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 PF PRISM IMB B.V., | ) | |
| Plaintiffs, | ) | C.A. No. _____ |
| v. | ) | |
| SYNTHON PHARMACEUTICALS, INC., SYNTHON B.V. and SYNTHON INTERNATIONAL HOLDING B.V., | ) | |
| Defendants. | ) | |

**COMPLAINT**

Pfizer Inc., Warner-Lambert Company LLC, PF PRISM C.V., Pfizer Manufacturing Holdings LLC, and PF PRISM IMB B.V. (collectively "Pfizer") file this Complaint for patent infringement against Synthon Pharmaceuticals, Inc., Synthon B.V., and Synthon International Holding B.V. (collectively, "Synthon"), 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 Synthon'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) tablets, 75 mg, 100 mg, and 125 mg, prior to the expiration of U.S. Patent No. 6,936,612 ("the '612 patent") and U.S. Patent No. RE47,739 ("the '739 patent"), U.S. Patent No. 7,456,168 ("the '168 patent"), and U.S. Patent No. 10,723,730 ("the '730 patent"). These four patents are referred to collectively herein as "the patents-in-suit."

2. Synthon Pharmaceuticals, Inc. notified Pfizer by letter dated January 13, 2021 ("Synthon's Notice Letter") that it had submitted to the FDA ANDA No. 215570 ("Synthon's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of generic Palbociclib tablets, 75mg, 100 mg, and 125 mg ("Synthon's ANDA Products") 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. 212436 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 PF PRISM IMB B.V. is a private limited liability company (*besloten venootschap*) organized under the law of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJessel, the Netherlands.

7. Upon information and belief, defendant Synthon International Holding B.V. is a corporation organized and existing under the law of the Netherlands, having a business address at Microweg 22, P.O. Box. 7071, 6503 GN Nijmegan, the Netherlands. Upon information and belief, Synthon International Holding B.V. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various Synthon entities, including Synthon Pharmaceuticals, Inc.

8. Upon information and belief, defendant Synthon B.V. is a corporation organized and existing under the law of the Netherlands, having a business address at Microweg 22, P.O. Box. 7071, 6503 GN Nijmegan, the Netherlands. Upon information and belief, Synthon B.V. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various Synthon entities, including Synthon Pharmaceuticals, Inc.

9. Upon information and belief, defendant Synthon Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of North Carolina, having a principal place of business at 1007 Slater Road, Suite 150, Durham, North Carolina 27703. Upon information and belief, Synthon Pharmaceuticals, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

10. Upon information and belief, Synthon Pharmaceuticals, Inc. and Synthon B.V. are subsidiaries of Synthon International Holding B.V.

11. Upon information and belief, Synthon Pharmaceuticals, Inc., Synthon B.V., and Synthon International Holding B.V. acted in concert to prepare and submit Synthon's ANDA to the FDA.

12. Upon information and belief, Synthon Pharmaceuticals, Inc., Synthon B.V., and Synthon International Holding B.V. know and intend that upon approval of Synthon's ANDA, Synthon Pharmaceuticals, Inc., Synthon B.V., and/or Synthon International Holding B.V. will manufacture, market, sell, and distribute Synthon's ANDA Products throughout the United States, including in Delaware. On information and belief, Synthon Pharmaceuticals, Inc., Synthon B.V., and Synthon International Holding B.V. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Synthon's ANDA Products, and enter into agreements that are nearer than arm's length. Upon information and belief, Synthon Pharmaceuticals, Inc., Synthon B.V., and Synthon International Holding B.V. participated, assisted, and cooperated in carrying out the acts complained of herein.

13. Upon information and belief, following any FDA approval of Synthon's ANDA, Synthon Pharmaceuticals, Inc., Synthon B.V., and Synthon International Holding B.V. will act in concert to distribute and sell Synthon's ANDA Products throughout the United States, including within Delaware.

