IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| PFIZER INC., WARNER-LAMBERT COMPANY LLC, PF PRISM C.V., PFIZER MANUFACTURING HOLDINGS LLC and PFIZER PFE IRELAND PHARMACEUTICALS HOLDING 1 B.V., | ) | |
| Plaintiff, | ) | |
| v. | ) | C.A. No. _____ |
| ZYDUS PHARMACEUTICALS (USA) INC., ZYDUS WORLDWIDE DMCC and CADILA HEALTHCARE, LTD., | ) | |
| Defendants. | ) | |

**COMPLAINT**

Pfizer Inc., Warner-Lambert Company LLC, PF PRISM C.V., Pfizer Manufacturing Holdings LLC, and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. (collectively "Pfizer") file this Complaint for patent infringement against Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide DMCC, and Cadila Healthcare, Ltd. (collectively, "Zydus"), and by their attorneys, hereby allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Zydus's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of IBRANCE® (Palbociclib) capsules, 75 mg, 100 mg, and 125 mg, prior to the expiration of U.S. Patent No. 6,936,612 ("the '612 patent"); U.S. Patent No. 7,208,489 ("the '489 patent"); and

U.S. Patent No. 7,456,168 ("the '168 patent"). These three patents are referred to collectively herein as "the patents-in-suit."

2. Zydus Worldwide DMCC notified Pfizer by letter dated March 26, 2019 ("Zydus's Notice Letter") that it had submitted to the FDA ANDA No. 213098. ("Zydus's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of generic Palbociclib capsules, 75mg, 100 mg, and 125 mg ("Zydus's ANDA Product") prior to the expiration of the patents-in-suit.

## PARTIES

3. 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. Pfizer Inc. is the holder of New Drug Application ("NDA") No. 207103 for the manufacture and sale of palbociclib tablets, 75 mg, 100 mg and 125 mg, which has been approved by the FDA.

4. Plaintiff Warner-Lambert Company 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.

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, 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.

6. Plaintiff Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. is a private limited liability company (*besloten vennootschap*) organized under the laws of the Netherlands, having

its registered seat in Rotterdam, the Netherlands, having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands.

7. Upon information and belief, defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

8. Upon information and belief, defendant Zydus Worldwide DMCC is a company organized and existing under the laws of the United Arab Emirates with its principal place of business at Unit No 908, Armada 2, Plot No JLT PH2 P2A, Jumeirah Lakes, Dubai, United Arab Emirates. Upon information and belief, Zydus Worldwide DMCC is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

9. Upon information and belief, defendant Cadila Healthcare Ltd. is a company organized and existing under the laws of the Republic of India, with its principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad, Gujarat 380015, India. Upon information and belief, Cadila Healthcare Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products through various operating subsidiaries, including Zydus Pharmaceuticals (USA) Inc.

10. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. and Zydus Worldwide DMCC are wholly owned indirect subsidiaries of Cadila Healthcare Ltd. Zydus

Pharmaceuticals (USA) Inc., Zydus Worldwide DMCC, and Cadila Healthcare Ltd. are collectively referred to herein as "Zydus."

11. Upon information and belief, Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. acted in concert to prepare and submit Zydus's ANDA to the FDA.

12. Upon information and belief, Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. know and intend that upon approval of Zydus's ANDA, Cadila Healthcare Ltd. will manufacture Zydus's ANDA Product and Zydus Pharmaceuticals (USA) Inc. and Zydus Worldwide DMCC will directly or indirectly market, sell, and distribute Zydus's ANDA Product throughout the United States, including in Delaware. Upon information and belief, Zydus Pharmaceuticals (USA) Inc., Cadila Healthcare Ltd., and Zydus Worldwide DMCC are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Zydus's ANDA Product, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Cadila Healthcare Ltd. and Zydus Pharmaceuticals (USA) Inc. participated in, assisted, and cooperated with Zydus Worldwide DMCC in the acts complained of herein.

13. Upon information and belief, following any FDA approval of Zydus's ANDA, Zydus Pharmaceuticals (USA) Inc., Cadila Healthcare Ltd., and Zydus Pharmaceuticals (USA) Inc. will act in concert to distribute and sell Zydus's ANDA Product throughout the United States, including within Delaware.

