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,	)	
v.	)	C.A. No. _____
CFT PHARMACEUTICALS LLC,	)	
Defendant.	)	

COMPLAINT

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

NATURE OF THE ACTION

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 CFT Pharmaceuticals LLC (hereinafter "CFT") of an Abbreviated New Drug Application ("ANDA") No. 205722 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. 7,879,828 ("the '828 patent"), and 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 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 235 East 42nd Street, New York, New York 10017. 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 under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and registered at the Trade Register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456 and that for all purposes is represented by and acting through its general partner Pfizer Manufacturing Holdings LLC, a limited liability company organized under the laws of the State of Delaware, USA, and having its address at 235 East 42nd Street, New York, New York 10017, registered in the register held by the Secretary of State of the State of Delaware under number 4869755. 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 CFT Pharmaceuticals LLC is a limited liability company organized and existing under the laws of Wisconsin, with a place of business at 10 E. Doty St., Suite 600, Madison, Wisconsin 53703.

8. Pfizer offers for sale and sells a substantial amount of TYGACIL® within this District on an annualized basis. Upon information and belief, if approved, CFT will engage in the commercial manufacture, use, or sale of its tigecycline lyophilized product for IV infusion containing 50 mg tigecycline within the United States, including in Delaware.

JURISDICTION AND VENUE

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

10. Upon information and belief, CFT 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. 205722 in the United States, including in Delaware; and, upon receiving FDA approval, it intends to offer to sell and sell the generic product described in ANDA No. 205722 in the United States, including in Delaware.

BACKGROUND

11. 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.

12. The '828 patent, entitled "Tigecycline Compositions and Methods of Preparation" (Exhibit A hereto), was duly and legally issued on February 1, 2011 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 '828 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."

13. In 2011, PF PRISM C.V. took an exclusive license to the '828 patent and 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.

14. The '995 patent, entitled "Crystalline Solid Forms of Tigecycline and Methods of Preparing Same" (Exhibit B 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."

15. Pfizer has all right, title, and interest in the '828 patent and the '995 patent, including the right to sue for infringement thereof.

16. By letter dated May 7, 2014 (the "Notice Letter"), CFT notified Pfizer that CFT had submitted to the FDA ANDA No. 205722 for tigecycline lyophilized product for IV infusion containing 50 mg tigecycline ("CFT's ANDA Product"). CFT's ANDA Product is a drug product that is a generic version of TYGACIL®.

17. The purpose of CFT's submission of ANDA No. 205722 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or

importation of CFT's ANDA Product prior to the expiration of the '828 patent and the '995 patent.

18. In the Notice Letter, CFT also notified Pfizer that, as part of its ANDA No. 205722, CFT 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 '828 patent and the '995 patent. Upon information and belief, CFT submitted ANDA No. 205722 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '828 patent and the '995 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of CFT's ANDA Product, or alternatively, that these patents are invalid.

19. The parties, while reserving all rights, ultimately negotiated terms under which Pfizer could review the CFT ANDA, but CFT refused to produce other CFT internal documents and data relevant to infringement.

20. 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. 7,879,828 UNDER 35 U.S.C. § 271(e)(2)

21. Pfizer incorporates each of the preceding paragraphs 1–20 as if fully set forth herein.

22. CFT's submission of ANDA No. 205722 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of CFT's ANDA Product prior to the expiration of the '828 patent was an act of infringement of the '828 patent under 35 U.S.C. § 271(e)(2)(A).

23. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of CFT's ANDA Product would infringe one or more claims of the '828 patent, either literally or under the doctrine of equivalents.

24. Upon information and belief, CFT will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of CFT's ANDA Product with its proposed labeling upon approval of ANDA No. 205722.

25. Upon information and belief, the use of CFT's ANDA Product in accordance with and as directed by CFT's proposed labeling for that product would infringe one or more claims of the '828 patent.

26. Upon information and belief, CFT plans and intends to, and will, actively induce infringement of the '828 patent when ANDA No. 205722 is approved, and plans and intends to, and will, do so after approval.

27. Upon information and belief, CFT knows that CFT's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '828 patent, and that CFT's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, CFT plans and intends to, and will, contribute to infringement of the '828 patent after approval of ANDA No. 205722.

28. Upon information and belief, after approval of ANDA No. 205722, CFT 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 '828 patent prior to the expiration of the patent.

29. The foregoing actions by CFT constitute and/or will constitute infringement of the ’828 patent, active inducement of infringement of the ’828 patent, and contribution to the infringement by others of the ’828 patent.