## JURISDICTION

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

15. Synthon International Holding B.V. is subject to personal jurisdiction in Delaware because, among other things, Synthon International Holding B.V., itself and through its subsidiaries Synthon B.V. and Synthon Pharmaceuticals, 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, Synthon International Holding B.V., itself and through its subsidiaries Synthon B.V. and Synthon Pharmaceuticals, 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, Synthon International Holding B.V. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Synthon Pharmaceuticals, Inc. and Synthon B.V., and therefore the activities of Synthon Pharmaceuticals, Inc. and Synthon B.V. in this jurisdiction are attributed to Synthon International Holding B.V.

16. Synthon B.V. is subject to personal jurisdiction in Delaware because, among other things, Synthon International Holding B.V., itself and through other Synthon entities, including Synthon Pharmaceuticals, 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, Synthon B.V., itself and through other Synthon entities, including Synthon Pharmaceuticals, 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. Upon information and belief, Synthon B.V. previously has been sued in this district, did not challenge venue or the Court's personal jurisdiction over it, and/or availed itself of the rights, benefits, and privileges of this forum by asserting counterclaims for the purpose of litigating patent infringement disputes under the Hatch-Waxman Act. *See In re: Copaxone 775 Patent Litigation*, C.A. No. 16-1267-GMS (consolidated), D.I. 146, at ¶¶ 13-17, 117-118, 125-129, 139-141, 164, pp. 48-62. In addition, Synthon B.V. is subject to personal jurisdiction in Delaware because, upon information and belief, it directs and coordinates the activities of Synthon Pharmaceuticals, Inc., and therefore the activities of Synthon Pharmaceuticals, Inc. in this jurisdiction are attributed to Synthon B.V.

17. Synthon Pharmaceuticals, 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, Synthon Pharmaceuticals, 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. Upon information and belief, Synthon Pharmaceuticals, Inc. previously has been sued in this district, did not challenge venue or the Court's personal jurisdiction over it, and/or availed itself of the rights, benefits, and privileges of this forum by asserting counterclaims for the purpose of litigating patent infringement disputes under the Hatch-Waxman Act. *See In re: Copaxone 775 Patent Litigation*, C.A. No. 16-1267-GMS (consolidated), D.I. 146, at ¶¶ 13-17, 117-118, 125-129, 139-141, 164, pp. 48-62.

18. Synthon has previously used 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, Synthon, with knowledge of the Hatch-Waxman Act process, directed Synthon's Notice Letter to Pfizer, an entity incorporated in Delaware, and alleged in Synthon's Notice Letter that Pfizer's patents are invalid. Upon information and belief, Synthon 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 Inc. suffers injury and consequences from Synthon's filing of Synthon's ANDA, challenging Pfizer's patent rights, in Delaware. Upon information and belief, Synthon knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. Synthon has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Synthon's Notice Letter to Pfizer Inc., a Delaware corporation, that it would be sued in Delaware for patent infringement.

21. Upon information and belief, if Synthon's ANDA is approved, Synthon will directly or indirectly manufacture, market, sell, and/or distribute Synthon's ANDA Products within the United States, including in Delaware, consistently with Synthon's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, following any FDA approval of ANDA No. 215570, Synthon knows and intends that Synthon's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware. Upon information and belief, Synthon 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, Synthon's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Synthon's ANDA Products 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 Synthon's ANDA Products are approved before the patents expire.

22. Upon information and belief, Synthon derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Synthon Pharmaceuticals, Inc. and/or for which Synthon Pharmaceuticals, Inc., Synthon B.V., or Synthon International Holding B.V. is the named applicant on approved ANDAs. Upon information and belief, various products for which Synthon Pharmaceuticals, Inc., Synthon B.V., or Synthon International Holding B.V. is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

## FACTUAL BACKGROUND

23. IBRANCE®, which contains palbociclib, is approved for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer.

24. Upon information and belief, Synthon's ANDA Products are a generic version of IBRANCE®.

25. Synthon's Notice Letter purported to include an "Offer of Confidential Access" to Pfizer to Synthon's ANDA. The offer, however, was subject to various unreasonably restrictive conditions. In an exchange of correspondence, counsel for Plaintiffs and counsel for Synthon discussed the terms of Synthon's Offer of Confidential Access, though the parties were unable to agree on terms under which Pfizer could review internal documents, data, and/or samples relevant to infringement, which are not publically available, on reasonable confidentiality terms.