## JURISDICTION

14. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

15. Zydus Pharmaceuticals (USA) Inc. is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Pfizer's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

16. Zydus Worldwide DMCC is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Zydus Worldwide DMCC develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Pfizer's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

17. Cadila Healthcare Ltd. is subject to personal jurisdiction in Delaware because, among other things, Cadila Healthcare Ltd., itself and through its wholly-owned indirect subsidiaries Zydus Worldwide DMCC and Zydus Pharmaceuticals (USA) Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Cadila Healthcare Ltd., itself and through its subsidiaries Zydus Worldwide DMCC and Zydus Pharmaceuticals (USA)

Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Cadila Healthcare Ltd. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Zydus Pharmaceuticals (USA) Inc. and Zydus Worldwide DMCC, and therefore the activities of Zydus Pharmaceuticals (USA) Inc. and Zydus Worldwide DMCC in this jurisdiction are attributed to Cadila Healthcare Ltd.

18. Zydus has previously used the process contemplated by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification 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), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

19. Upon information and belief, Zydus, with knowledge of the Hatch-Waxman Act process, directed Zydus's Notice Letter to, *inter alia*, Pfizer Inc., an entity incorporated in Delaware, and alleged in Zydus's Notice Letter that Pfizer's patents are invalid. Upon information and belief, Zydus knowingly and deliberately challenged Pfizer's patent rights, and

knew when it did so that it was triggering the forty-five day period for Pfizer to bring an action for patent infringement under the Hatch-Waxman Act.

20. Because Pfizer Inc. is incorporated in Delaware, Pfizer suffers injury and consequences from Zydus's filing of Zydus's ANDA, challenging Pfizer's patent rights, in Delaware. Upon information and belief, Zydus knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. Zydus has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Zydus's Notice Letter to Pfizer, a Delaware corporation, that it would be sued in Delaware for patent infringement.

21. Upon information and belief, if Zydus's ANDA is approved, Zydus will directly or indirectly manufacture, market, sell, and/or distribute Zydus's ANDA Product within the United States, including in Delaware, consistently with Zydus's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Zydus regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Zydus's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Zydus's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Pfizer's patents in the event that Zydus's ANDA Product is approved before the patents expire.

22. Upon information and belief, Zydus derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Zydus and/or for which Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc. or Cadila Healthcare Ltd. is the named applicant on approved ANDAs. Upon information and belief, various products for which Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide DMCC, or Cadila Healthcare Ltd. is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

**COUNT I - INFRINGEMENT OF THE '612 PATENT**

23. Pfizer incorporates each of the preceding paragraphs 1–22 as if fully set forth herein.

24. The inventors named on the '612 patent are Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou.

25. The '612 patent, entitled "2-(Pyridin-2-ylamino)-pyrido[2,3-d]pyrimidin-7-ones" (attached as Exhibit A), was duly and legally issued on August 30, 2005.

26. Pfizer is the owner and assignee of the '612 patent.

27. Claim 1 of the '612 patent recites "[a] compound which is 6-Acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one."

28. Claim 2 of the '612 patent recites "A pharmaceutical composition comprising a therapeutically effective amount of the compound according to claim 1 and a pharmaceutical carrier therefor."

29. IBRANCE® is covered by claims 1 and 2 of the '612 patent, and the '612 patent has been listed in connection with IBRANCE® in the FDA's Orange Book.

30. In Zydus's Notice Letter, Zydus notified Pfizer of the submission of Zydus's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the expiration of the '612 patent.

31. In Zydus's Notice Letter, Zydus also notified Pfizer that, as part of its ANDA, Zydus had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '612 patent. On information and belief, Zydus submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '612 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product.

32. Zydus's ANDA Product and the use of Zydus's ANDA Product are covered by claims 1 and 2 of the '612 patent.

33. In Zydus's Notice Letter, Zydus did not contest the infringement of claim 1 or 2 of the '612 patent on any basis other than the alleged invalidity of those claims.

34. Zydus's submission of Zydus's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product before the expiration of the '612 patent was an act of infringement of the '612 patent under 35 U.S.C. § 271(e)(2)(A).

35. On information and belief, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product immediately and imminently upon approval of its ANDA.

36. The manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product would infringe claims 1 and 2 of the '612 patent.

37. On information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe claims 1 and 2 of the '612 patent.

38. On information and belief, Zydus plans and intends to, and will, actively induce infringement of the '612 patent when Zydus's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Zydus's activities will be done with knowledge of the '612 patent and specific intent to infringe that patent.