30. Upon information and belief, CFT has acted with full knowledge of the ’828 patent and without a reasonable basis for believing that it would not be liable for infringing the ’828 patent, actively inducing infringement of the ’828 patent, and contributing to the infringement by others of the ’828 patent.

31. Unless CFT is enjoined from infringing the ’828 patent, actively inducing infringement of the ’828 patent, and contributing to the infringement by others of the ’828 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT II – 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. CFT’s submission of ANDA No. 205722 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of CFT’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 CFT’s ANDA Product would infringe one or more claims of the ’995 patent, either literally or under the doctrine of equivalents.

35. Upon information and belief, CFT will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of CFT’s ANDA Product with its proposed labeling upon approval of ANDA No. 205722.

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

37. Upon information and belief, CFT plans and intends to, and will, actively induce infringement of the '995 patent when ANDA No. 205722 is approved, and plans and intends to, and will, do so after approval.

38. Upon information and belief, CFT knows that CFT's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '995 patent, and that CFT's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, CFT plans and intends to, and will, contribute to infringement of the '995 patent after approval of ANDA No. 205722.

39. Upon information and belief, after approval of ANDA No. 205722, CFT 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 CFT 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, CFT 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 CFT 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 III – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,879,828

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

44. CFT has knowledge of the ’828 patent.

45. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of CFT’s ANDA Product would infringe one or more claims of the ’828 patent, either literally or under the doctrine of equivalents.

46. Upon information and belief, CFT will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of CFT’s ANDA Product with its proposed labeling after approval of ANDA No. 205722.

47. Upon information and belief, the use of CFT’s ANDA Product in accordance with and as directed by CFT’s proposed labeling for that product would infringe one or more claims of the ’828 patent.

48. Upon information and belief, CFT plans and intends to, and will, actively induce infringement of the ’828 patent when ANDA No. 205722 is approved, and plans and intends to, and will, do so after approval.

49. Upon information and belief, CFT knows that CFT’s ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’828 patent, and that CFT’s ANDA Product and its proposed labeling are not suitable for substantial noninfringing

use. Upon information and belief, CFT plans and intends to, and will, contribute to infringement of the ’828 patent after approval of ANDA No. 205722.

50. Upon information and belief, after approval of ANDA No. 205722, CFT 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 ’828 patent prior to the expiration of the patent.

51. The foregoing actions by CFT constitute and/or will constitute infringement of the ’828 patent, active inducement of infringement of the ’828 patent, and contribution to the infringement by others of the ’828 patent.

52. Upon information and belief, CFT acted without a reasonable basis for believing that it would not be liable for infringing the ’828 patent, actively inducing infringement of the ’828 patent, and contributing to the infringement by others of the ’828 patent.

53. Unless CFT is enjoined from infringing the ’828 patent, actively inducing infringement of the ’828 patent, and contributing to the infringement by others of the ’828 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

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

54. Pfizer incorporates each of the preceding paragraphs 1–53 as if fully set forth herein.

55. CFT has knowledge of the ’995 patent.

56. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of CFT’s ANDA Product would infringe one or more claims of the ’995 patent, either literally or under the doctrine of equivalents.

57. Upon information and belief, CFT will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of CFT's ANDA Product with its proposed labeling after approval of ANDA No. 205722.

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

59. Upon information and belief, CFT plans and intends to, and will, actively induce infringement of the '995 patent when ANDA No. 205722 is approved, and plans and intends to, and will, do so after approval.

60. Upon information and belief, CFT knows that CFT's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '995 patent, and that CFT's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, CFT plans and intends to, and will, contribute to infringement of the '995 patent after approval of ANDA No. 205722.

61. Upon information and belief, after approval of ANDA No. 205722, CFT 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.

62. The foregoing actions by CFT 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.

63. Upon information and belief, CFT 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.

64. Unless CFT 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 CFT has infringed the ’828 patent and the ’995 patent;

(b) A judgment ordering that the effective date of any FDA approval for CFT to make, use, offer for sale, sell, market, distribute, or import CFT’s ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the ’828 patent or the ’995 patent be not earlier than the expiration date of the ’828 patent or the ’995 patent, respectively, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining CFT, and all persons acting in concert with CFT, from making, using, selling, offering for sale, marketing, distributing, or importing CFT’s ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the ’828 patent or the ’995 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’828 patent or the ’995 patent, respectively, 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 CFT’s ANDA Product, or any product or compound the

making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '828 patent or the '995 patent, prior to the expiration date of the '828 patent or the '995 patent, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '828 patent or 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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