26. Plaintiffs are filing this Complaint within forty-five days of receipt of Synthon's Notice Letter.

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

27. Pfizer incorporates each of the preceding paragraphs 1–26 as if fully set forth herein.

28. 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.

29. 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.

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

31. 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."

32. 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."

33. 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.

34. In Synthon's Notice Letter, Synthon notified Pfizer of the submission of Synthon'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 Synthon's ANDA Product prior to the expiration of the '612 patent.

35. In Synthon's Notice Letter, Synthon also notified Pfizer that, as part of its ANDA, Synthon 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, Synthon 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 Synthon's ANDA Products.

36. Synthon's ANDA Products and the use of Synthon's ANDA Products are covered by claims 1 and 2 of the '612 patent.

37. In Synthon's Notice Letter, Synthon 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.

38. Synthon's submission of Synthon's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Synthon's ANDA Products 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).

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

40. The manufacture, use, sale, offer for sale, or importation of Synthon's ANDA Products would infringe claims 1 and 2 of the '612 patent.

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

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

43. On information and belief, Synthon knows that Synthon's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '612 patent, that Synthon's ANDA Products are not staple articles or commodities of commerce, and that Synthon's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Synthon plans and intends to, and will, contribute to infringement of the '612 patent immediately and imminently upon approval of Synthon's ANDA.

44. Notwithstanding Synthon's knowledge of the claims of the '612 patent, Synthon has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Synthon's ANDA Products with their proposed labeling following FDA approval of Synthon's ANDA prior to the expiration of the '612 patent.

45. The foregoing actions by Synthon 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.

46. On information and belief, Synthon 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.

47. Pfizer will be substantially and irreparably damaged by infringement of the '612 patent.

48. Unless Synthon 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**

49. Pfizer incorporates each of the preceding paragraphs 1–48 as if fully set forth herein.

50. 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 Synthon on the other regarding Synthon's infringement, active inducement of infringement, and contribution to the infringement by others of the '612 patent, and/or validity of the '612 patent.

51. 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."

52. 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."

53. In Synthon's Initial Notice Letter, Synthon notified Pfizer of the submission of Synthon'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 Synthon's ANDA Products prior to the expiration of the '612 patent.

54. In Synthon's Notice Letter, Synthon also notified Pfizer that, as part of its ANDA, Synthon 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, Synthon 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 Synthon's ANDA Products.

55. Synthon's ANDA Products and the use of Synthon's ANDA Products are covered by claims 1 and 2 of the '612 patent.

56. In Synthon's Notice Letter, Synthon 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.

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

58. The manufacture, use, sale, offer for sale, or importation of Synthon's ANDA Products would infringe claims 1 and 2 of the '612 patent.

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

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

61. On information and belief, Synthon knows that Synthon's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '612 patent, that Synthon's ANDA Products are not staple articles or commodities of commerce, and that Synthon's ANDA Products and their proposed labeling are not suitable for substantial noninfringing use. On

information and belief, Synthon plans and intends to, and will, contribute to infringement of the '612 patent immediately and imminently upon approval of Synthon's ANDA.

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

63. The foregoing actions by Synthon 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.

64. On information and belief, Synthon 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.

65. Pfizer will be substantially and irreparably damaged by infringement of the '612 patent.

66. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Synthon's ANDA Products with their proposed labeling, or any other Synthon 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 '739 PATENT**

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

68. The inventors named on the '739 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.

69. The '739 patent, entitled "2-(pyridin-2-ylamino)-pyrido [2,3-d]pyrimidin-7-ones" (attached as Exhibit B), was duly and legally issued on November 26, 2019.

70. Pfizer is the owner and assignee of the '739 patent.

71. The '739 patent claims, inter alia, a compound of the formula recited in claim 2 of the '739 patent.

72. IBRANCE® is covered by one or more claims of the '739 patent, including claims 2, 6, 7 and 9–12 of the '739 patent, and the '739 patent has been listed in connection with IBRANCE® in the FDA's Orange Book.