39. On information and belief, Zydus knows that Zydus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '612 patent, that Zydus's ANDA Product is not a staple article or commodity of commerce, and that Zydus's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Zydus plans and intends to, and will, contribute to infringement of the '612 patent immediately and imminently upon approval of Zydus's ANDA.

40. Notwithstanding Zydus's knowledge of the claims of the '612 patent, Zydus has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Zydus's ANDA Product with its product labeling following FDA approval of Zydus's ANDA prior to the expiration of the '612 patent.

41. The foregoing actions by Zydus constitute and/or will constitute infringement of the '612 patent; active inducement of infringement of the '612 patent; and contribution to the infringement by others of the '612 patent.

42. On information and belief, Zydus has acted with full knowledge of the ’612 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’612 patent; active inducement of infringement of the ’612 patent; and/or contribution to the infringement by others of the ’612 patent.

43. Pfizer will be substantially and irreparably damaged by infringement of the ’612 patent.

44. Unless Zydus is enjoined from infringing the ’612 patent, actively inducing infringement of the ’612 patent, and contributing to the infringement by others of the ’612 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

**COUNT II - DECLARATORY JUDGMENT**
**OF INFRINGEMENT OF THE ’612 PATENT**

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

46. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer on the one hand and Zydus on the other regarding Zydus’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’612 patent, and/or the validity of the ’612 patent.

47. Claim 1 of the ’612 patent recites “[a] compound which is 6-Acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one.”

48. Claim 2 of the ’612 patent recites “A pharmaceutical composition comprising a therapeutically effective amount of the compound according to claim 1 and a pharmaceutical carrier therefor.”

49. In Zydus's Notice Letter, Zydus notified Pfizer of the submission of Zydus's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the expiration of the '612 patent.

50. In Zydus's Notice Letter, Zydus also notified Pfizer that, as part of its ANDA, Zydus had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '612 patent. On information and belief, Zydus submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '612 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product.

51. Zydus's ANDA Product and the use of Zydus's ANDA Product are covered by claims 1 and 2 of the '612 patent.

52. In Zydus's Notice Letter, Zydus did not contest the infringement of claim 1 or 2 of the '612 patent on any basis other than the alleged invalidity of those claims.

53. On information and belief, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product immediately and imminently upon approval of its ANDA.

54. The manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product would infringe claims 1 and 2 of the '612 patent.

55. On information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe claims 1 and 2 of the '612 patent.

56. On information and belief, Zydus plans and intends to, and will, actively induce infringement of the ’612 patent when Zydus’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Zydus’s activities will be done with knowledge of the ’612 patent and specific intent to infringe that patent.

57. On information and belief, Zydus knows that Zydus’s ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’612 patent, that Zydus’s ANDA Product is not a staple article or commodity of commerce, and that Zydus’s ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Zydus plans and intends to, and will, contribute to infringement of the ’612 patent immediately and imminently upon approval of Zydus’s ANDA.

58. Notwithstanding Zydus’s knowledge of the claims of the ’612 patent, Zydus has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Zydus’s ANDA Product with its product labeling following FDA approval of Zydus’s ANDA prior to the expiration of the ’612 patent.

59. The foregoing actions by Zydus constitute and/or will constitute infringement of the ’612 patent; active inducement of infringement of the ’612 patent; and contribution to the infringement by others of the ’612 patent.

60. On information and belief, Zydus has acted with full knowledge of the ’612 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’612 patent; active inducement of infringement of the ’612 patent; and/or contribution to the infringement by others of the ’612 patent.

61. Pfizer will be substantially and irreparably damaged by infringement of the ’612 patent.

62. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Zydus's ANDA Product with its proposed labeling, or any other Zydus drug product that is covered by or whose use is covered by the '612 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '612 patent, and that the claims of the '612 patent are not invalid.

**COUNT III - INFRINGEMENT OF THE '489 PATENT**

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

64. The inventors named on the '489 patent are Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou.

65. The '489 patent, entitled "2-(pyridin-2-ylamino)-pyrido [2,3-d]pyrimidin-7-ones" (attached as Exhibit B), was duly and legally issued on April 24, 2007.

