and Apotex Inc.*, No. 09-cv-798-LDD (D. Del.); *Warner Chilcott Company, LLC and Hoffmann-La Roche, Inc. v. Apotex Inc. and Apotex Corp.*, No. 10-cv-01111-LPS (D. Del.); *Pfizer Inc. et al. v. Apotex,*

Inc. and Apotex Corp., No. 11-cv-606-GMS (D. Del.); *Senju Pharmaceutical Co., Ltd. et al. v. Apotex Inc. and Apotex Corp.*, No. 12-cv-0159-SLR; *Alcon Pharmaceuticals and Alcon Research Ltd. v. Apotex Inc. and Apotex Corp.*, No. 12-cv-00960 (D. Del.); *Pfizer Inc., et al. v. Apotex Inc. and Apotex Corp.*, No. 12-cv-00809-SLR (D. Del.); and most recently when they answered a complaint for infringement and asserted counterclaims on September 9, 2013 in *UCB Inc., et al. v. Apotex Corp., et al.*, No. 13-cv-01209 (D. Del.).

19. Upon information and belief, Apotex Inc. and Apotex Corp. have availed themselves of the legal protections of the state of Delaware by filing claims or counterclaims affirmatively seeking relief in other prior actions in this Court, including in *Torpharm, Inc., Apotex Corp. and Apotex Inc v. Pfizer Inc. and Warner-Lambert Company*, No. 03-cv-00990-SLR (D. Del.); *Apotex Inc. v AstraZeneca Pharmaceuticals LP*, No. 08-cv-00358-JJF-LPS (D. Del.); *Aventis-Pharma SA. and Sanofi-Aventis US, LLC v Apotex Inc and Apotex Corp.*, No. 08-cv-00496-GMS (D. Del.); *Forest Laboratories, Inc., et al. v. Cobalt Laboratories Inc., et al.*, No. 08-cv-00021-LPS (D. Del.); *Boehringer Ingelheim Pharmaceuticals, Inc. v. Apotex Inc. and Apotex Corp.*, No. 08-cv-00065-SLR (D. Del.); *Sanofi-Aventis and Sanofi-Aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, No. 08-cv-00347 (D. Del.); *The Procter & Gamble Company and Hoffmann-La Roche, Inc. v. Apotex, Inc. and Apotex Corp.*, No. 09-cv-00143-LPS (D. Del.); *Pronova Biopharma Norge AS v. Apotex Corp. and Apotex Inc.*, No. 09-00304-SLR-MPT (D. Del.); *Daiichi Sankyo Co., Ltd. and Daiichi Sankyo, Inc. v. Apotex Inc. and Apotex Corp.*, No. 09-cv-00470 (D. Del.); *Cephalon, Inc. and Cephalon France v. Apotex Corp. and Apotex Inc.*, No. 10-cv-01078-GMS (D. Del.); *Alcon Research Ltd. v. Apotex Corp. and Apotex Inc.*, No. 09-cv-798-LDD (D. Del.); *Warner Chilcott Company, LLC and Hoffmann-La Roche, Inc. v. Apotex Inc. and Apotex Corp.*, No. 10-cv-01111-LPS (D. Del.); *Pfizer Inc. et al. v. Apotex, Inc. and*

Apotex Corp., No. 11-cv-606-GMS (D. Del.); *Senju Pharmaceutical Co., Ltd. et al. v. Apotex , Inc. and Apotex Corp.*, No. 12-cv-0159-SLR; *Alcon Pharmaceuticals and Alcon Research Ltd. v. Apotex Inc. and Apotex Corp.*, No. 12-cv-00960 (D. Del.); *Pfizer Inc., et al. v. Apotex Inc. and Apotex Corp.*, No. 12-cv-00809-SLR (D. Del.); and, most recently, on September 9, 2013 in *UCB Inc., et al. v. Apotex Corp., et al.*, No. 13-cv-01209 (D. Del.).

BACKGROUND

20. TYGACIL® is a tetracycline class antibacterial indicated for the treatment of complicated skin and skin structure infections, complicated intra-abdominal infections, and community-acquired bacterial pneumonia, in adults. Each TYGACIL® vial contains 50 mg tigecycline lyophilized powder for reconstitution for intravenous infusion and 100 mg of lactose monohydrate.

21. In 2011, PF PRISM C.V. took an exclusive license to application no. 11/440,032 (which later issued as the '995 patent). Thereafter, PF PRISM C.V. contributed its rights under the exclusive license to Pfizer Pharmaceuticals LLC.

22. The '995 patent, entitled "Crystalline Solid Forms of Tigecycline and Methods of Preparing Same" (Exhibit A hereto), was duly and legally issued on February 12, 2013 to Wyeth LLC, as assignee, and subject to the exclusive license referenced herein. TYGACIL® and the use thereof are covered by one or more claims of the '995 patent, which has been listed in connection with TYGACIL® in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

23. Pfizer has all right, title, and interest in the '995 patent, including the right to sue for infringement thereof.

24. By letter dated August 13, 2013 (the "Notice Letter"), Apotex notified Pfizer that Apotex had submitted to the FDA ANDA No. 204439 for tigecycline injectable IV infusion, 50 mg/vial ("Apotex's ANDA Product"). Apotex's ANDA Product is a drug product that is a generic version of TYGACIL®.

25. The purpose of Apotex's submission of ANDA No. 204439 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product prior to the expiration of the '995 patent.

26. In the Notice Letter, Apotex also notified Pfizer that, as part of its ANDA No. 204439, Apotex had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '995 patent. Upon information and belief, Apotex submitted ANDA No. 204439 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '995 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Product.