73. In Synthon's Notice Letter, Synthon notified Pfizer of the submission of Synthon'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 Synthon's ANDA Products prior to the expiration of the '739 patent.

74. In Synthon's Supplemental Notice Letters, Synthon also notified Pfizer that, as part of its ANDA, Synthon 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 '739 patent. On information and belief, Synthon submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '739 patent is invalid, unenforceable, and/or will not be

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

75. Synthon's ANDA Products and the use of Synthon's ANDA Products are covered by at least claims 2, 6, 7 and 9–12 of the '739 patent.

76. In Synthon's Notice Letter, Synthon did not contest the infringement of claims 2, 6, 7 and 9–12 of the '739 patent on any basis other than the alleged invalidity of those claims.

77. Synthon's submission of Synthon's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Synthon's ANDA Products before the expiration of the '739 patent was an act of infringement of the '739 patent under 35 U.S.C. § 271(e)(2)(A).

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

79. The manufacture, use, sale, offer for sale, or importation of Synthon's ANDA Products would infringe one or more claims of the '739 patent, including, *inter alia*, claims 2, 6, 7 and 9–12 of the '739 patent.

80. On information and belief, the manufacture, use, sale, offer for sale, or importation of Synthon's ANDA Products in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '739 patent, including, inter alia, claims 2, 6, 7 and 9–12 of the '739 patent.

81. On information and belief, Synthon plans and intends to, and will, actively induce infringement of the '739 patent when Synthon's ANDA is approved, and plans and intends to, and

will, do so immediately and imminently upon approval. Synthon's activities will be done with knowledge of the '739 patent and specific intent to infringe that patent.

82. On information and belief, Synthon knows that Synthon's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '739 patent, that Synthon's ANDA Products are not staple articles or commodities of commerce, and that Synthon's ANDA Products and their proposed labeling are not suitable for substantial noninfringing use. On information and belief, Synthon plans and intends to, and will, contribute to infringement of the '739 patent immediately and imminently upon approval of Synthon's ANDA.

83. Notwithstanding Synthon's knowledge of the claims of the '739 patent, Synthon has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Synthon's ANDA Products with their product labeling following FDA approval of Synthon's ANDA prior to the expiration of the '739 patent.

84. The foregoing actions by Synthon constitute and/or will constitute infringement of the '739 patent; active inducement of infringement of the '739 patent; and contribution to the infringement by others of the '739 patent.

85. On information and belief, Synthon has acted with full knowledge of the '739 patent and without a reasonable basis for believing that it would not be liable for infringement of the '739 patent; active inducement of infringement of the '739 patent; and/or contribution to the infringement by others of the '739 patent.

86. Pfizer will be substantially and irreparably damaged by infringement of the '739 patent.

87. Unless Synthon is enjoined from infringing the '739 patent, actively inducing infringement of the '739 patent, and contributing to the infringement by others of the '739 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

**COUNT IV - DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '739 PATENT**

88. Pfizer incorporates each of the preceding paragraphs 1–87 as if fully set forth herein.

89. 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 Synthon on the other regarding Synthon's infringement, active inducement of infringement, and contribution to the infringement by others of the '739 patent, and/or the validity of the '739 patent.

90. The '739 patent claims, inter alia, a compound of the formula recited in claim 2 of the '739 patent.

91. In Synthon's Notice Letter, Synthon notified Pfizer of the submission of Synthon'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 Synthon's ANDA Products prior to the expiration of the '739 patent.

92. In Synthon's Notice Letter, Synthon also notified Pfizer that, as part of its ANDA, Synthon 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 '739 patent. On information and belief, Synthon submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '739 patent is invalid, unenforceable, and/or will not be

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

93. Synthon's ANDA Products and the use of Synthon's ANDA Products are covered by at least claims 2, 6, 7 and 9–12 of the '739 patent.