66. Pfizer is the owner and assignee of the '489 patent.

67. The '489 patent claims, *inter alia*, a compound of the formula recited in claim 1 of the '489 patent.

68. IBRANCE® is covered by one or more claims of the '489 patent, including claim 1–7 and 9 of the '489 patent, and the '489 patent has been listed in connection with IBRANCE® in the FDA's Orange Book.

69. In Zydus's Notice Letter, Zydus notified Pfizer of the submission of Zydus's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the expiration of the '489 patent.

70. In Zydus's Notice Letter, Zydus also notified Pfizer that, as part of its ANDA, Zydus had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '489 patent. On information and belief, Zydus submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '489 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product.

71. Zydus's ANDA Product and the use of Zydus's ANDA Product are covered by at least claims 1–7 and 9 of the '489 patent.

72. In Zydus's Notice Letter, Zydus did not contest the infringement of claim 1–7 and 9 of the '489 patent on any basis other than the alleged invalidity of those claims.

73. Zydus's submission of Zydus's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product before the expiration of the '489 patent was an act of infringement of the '489 patent under 35 U.S.C. § 271(e)(2)(A).

74. On information and belief, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product immediately and imminently upon approval of its ANDA.

75. The manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product would infringe one or more claims of the '489 patent, including, *inter alia*, claims 1–7 and 9 of the '489 patent.

76. On information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product in accordance with, and as directed by, its proposed

product labeling would infringe one or more claims of the '489 patent, including, *inter alia*, claims 1–7 and 9 of the '489 patent.

77. On information and belief, Zydus plans and intends to, and will, actively induce infringement of the '489 patent when Zydus's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Zydus's activities will be done with knowledge of the '489 patent and specific intent to infringe that patent.

78. On information and belief, Zydus knows that Zydus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '489 patent, that Zydus's ANDA Product is not a staple article or commodity of commerce, and that Zydus's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Zydus plans and intends to, and will, contribute to infringement of the '489 patent immediately and imminently upon approval of Zydus's ANDA.

79. Notwithstanding Zydus's knowledge of the claims of the '489 patent, Zydus has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Zydus's ANDA Product with its product labeling following FDA approval of Zydus's ANDA prior to the expiration of the '489 patent.

80. The foregoing actions by Zydus constitute and/or will constitute infringement of the '489 patent; active inducement of infringement of the '489 patent; and contribution to the infringement by others of the '489 patent.

81. On information and belief, Zydus has acted with full knowledge of the '489 patent and without a reasonable basis for believing that it would not be liable for infringement of the '489 patent; active inducement of infringement of the '489 patent; and/or contribution to the infringement by others of the '489 patent.

82. Pfizer will be substantially and irreparably damaged by infringement of the ’489 patent.

83. Unless Zydus is enjoined from infringing the ’489 patent, actively inducing infringement of the ’489 patent, and contributing to the infringement by others of the ’489 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

**COUNT IV - DECLARATORY JUDGMENT**
**OF INFRINGEMENT OF THE ’489 PATENT**

84. Pfizer incorporates each of the preceding paragraphs 1–83 as if fully set forth herein.

85. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer on the one hand and Zydus on the other regarding Zydus’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’489 patent, and/or the validity of the ’489 patent.

86. The ’489 patent claims, *inter alia*, a compound of the formula recited in claim 1 of the ’489 patent.

87. In Zydus’s Notice Letter, Zydus notified Pfizer of the submission of Zydus’s ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus’s ANDA Product prior to the expiration of the ’489 patent.

88. In Zydus’s Notice Letter, Zydus also notified Pfizer that, as part of its ANDA, Zydus had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the ’489 patent. On information and belief, Zydus submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV) asserting that the ’489 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus’s ANDA Product.

89. Zydus’s ANDA Product and the use of Zydus’s ANDA Product are covered by at least claims 1–7 and 9 of the ’489 patent.

90. In Zydus’s Notice Letter, Zydus did not contest the infringement of claim 1–7 and 9 of the ’489 patent on any basis other than the alleged invalidity of those claims.

91. Zydus’s submission of Zydus’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus’s ANDA Product before the expiration of the ’489 patent was an act of infringement of the ’489 patent under 35 U.S.C. § 271(e)(2)(A).

92. On information and belief, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus’s ANDA Product immediately and imminently upon approval of its ANDA.

93. The manufacture, use, sale, offer for sale, or importation of Zydus’s ANDA Product would infringe one or more claims of the ’489 patent, including, *inter alia*, claims 1–7 and 9 of the ’489 patent.

