IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

PFIZER INC., WYETH LLC, PFIZER PHARMACEUTICALS LLC, PF PRISM C.V., and PFIZER MANUFACTURING HOLDINGS LLC, Plaintiffs, v. MYLAN INC., AGILA SPECIALTIES PRIVATE LTD., and MYLAN PHARMACEUTICALS INC., Defendants.	Civil Action No. 1:15-CV-4

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 Mylan Inc., Agila Specialties Private Ltd., and Mylan Pharmaceuticals Inc. (collectively "Defendants") of an Abbreviated New Drug Application ("ANDA") No. 203309 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 the State 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 the State 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 the State 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, 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 the State 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 Mylan Inc. ("Mylan") is a corporation organized and existing under the laws of the State of Pennsylvania, having a place of business at Robert J. Coury Global Center, 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

8. Upon information and belief, defendant Agila Specialties Private Limited ("Agila") is a corporation organized and existing under the laws of India, with a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Agila is a wholly owned subsidiary of Mylan.

9. Upon information and belief, defendant Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") is a corporation organized and existing under the laws of the State of West Virginia, with a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan.

10. Upon information and belief, Agila's preparation and submission of ANDA No. 203309 was done at the direction, under the control, and for the direct benefit of Mylan and/or Mylan Pharmaceuticals. Upon information and belief, Mylan and/or Mylan Pharmaceuticals directed Agila to submit ANDA No. 203309.

11. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 203309, Defendants will act in concert to distribute and sell the generic product described in ANDA No. 203309 throughout the United States and within West Virginia.

JURISDICTION AND VENUE

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

13. Defendants are subject to personal jurisdiction in West Virginia because, among other things, they regularly transact and/or solicit business in West Virginia and have purposefully availed themselves of this forum such that they should reasonably anticipate being haled into court here. Upon information and belief, Defendants have had persistent and continuous contacts with this judicial district, including developing and/or manufacturing pharmaceutical products in this judicial district, which are sold in this judicial district. Mylan, Agila, and Mylan Pharmaceuticals have done so with each other's authorization, participation, or assistance, or acting in concert with each other.

14. Upon information and belief, Defendants conduct business throughout the United States, including West Virginia, under the trade name "Mylan Pharmaceuticals."

15. Upon information and belief, Defendants are subject to personal jurisdiction in West Virginia because they maintain and conduct ongoing business out of offices in this judicial district. Upon information and belief, Defendants maintain a headquarters in West Virginia and manufacturing operations in West Virginia.

16. According to Mylan's website (www.mylan.com), it is "one of the largest generics and specialty pharmaceutical companies in the world," and it applies "one global quality standard across [its] facilities and across [its] product line . . . regardless of the market."

17. On information and belief, Mylan, Agila, and/or Mylan Pharmaceuticals regularly do business in West Virginia and have engaged in a persistent course of conduct within West Virginia by continuously and systematically placing goods into the stream of commerce for

distribution throughout the United States, including West Virginia, and/or by directly selling pharmaceutical products in West Virginia. Mylan, Agila, and Mylan Pharmaceuticals have done so with each other's authorization, participation, or assistance, or acting in concert with each other.

18. Upon information and belief, Mylan, Agila, and Mylan Pharmaceuticals operate as an integrated, unitary generic pharmaceutical business. For example, Mylan includes in its Annual Reports, published on its website, the activities of Agila and Mylan Pharmaceuticals, including the revenue earned and other financial information. Mylan's website provides information about Mylan, Agila, and Mylan Pharmaceuticals, such as stating that Mylan's "global manufacturing platform" includes locations in India, where Agila is incorporated, and West Virginia, where Mylan Pharmaceuticals is incorporated. Neither Agila nor Mylan Pharmaceuticals maintain separate websites. Mylan is divided into a number of business units, including the "Generics" business. Upon information and belief, Agila and Mylan Pharmaceuticals in whole or in part comprise this "Generics" business.

19. Upon information and belief, Mylan, Agila, and Mylan Pharmaceuticals have overlapping officers and directors, with management and operation of Agila, Mylan Pharmaceuticals, and the Generics business occurring, at least in part, at the respective headquarters of Mylan, Agila, and/or Mylan Pharmaceuticals. Upon information and belief, Mylan issues press releases when generic drugs are approved by the FDA or when other events concerning the commercialization of a generic drug occur involving its Generics business. For example, when Agila recalls defective drugs, Mylan notifies consumers of the recall and consumers are directed to contact Mylan Customer Service with concerns.

20. Upon information and belief, Mylan recently acquired Agila and has represented to the public that Agila and Mylan now operate as a single entity. For example, a Current Report issued

October 30, 2014 published on Mylan's website states that Agila was "legally merge[d] . . . into Mylan Laboratories Limited," another Mylan subsidiary. Mylan further explains in its Annual Reports that the "Agila Acquisition involves the integration of Agila with our existing businesses," that Mylan will "devote significant management attention and resources to integrating Agila," and that integrating Agila will "combin[e] corporate cultures." Mylan stated in its Annual Report that by acquiring Agila is has become a "global pharmaceutical company" that includes a "vertically-integrated manufacturing platform." Mylan's CEO publicly commented that the acquisition involved "taking the Agila pipeline, assets, capacity, [and] marrying that up with [Mylan's] infrastructure." Mylan's President publicly stated that the "acquisition of Agila transforms Mylan into a global powerhouse," and that "the combination strengthens Mylan's existing platform in developed markets, such as the U.S., where Mylan can now offer customers an even more comprehensive portfolio of high quality products." Mylan's Executive Chairman publicly "welcome[d] Agila's employees to Mylan," and noted that they would "be able to integrate our businesses seamlessly and efficiently."