94. In Synthon's Notice Letter, Synthon did not contest the infringement of claims 2, 6, 7 and 9–12 of the '739 patent on any basis other than the alleged invalidity of those claims.

95. Synthon's submission of Synthon's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Synthon's ANDA Products before the expiration of the '739 patent was an act of infringement of the '739 patent under 35 U.S.C. § 271(e)(2)(A).

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

97. The manufacture, use, sale, offer for sale, or importation of Synthon's ANDA Products would infringe one or more claims of the '739 patent, including, inter alia, claims 2, 6, 7 and 9–12 of the '739 patent.

98. On information and belief, the manufacture, use, sale, offer for sale, or importation of Synthon's ANDA Products in accordance with, and as directed by, their proposed product labeling would infringe one or more claims of the '739 patent, including, inter alia, claims 2, 6, 7 and 9–12 of the '739 patent.

99. On information and belief, Synthon plans and intends to, and will, actively induce infringement of the '739 patent when Synthon's ANDA is approved, and plans and intends to, and

will, do so immediately and imminently upon approval. Synthon's activities will be done with knowledge of the '739 patent and specific intent to infringe that patent.

100. On information and belief, Synthon knows that Synthon's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '739 patent, that Synthon's ANDA Products are not staple articles or commodities of commerce, and that Synthon's ANDA Products and their proposed labeling are not suitable for substantial noninfringing use. On information and belief, Synthon plans and intends to, and will, contribute to infringement of the '739 patent immediately and imminently upon approval of Synthon's ANDA.

101. Notwithstanding Synthon's knowledge of the claims of the '739 patent, Synthon has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Synthon's ANDA Products with their product labeling following FDA approval of Synthon's ANDA prior to the expiration of the '739 patent.

102. The foregoing actions by Synthon constitute and/or will constitute infringement of the '739 patent; active inducement of infringement of the '739 patent; and contribution to the infringement by others of the '739 patent.

103. On information and belief, Synthon has acted with full knowledge of the '739 patent and without a reasonable basis for believing that it would not be liable for infringement of the '739 patent; active inducement of infringement of the '739 patent; and/or contribution to the infringement by others of the '739 patent.

104. Pfizer will be substantially and irreparably damaged by infringement of the '739 patent.

105. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Synthon's ANDA Products with its proposed labeling, or any other Synthon drug

product that is covered by or whose use is covered by the '739 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '739 patent, and that the claims of the '739 patent are not invalid.

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

106. Pfizer incorporates each of the preceding paragraphs 1–105 as if fully set forth herein.

107. 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.

108. 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.

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

110. 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.

111. 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.

112. In Synthon's Notice Letter, Synthon notified Pfizer of the submission of Synthon'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 Synthon's ANDA Products prior to the expiration of the '168 patent.

113. In Synthon's Notice Letter, Synthon also notified Pfizer that, as part of its ANDA, Synthon 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, Synthon 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 Synthon's ANDA Products.

114. The use of Synthon's ANDA Products is covered by claims 1–4 of the '168 patent.

115. Synthon's submission of Synthon's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Synthon's ANDA Products 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).

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

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

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

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

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

120. On information and belief, Synthon knows that Synthon's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '168 patent, that Synthon's ANDA Products are not staple articles or commodities of commerce, and that Synthon's ANDA Products and their proposed labeling are not suitable for substantial noninfringing use. On information and belief, Synthon plans and intends to, and will, contribute to infringement of the '168 patent immediately and imminently upon approval of Synthon's ANDA.

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

122. The foregoing actions by Synthon 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.

123. On information and belief, Synthon 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.

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

125. Unless Synthon 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**

126. Pfizer incorporates each of the preceding paragraphs 1–125 as if fully set forth herein.

127. 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 Synthon on the other regarding Synthon's infringement, active inducement of infringement, and contribution to the infringement by others of the '168 patent, and/or validity of the '612 patent.

128. 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.

129. In Synthon's Notice Letter, Synthon notified Pfizer of the submission of Synthon'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 Synthon's ANDA Products prior to the expiration of the '168 patent.