94. On information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus’s ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the ’489 patent, including, *inter alia*, claims 1–7 and 9 of the ’489 patent.

95. On information and belief, Zydus plans and intends to, and will, actively induce infringement of the ’489 patent when Zydus’s ANDA is approved, and plans and intends to, and

will, do so immediately and imminently upon approval. Zydus's activities will be done with knowledge of the '489 patent and specific intent to infringe that patent.

96. On information and belief, Zydus knows that Zydus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '489 patent, that Zydus's ANDA Product is not a staple article or commodity of commerce, and that Zydus's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Zydus plans and intends to, and will, contribute to infringement of the '489 patent immediately and imminently upon approval of Zydus's ANDA.

97. Notwithstanding Zydus's knowledge of the claims of the '489 patent, Zydus has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Zydus's ANDA Product with its product labeling following FDA approval of Zydus's ANDA prior to the expiration of the '489 patent.

98. The foregoing actions by Zydus constitute and/or will constitute infringement of the '489 patent; active inducement of infringement of the '489 patent; and contribution to the infringement by others of the '489 patent.

99. On information and belief, Zydus has acted with full knowledge of the '489 patent and without a reasonable basis for believing that it would not be liable for infringement of the '489 patent; active inducement of infringement of the '489 patent; and/or contribution to the infringement by others of the '489 patent.

100. Pfizer will be substantially and irreparably damaged by infringement of the '489 patent.

101. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Zydus's ANDA Product with its proposed labeling, or any other Zydus

drug product that is covered by or whose use is covered by the '489 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '489 patent, and that the claims of the '489 patent are not invalid.

**COUNT V - INFRINGEMENT OF THE '168 PATENT**

102. Pfizer incorporates each of the preceding paragraphs 1–101 as if fully set forth herein.

103. The inventors named on the '168 patent are Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou.

104. The '168 patent, entitled "2-(pyridin-2-ylamino)-pyrido [2,3-d]pyrimidin-7-ones" (attached as Exhibit C), was duly and legally issued on November 25, 2008.

105. Pfizer is the owner and assignee of the '168 patent.

106. The '168 patent claims, *inter alia*, "[a] method of treating breast cancer in a mammal comprising administering to said mammal an amount of a compound of" the formula recited in claim 1 of the '168 patent.

107. IBRANCE®, as well as methods of using IBRANCE®, are covered by one or more claims of the '168 patent, including claim 1 of the '168 patent, and the '168 patent has been listed in connection with IBRANCE® in the FDA's Orange Book.

108. In Zydus's Notice Letter, Zydus notified Pfizer of the submission of Zydus's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the expiration of the '168 patent.

109. In Zydus's Notice Letter, Zydus also notified Pfizer that, as part of its ANDA, Zydus had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA,

21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '168 patent. On information and belief, Zydus submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '168 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product.

110. The use of Zydus's ANDA Product is covered by claims 1–4 of the '168 patent.

111. In Zydus's Notice Letter, Zydus did not contest the infringement of claim 1–4 of the '168 patent on any basis other than the alleged invalidity of those claims.

112. Zydus's submission of Zydus's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product before the expiration of the '168 patent was an act of infringement of the '168 patent under 35 U.S.C. § 271(e)(2)(A).

113. On information and belief, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product immediately and imminently upon approval of its ANDA.

114. The manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product would directly and/or indirectly infringe claims 1–4 of the '168 patent.

115. On information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product in accordance with, and as directed by, its proposed product labeling would directly and/or indirectly infringe claims 1–4 of the '168 patent.

116. On information and belief, Zydus plans and intends to, and will, actively induce infringement of the '168 patent when Zydus's ANDA is approved, and plans and intends to, and

will, do so immediately and imminently upon approval. Zydus's activities will be done with knowledge of the '168 patent and specific intent to infringe that patent.

117. On information and belief, Zydus knows that Zydus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '168 patent, that Zydus's ANDA Product is not a staple article or commodity of commerce, and that Zydus's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Zydus plans and intends to, and will, contribute to infringement of the '168 patent immediately and imminently upon approval of Zydus's ANDA.

118. Notwithstanding Zydus's knowledge of the claims of the '168 patent, Zydus has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Zydus's ANDA Product with its product labeling following FDA approval of Zydus's ANDA prior to the expiration of the '168 patent.