27. In the Notice Letter, Apotex asserted that the Apotex ANDA Product does not infringe any claim of the '995 patent because it is "amorphous, and does not have X-ray powder diffraction peaks at about 5.2° 2Θ, about 8.3° 2Θ, about 11.1° 2Θ, and about 24.8° 2Θ." Apotex also asserted that the Apotex ANDA Product would not infringe any claim of the '995 patent because "the three claimed peaks are each independent required limitations of claims 1-10."

28. In the Notice Letter, Apotex included an Offer of Confidential Access to "certain information from its ANDA 204439," subject to certain specified conditions. Apotex did not specify what information from its ANDA that it was willing to provide, and the

conditions were unreasonably more stringent than the conditions customarily included in protective orders in ANDA litigation.

29. On September 11, 2013, Pfizer, through counsel, sent Mr. Omar Jabri, Esq., the contact person listed in Apotex's Offer of Confidential Access, a letter (the "Request for Confidential Access"). The Request for Confidential Access was sent by Federal Express, and, upon information and belief, was successfully received by September 12, 2013. The Request for Confidential Access proposed certain modifications to the conditions specified in Apotex's Offer of Confidential Access, including the ability to share samples and data with expert consultants retained on behalf of Pfizer. The Request for Confidential Access also requested particular documents, data, and samples necessary to verify the accuracy of Apotex's noninfringement claims and to determine whether Apotex's ANDA Product infringes the '995 patent.

30. On September 16, 2013, counsel for Apotex and counsel for Pfizer discussed the terms of Pfizer's Request for Confidential Access. Counsel for Apotex made clear that absent a lawsuit, Apotex would provide only ANDA No. 204439 and the "open" part of the Drug Master File to which the ANDA makes reference. Apotex refused to provide any samples of the Apotex ANDA Product or other materials requested in the Request for Confidential Access, though counsel for Pfizer indicated that such materials were relevant to the determination whether Apotex's ANDA Product infringes the '995 patent.

31. This action is being commenced before the expiration of forty-five days from the date of the receipt of the Notice Letter.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 8,372,995 UNDER 35 U.S.C. § 271(e)(2)

32. Pfizer incorporates each of the preceding paragraphs 1–31 as if fully set forth herein.

33. Apotex's submission of ANDA No. 204439 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product prior to the expiration of the '995 patent was an act of infringement of the '995 patent under 35 U.S.C. § 271(e)(2)(A).

34. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product would infringe one or more claims of the '995 patent.

35. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling upon approval of ANDA No. 204439.

36. Upon information and belief, the use of Apotex's ANDA Product in accordance with and as directed by Apotex's proposed labeling for that product would infringe one or more claims of the '995 patent.

37. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '995 patent when ANDA No. 204439 is approved, and plans and intends to, and will, do so after approval.

38. Upon information and belief, Apotex knows that Apotex's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '995 patent, and that Apotex's ANDA Product and its proposed labeling are not suitable for substantial

noninfringing use. Upon information and belief, Apotex plans and intends to, and will, contribute to infringement of the '995 patent after approval of ANDA No. 204439.

39. Upon information and belief, after approval of ANDA No. 204439, Apotex will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the '995 patent prior to the expiration of the patent.

40. The foregoing actions by Apotex constitute and/or will constitute infringement of the '995 patent, active inducement of infringement of the '995 patent, and contribution to the infringement by others of the '995 patent.

41. Upon information and belief, Apotex has acted with full knowledge of the '995 patent and without a reasonable basis for believing that it would not be liable for infringing the '995 patent, actively inducing infringement of the '995 patent, and contributing to the infringement by others of the '995 patent.

42. Unless Apotex is enjoined from infringing the '995 patent, actively inducing infringement of the '995 patent, and contributing to the infringement by others of the '995 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,372,995

43. Pfizer incorporates each of the preceding paragraphs 1–42 as if fully set forth herein.

44. Apotex has knowledge of the '995 patent.

45. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product would infringe one or more claims of the '995 patent.

46. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling after approval of ANDA No. 204439.

47. Upon information and belief, the use of Apotex's ANDA Product in accordance with and as directed by Apotex's proposed labeling for that product would infringe one or more claims of the '995 patent.

48. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '995 patent when ANDA No. 204439 is approved, and plans and intends to, and will, do so after approval.

49. Upon information and belief, Apotex knows that Apotex's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '995 patent, and that Apotex's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Apotex plans and intends to, and will, contribute to infringement of the '995 patent after approval of ANDA No. 204439.

50. Upon information and belief, after approval of ANDA No. 204439, Apotex will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the '995 patent prior to the expiration of the patent.

51. The foregoing actions by Apotex constitute and/or will constitute infringement of the '995 patent, active inducement of infringement of the '995 patent, and contribution to the infringement by others of the '995 patent.

52. Upon information and belief, Apotex acted without a reasonable basis for believing that it would not be liable for infringing the '995 patent, actively inducing infringement of the '995 patent, and contributing to the infringement by others of the '995 patent.

53. Unless Apotex is enjoined from infringing the '995 patent, actively inducing infringement of the '995 patent, and contributing to the infringement by others of the '995 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

WHEREFORE, Pfizer requests the following relief:

(a) A judgment that Apotex has infringed the '995 patent;

(b) A judgment ordering that the effective date of any FDA approval for Apotex to make, use, offer for sale, sell, market, distribute, or import Apotex's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '995 patent, be not earlier than the expiration date of the '995 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Apotex, and all persons acting in concert with Apotex, from making, using, selling, offering for sale, marketing, distributing, or importing Apotex's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '995 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '995 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Apotex's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes

the '995 patent, prior to the expiration date of the '995 patent, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '995 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Pfizer's costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

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