130. In Synthon's Notice Letter, Synthon also notified Pfizer that, as part of its ANDA, Synthon 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, Synthon 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 Synthon's ANDA Products.

131. The use of Synthon's ANDA Products is covered by claims 1–4 of the '168 patent.

132. Synthon's submission of Synthon's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Synthon's ANDA Products 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).

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

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

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

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

137. On information and belief, Synthon knows that Synthon's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '168 patent, that Synthon's ANDA Products are not staple articles or commodities of commerce, and that Synthon's ANDA Products and their proposed labeling are not suitable for substantial noninfringing use. On

information and belief, Synthon plans and intends to, and will, contribute to infringement of the '168 patent immediately and imminently upon approval of Synthon's ANDA.

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

139. The foregoing actions by Synthon 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.

140. On information and belief, Synthon 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.

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

142. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Synthon's ANDA Products with their proposed labeling, or any other Synthon 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.

**COUNT VII – INFRINGEMENT OF THE '730 PATENT**

143. Pfizer incorporates each of the preceding paragraphs 1–142 as if fully set forth herein.

144. The inventors of the '730 patent are Brian Patrick Chekal and Nathan D. Ide.

145. The '730 patent, entitled "Solid Forms of a Selective Cdk4/6 Inhibitor" (attached as Exhibit D), was duly and legally issued on July 28, 2020.

146. Pfizer is the owner and assignee of the '730 patent.

147. IBRANCE® is covered by one or more claims of the '730 patent, which has been listed in connection with IBRANCE® in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as "the Orange Book").

148. In Synthon's Notice Letter, Synthon notified Pfizer of the submission of Synthon'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 Synthon's ANDA Products prior to the expiration of the '730 patent.

149. In Synthon's Notice Letter, Synthon also notified Pfizer that, as part of its ANDA, Synthon had filed a certification 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 '730 patent. Upon information and belief, Synthon submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '730 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Synthon's ANDA Products.

150. Upon information and belief, Synthon's ANDA Products and the use of Synthon's ANDA Products are covered by one or more claims of the '730 patent, either literally or under the doctrine of equivalents.

151. As an example, claim 1 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-

> one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a primary particle size distribution characterized by a D90 value of from about 30 µm to about 65 µm.

152. Upon information and belief, Synthon's ANDA Products infringe claim 1 of the '730 patent, literally or under the doctrine of equivalents.

153. As an example, Claim 7 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 µm to about 40 µm.

154. Upon information and belief, Synthon's ANDA Products infringe claim 7 of the '730 patent, literally or under the doctrine of equivalents.

155. As an example, Claim 15 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 µm to about 30 µm.

156. Upon information and belief, Synthon's ANDA Products infringe claim 15 of the '730 patent, literally or under the doctrine of equivalents.

157. Synthon's submission of Synthon's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Synthon's ANDA Products before the expiration of the '730 patent was an act of infringement of the '730 patent under 35 U.S.C. § 271(e)(2)(A).

158. Upon information and belief, Synthon will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Synthon's ANDA Products immediately and imminently upon approval of its ANDA.

159. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Synthon's ANDA Products would infringe one or more claims of the '730 patent, either literally or under the doctrine of equivalents.

160. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Synthon's ANDA Products in accordance with, and as directed by, their proposed product labeling would infringe one or more claims of the '730 patent.

161. Upon information and belief, Synthon plans and intends to, and will, actively induce infringement of the '730 patent when Synthon's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Synthon's activities will be done with knowledge of the '730 patent and specific intent to infringe that patent.

162. Upon information and belief, Synthon knows that Synthon's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '730 patent, that Synthon's ANDA Products are not staple articles or commodities of commerce, and that Synthon's ANDA Products and their proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Synthon plans and intends to, and will, contribute to infringement of the '730 patent immediately and imminently upon approval of Synthon's ANDA.

163. Notwithstanding Synthon's knowledge of the claims of the '730 patent, Synthon has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Synthon's ANDA Products with their product labeling following FDA approval of Synthon's ANDA prior to the expiration of the '730 patent.