119. The foregoing actions by Zydus constitute and/or will constitute infringement of the '168 patent; active inducement of infringement of the '168 patent; and contribution to the infringement by others of the '168 patent.

120. On information and belief, Zydus has acted with full knowledge of the '168 patent and without a reasonable basis for believing that it would not be liable for infringement of the '168 patent; active inducement of infringement of the '168 patent; and/or contribution to the infringement by others of the '168 patent.

121. Pfizer will be substantially and irreparably damaged by infringement of the '168 patent.

122. Unless Zydus is enjoined from infringing the '168 patent, actively inducing infringement of the '168 patent, and contributing to the infringement by others of the '168 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

**COUNT VI - DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '168 PATENT**

123. Pfizer incorporates each of the preceding paragraphs 1–122 as if fully set forth herein.

124. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer on the one hand and Zydus on the other regarding Zydus's infringement, active inducement of infringement, and contribution to the infringement by others of the '168 patent, and/or the validity of the '168 patent.

125. The '168 patent claims, *inter alia*, "[a] method of treating breast cancer in a mammal comprising administering to said mammal an amount of a compound of" the formula recited in claim 1 of the '168 patent.

126. In Zydus's Notice Letter, Zydus notified Pfizer of the submission of Zydus's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the expiration of the '168 patent.

127. In Zydus's Notice Letter, Zydus also notified Pfizer that, as part of its ANDA, Zydus had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '168 patent. On information and belief, Zydus submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '168 patent is invalid, unenforceable, and/or will not be

infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product.

128. The use of Zydus's ANDA Product is covered by claims 1–4 of the '168 patent.

129. In Zydus's Notice Letter, Zydus did not contest the infringement of claim 1–4 of the '168 patent on any basis other than the alleged invalidity of those claims.

130. Zydus's submission of Zydus's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product before the expiration of the '168 patent was an act of infringement of the '168 patent under 35 U.S.C. § 271(e)(2)(A).

131. On information and belief, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product immediately and imminently upon approval of its ANDA.

132. The manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product would directly and/or indirectly infringe claims 1–4 of the '168 patent.

133. On information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product in accordance with, and as directed by, its proposed product labeling would directly and/or indirectly infringe claims 1–4 of the '168 patent.

134. On information and belief, Zydus plans and intends to, and will, actively induce infringement of the '168 patent when Zydus's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Zydus's activities will be done with knowledge of the '168 patent and specific intent to infringe that patent.

135. On information and belief, Zydus knows that Zydus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '168 patent, that

Zydus's ANDA Product is not a staple article or commodity of commerce, and that Zydus's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Zydus plans and intends to, and will, contribute to infringement of the '168 patent immediately and imminently upon approval of Zydus's ANDA.

136. Notwithstanding Zydus's knowledge of the claims of the '168 patent, Zydus has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Zydus's ANDA Product with its product labeling following FDA approval of Zydus's ANDA prior to the expiration of the '168 patent.

137. The foregoing actions by Zydus constitute and/or will constitute infringement of the '168 patent; active inducement of infringement of the '168 patent; and contribution to the infringement by others of the '168 patent.

138. On information and belief, Zydus has acted with full knowledge of the '168 patent and without a reasonable basis for believing that it would not be liable for infringement of the '168 patent; active inducement of infringement of the '168 patent; and/or contribution to the infringement by others of the '168 patent.

139. Pfizer will be substantially and irreparably damaged by infringement of the '168 patent.

140. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Zydus's ANDA Product with its proposed labeling, or any other Zydus drug product that is covered by or whose use is covered by the '168 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '168 patent, and that the claims of the '168 patent are not invalid.

## PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

(a) A judgment that each of the patents-in-suit has been infringed under 35 U.S.C. § 271(e)(2) by Zydus's submission to the FDA of Zydus's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Zydus's ANDA Products, or any other drug product that infringes or the use of which infringes one or more of the patents-in-suit, be not earlier than the latest of the expiration dates of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Zydus, and all persons acting in concert with Zydus, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Products, or any other drug product covered by or whose use is covered by one or more of the patents-in-suit, prior to the expiration of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Zydus's ANDA Products, or any other drug product which is covered by or whose use is covered by one-or-more of the patents-in-suit, prior to the expiration of said patents, will infringe, induce the infringement of, and contribute to the infringement by others of, said patents;

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

(f) 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/ Jack B. Blumenfeld*

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