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. _____
AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Pfizer Inc., Wyeth LLC, Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer 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 defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively "Aurobindo") of an Abbreviated New Drug Application ("ANDA") No. 206335 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 Aurobindo Pharma Ltd. ("Aurobindo Pharma") is a corporation organized and existing under the laws of India, with a place of

business at Water Mark Building, Plot No. 11, Survey no.9, Kondapur, Hitech City, Hyderabad - 500 084, Andhra Pradesh, India.

8. Upon information and belief, defendant Aurobindo Pharma USA, Inc. ("Aurobindo USA") is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 6, Wheeling Road, Dayton, New Jersey 08810 and is a wholly-owned subsidiary of Aurobindo Pharma.

9. Upon information and belief, Aurobindo USA's preparation and submission of ANDA No. 206335 was done at the direction, under the control, and for the direct benefit of Aurobindo Pharma. Upon information and belief, Aurobindo Pharma directed Aurobindo USA to submit ANDA No. 206335.

10. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 206335, Aurobindo Pharma and Aurobindo USA will act in concert to distribute and sell the generic product described in ANDA No. 206335 throughout the United States and within Delaware.

JURISDICTION AND VENUE

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

12. Aurobindo is subject to personal jurisdiction in Delaware because, among other things, it regularly transacts and/or solicits business in Delaware, has consented to jurisdiction in Delaware in cases arising out of its filing of ANDAs, and has purposefully availed itself of this forum such that it should reasonably anticipate being haled into court here.

13. Upon information and belief, Aurobindo 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. 206335 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. 206335 in the United States, including in Delaware.

14. Upon information and belief, Aurobindo USA is a corporation organized and existing under the laws of the State of Delaware and has a registered agent in Delaware (The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., 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.

15. Upon information and belief, Aurobindo USA in concert with Aurobindo Pharma is in the business of manufacturing drug products, which Aurobindo manufactures, distributes, sells, or offers to sell throughout the United States, including in Delaware; it derives substantial revenue from services or things used or consumed 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; 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. 206335 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. 206335 in the United States, including in Delaware.

16. Upon information and belief, Aurobindo Pharma formed Aurobindo USA as its U.S. marketing arm and all of the products Aurobindo USA sells are manufactured by Aurobindo Pharma. Upon information and belief, Aurobindo Pharma continues to closely control and dominate Aurobindo USA by including Aurobindo Pharma directors, officers, and executives on Aurobindo

USA's board of directors; the Chairman of Aurobindo Pharma has routinely appointed those board members to the board of Aurobindo USA; the board of directors for Aurobindo USA has never met, nor voted on a chairman. Upon information and belief, the Chairman of Aurobindo Pharma directs the corporate strategy for Aurobindo USA and makes primary decisions without input from Aurobindo USA with respect to real estate transactions, financial decisions, delegation of manufacturing and other corporate-related responsibilities, including the spinning off of subsidiaries from Aurobindo USA.

17. Aurobindo Pharma has represented to the public that Aurobindo USA and Aurobindo Pharma operate as a single entity. For example, in its Annual Reports, published on its website (www.aurobindo.com), Aurobindo Pharma includes the financials of Aurobindo USA and has in prior years explicitly identified Aurobindo USA as among "companies under the same management."

18. Upon information and belief, Aurobindo has availed itself of the legal protections of the state of Delaware by filing counterclaims affirmatively seeking relief in other prior actions in this Court, including in *Sanofi-Aventis et al.* v. *Actavis South Atlantic LLC et al.*, 1:2007-cv-00572 (D. Del.); *Helsinn Healthcare SA et al.* v. *Aurobindo Pharma Ltd. et al.*, 1:2013-cv-00688 (D. Del.); and *UCB Inc. et al.* v. *Aurobindo Pharma Ltd., et al.*, 1:2013-cv-01210 (D. Del.).

BACKGROUND

19. 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.

20. 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."

21. 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.

22. 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."

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

24. By letter dated May 19, 2014 (the "Notice Letter"), Aurobindo notified Pfizer that Aurobindo had submitted to the FDA ANDA No. 206335 for tigecycline lyophilized product for IV infusion containing 50 mg tigecycline ("Aurobindo's ANDA Product"). Aurobindo's ANDA Product is a drug product that is a generic version of TYGACIL®.