164. The foregoing actions by Synthon constitute and/or will constitute infringement of the ’730 patent; active inducement of infringement of the ’730 patent; and contribution to the infringement by others of the ’730 patent.

165. Upon information and belief, Synthon has acted with full knowledge of the ’730 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’730 patent; active inducement of infringement of the ’730 patent; and/or contribution to the infringement by others of the ’730 patent.

166. Pfizer will be substantially and irreparably harmed by infringement of the ’730 patent.

167. Unless Synthon is enjoined from infringing the ’730 patent, actively inducing infringement of the ’730 patent, and contributing to the infringement by others of the ’730 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

**COUNT VIII – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’730 PATENT**

168. Pfizer incorporates each of the preceding paragraphs 1–167 as if fully set forth herein.

169. 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 one hand and Synthon on the other regarding Synthon’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’730 patent, and/or the validity of the ’730 patent.

170. In Synthon’s Notice Letter, Synthon notified Pfizer of the submission of Synthon’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 Synthon's ANDA Products prior to the expiration of the '730 patent.

171. In Synthon's Notice Letter, Synthon also notified Pfizer that, as part of its ANDA, Synthon 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 '730 patent. Upon information and belief, Synthon submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '730 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Synthon's ANDA Products.

172. Upon information and belief, Synthon's ANDA Products and the use of Synthon's ANDA Products are covered by one or more claims of the '730 patent.

173. As an example, claim 1 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a primary particle size distribution characterized by a D90 value of from about 30 µm to about 65 µm.

174. Upon information and belief, Synthon's ANDA Products infringe claim 1 of the '730 patent, literally or under the doctrine of equivalents.

175. As an example, Claim 7 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 µm to about 40 µm.

176. Upon information and belief, Synthon's ANDA Products infringe claim 7 of the '730 patent, literally or under the doctrine of equivalents.

177. As an example, Claim 15 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 μm to about 30 μm.

178. Upon information and belief, Synthon's ANDA Products infringe claim 15 of the '730 patent, literally or under the doctrine of equivalents.

179. Upon information and belief, Synthon will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Synthon's ANDA Products immediately and imminently upon approval of its ANDA.

180. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Synthon's ANDA Products would infringe one or more claims of the '730 patent.

181. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Synthon's ANDA Products in accordance with, and as directed by, their proposed labeling would infringe one or more claims of the '730 patent.

182. Upon information and belief, Synthon plans and intends to, and will, actively induce infringement of the '730 patent when Synthon's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Synthon's activities will be done with knowledge of the '730 patent and specific intent to infringe that patent.

183. Upon information and belief, Synthon knows that Synthon's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '730 patent, that Synthon's ANDA Products are not staple articles or commodities of commerce, and that Synthon's ANDA Products and their proposed labeling are not suitable for substantial noninfringing use.

Upon information and belief, Synthon plans and intends to, and will, contribute to infringement of the '730 patent immediately and imminently upon approval of Synthon's ANDA.

184. Notwithstanding Synthon's knowledge of the claims of the '730 patent, Synthon has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Synthon's ANDA Products with their proposed labeling following FDA approval of Synthon's ANDA prior to the expiration of the '730 patent.

185. The foregoing actions by Synthon constitute and/or will constitute infringement of the '730 patent; active inducement of infringement of the '730 patent; and contribution to the infringement by others of the '730 patent.

186. Upon information and belief, Synthon has acted with full knowledge of the '730 patent and without a reasonable basis for believing that it would not be liable for infringement of the '730 patent; active inducement of infringement of the '730 patent; and/or contribution to the infringement by others of the '730 patent.

187. Pfizer will be substantially and irreparably damaged by infringement of the '730 patent.

188. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of Synthon's ANDA Products with their proposed labeling, or any other Synthon drug product that is covered by or whose use is covered by the '730 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '730 patent, and that the claims of the '730 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 Synthon's submission to the FDA of Synthon's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Synthon'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 Synthon and all persons acting in concert with Synthon, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Synthon'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 Synthon'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/ Megan E. Dellinger*

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