21. In a letter dated November 26, 2014 notifying Pfizer pursuant to the FDCA that Agila had filed ANDA No. 203309 (the "Notice Letter"), Agila carbon-copied Jill M. Ondos, Esq., Mylan's Senior Vice President and Global General Counsel for IP and Litigation.

22. Upon information and belief, Defendants together are in the business of manufacturing drug products, which Defendants manufacture, distribute, sell, or offer to sell throughout the United States, including in West Virginia; they derive substantial revenue from services or things used or consumed in West Virginia; as part of their ordinary business practice of engaging in U.S. patent litigation, they have regularly and routinely litigated ANDA cases without contesting jurisdiction in this judicial district; they have, 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. 203309 in the United States, including in West Virginia; and, upon receiving FDA approval, they intend to offer to sell and sell the generic product described in ANDA No. 203309 in the United States, including in West Virginia, and thereby cause Pfizer to lose sales in West Virginia.

BACKGROUND

23. 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.

24. 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."

25. 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.

26. 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."

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

28. Defendants notified Pfizer in the Notice Letter that Defendants had submitted to the FDA ANDA No. 203309 for tigecycline lyophilized product for IV infusion containing 50 mg tigecycline ("Defendants' ANDA Product"). Defendants' ANDA Product is a drug product that is a generic version of TYGACIL®.

29. The purpose of Defendants' submission of ANDA No. 203309 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product prior to the expiration of the '828 patent and the '995 patent.

30. In the Notice Letter, Defendants also notified Pfizer that, as part of their ANDA No. 203309, Defendants 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, Defendants submitted ANDA No. 203309 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 Defendants' ANDA Product, or alternatively, that these patents are invalid.

31. In an exchange of correspondence, counsel for Defendants and counsel for Pfizer discussed the terms of Pfizer's Request for Confidential Access. The parties were unable to agree on terms under which Pfizer could review Defendants' ANDA, and Defendants refused to produce other internal documents and data relevant to infringement.

32. 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)

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

34. Defendants' submission of ANDA No. 203309 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' 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).

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

36. Upon information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' ANDA Product with its proposed labeling upon approval of ANDA No. 203309.

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

38. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '828 patent when ANDA No. 203309 is approved, and plan and intend to, and will, do so after approval.

39. Upon information and belief, Defendants know that their ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '828 patent, and that

their ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '828 patent after approval of ANDA No. 203309.

40. Upon information and belief, after approval of ANDA No. 203309, Defendants 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.

41. The foregoing actions by Defendants 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.

42. Upon information and belief, Defendants have acted with full knowledge of the '828 patent and without a reasonable basis for believing that they 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.

43. Unless Defendants are 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)

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

45. Defendants' submission of ANDA No. 203309 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' 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).

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

47. Upon information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' ANDA Product with its proposed labeling upon approval of ANDA No. 203309.

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

49. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '995 patent when ANDA No. 203309 is approved, and plan and intend to, and will, do so after approval.

50. Upon information and belief, Defendants know that their ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '995 patent, and that their ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '995 patent after approval of ANDA No. 203309.

51. Upon information and belief, after approval of ANDA No. 203309, Defendants 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.

52. The foregoing actions by Defendants 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.

53. Upon information and belief, Defendants have 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.

54. Unless Defendants are 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

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

56. Defendants have knowledge of the '828 patent.

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

58. Upon information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' ANDA Product with its proposed labeling after approval of ANDA No. 203309.

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

60. Upon information and belief, Defendants plan and intend to, and will, actively

induce infringement of the '828 patent when ANDA No. 203309 is approved, and plan and intend to, and will, do so after approval.

61. Upon information and belief, Defendants know that their ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '828 patent, and that their ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '828 patent after approval of ANDA No. 203309.

62. Upon information and belief, after approval of ANDA No. 203309, Defendants 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.

63. The foregoing actions by Defendants 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.

64. Upon information and belief, Defendants 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.

65. Unless Defendants are 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

66. Pfizer incorporates each of the preceding paragraphs 1–65 as if fully set forth herein.

67. Defendants have knowledge of the '995 patent.

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

69. Upon information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' ANDA Product with its proposed labeling after approval of ANDA No. 203309.

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

71. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '995 patent when ANDA No. 203309 is approved, and plan and intend to, and will, do so after approval.

72. Upon information and belief, Defendants know that their ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '995 patent, and that their ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '995 patent after approval of ANDA No. 203309.

73. Upon information and belief, after approval of ANDA No. 203309, Defendants 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.

74. The foregoing actions by Defendants 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.

75. Upon information and belief, Defendants 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.

76. Unless Defendants are 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 Defendants have infringed the '828 patent and the '995 patent;

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

Dated: January 9, 2015

SCHRADER BYRD & COMPANION, PLLC

/s/ James F. Companion

James F. Companion (#790)
Yolonda G. Lambert (#2130)
The Maxwell Centre
32-20th Street, Suite 500
Wheeling, WV 26003
Phone: (304) 233-3390
Fax: (304) 233-2769
jfc@schraderlaw.com
ygl@schraderlaw.com

Attorneys for Plaintiffs

OF COUNSEL:

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