25. The purpose of Aurobindo's submission of ANDA No. 206335 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to the expiration of the '828 patent and the '995 patent.

26. In the Notice Letter, Aurobindo also notified Pfizer that, as part of its ANDA No. 206335, Aurobindo had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, with respect to the '828 patent and the '995 patent. Upon information and belief, Aurobindo submitted ANDA No. 206335 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 Aurobindo's ANDA Product, or alternatively, that these patents are invalid.

27. The parties were unable to agree on terms under which Pfizer could review Aurobindo's ANDA, and Aurobindo refused to produce other Aurobindo internal documents and data relevant to infringement.

28. 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)

29. Pfizer incorporates each of the preceding paragraphs 1–28 as if fully set forth herein.

30. Aurobindo's submission of ANDA No. 206335 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo'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).

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

32. Upon information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product with its proposed labeling upon approval of ANDA No. 206335.

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

34. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '828 patent when ANDA No. 206335 is approved, and plans and intends to, and will, do so after approval.

35. Upon information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '828 patent, and that Aurobindo's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '828 patent after approval of ANDA No. 206335.

36. Upon information and belief, after approval of ANDA No. 206335, Aurobindo 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.

37. The foregoing actions by Aurobindo 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.

38. Upon information and belief, Aurobindo 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.

39. Unless Aurobindo 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)

40. Pfizer incorporates each of the preceding paragraphs 1–39 as if fully set forth herein.

41. Aurobindo's submission of ANDA No. 206335 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo'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).

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

43. Upon information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product with its proposed labeling upon approval of ANDA No. 206335.

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

45. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '995 patent when ANDA No. 206335 is approved, and plans and intends to, and will, do so after approval.

46. Upon information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '995 patent, and that Aurobindo's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '995 patent after approval of ANDA No. 206335.

47. Upon information and belief, after approval of ANDA No. 206335, Aurobindo 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.

48. The foregoing actions by Aurobindo 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.

49. Upon information and belief, Aurobindo 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.

50. Unless Aurobindo 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

51. Pfizer incorporates each of the preceding paragraphs 1–50 as if fully set forth herein.

52. Aurobindo has knowledge of the '828 patent.

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

54. Upon information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product with its proposed labeling after approval of ANDA No. 206335.

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

56. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '828 patent when ANDA No. 206335 is approved, and plans and intends to, and will, do so after approval.

57. Upon information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '828 patent, and that Aurobindo's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '828 patent after approval of ANDA No. 206335.

58. Upon information and belief, after approval of ANDA No. 206335, Aurobindo 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.

59. The foregoing actions by Aurobindo 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.

60. Upon information and belief, Aurobindo 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.

61. Unless Aurobindo 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

62. Pfizer incorporates each of the preceding paragraphs 1–61 as if fully set forth herein.

63. Aurobindo has knowledge of the '995 patent.

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

65. Upon information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product with its proposed labeling after approval of ANDA No. 206335.

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

67. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '995 patent when ANDA No. 206335 is approved, and plans and intends to, and will, do so after approval.

68. Upon information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '995 patent, and that Aurobindo's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '995 patent after approval of ANDA No. 206335.

69. Upon information and belief, after approval of ANDA No. 206335, Aurobindo 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.

70. The foregoing actions by Aurobindo 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.

71. Upon information and belief, Aurobindo 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.

72. Unless Aurobindo 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 Aurobindo has infringed the '828 patent and the '995 patent;

(b) A judgment ordering that the effective date of any FDA approval for Aurobindo to make, use, offer for sale, sell, market, distribute, or import Aurobindo'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 Aurobindo, and all persons acting in concert with Aurobindo, from making, using, selling, offering for sale, marketing, distributing, or importing Aurobindo'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 Aurobindo'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

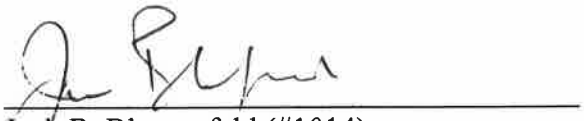
'995 patent, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '828 patent or the '995 patent;

(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



Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Thomas H.L. Selby
David I. Berl
Stanley E. Fisher
Adam D. Harber
Martha C. Kidd
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000

July 2, 2014