Charles H. Chevalier
Gibbons P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Phone: (973) 596-4500
cchevalier@gibbonslaw.com

OF COUNSEL
David I. Berl
Christopher J. Mandernach
Michael Xun Liu
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, D.C. 20005
(202) 434-5000

Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PFIZER INC., WARNER-LAMBERT COMPANY LLC, PF PRISM C.V., PFIZER MANUFACTURING HOLDINGS LLC, and PFIZER PFE IRELAND PHARMACEUTICALS HOLDING 1 B.V. *Plaintiffs*, v. SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMA GLOBAL FZE, and SUN PHARMACEUTICAL INDUSTRIES, INC. *Defendants*.	C.A. No. _____

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 Sun Pharmaceutical Industries, Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. (collectively, "Sun Pharmaceutical"), 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 Sun Pharmaceutical'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") and U.S. Patent No. 7,208,489 ("the '489 patent"). These two patents are referred to collectively herein as "the patents-in-suit."

2. Sun Pharmaceutical Industries Ltd. notified Pfizer by letter dated March 27, 2019 ("Sun Pharmaceutical's Notice Letter") that it had submitted to the FDA ANDA No. 213107 ("Sun Pharmaceutical'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 ("Sun Pharmaceutical'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 Sun Pharmaceutical Industries Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, India. Upon information and belief, Sun Pharmaceutical Industries Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical

drugs through various operating subsidiaries, including Sun Pharmaceutical Industries, Inc.

8. Upon information and belief, defendant Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of the State of Michigan with its principal place of business at 1 Commerce Drive, Cranbury, New Jersey 08512. Upon information and belief, Sun Pharmaceutical Industries, Inc. 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 Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates, with places of business at Office #43, Block Y, SAIF Zone, P.O. Box. No. 122304, Sharjah, United Arab Emirates, and DMCC Branch, 704 Jumeirah Business Center 1, Cluster G, JLT, P.O. Box No. 643561, Dubai, United Arab Emirates. Upon information and belief, Sun Pharma Global FZE 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, Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE are wholly owned subsidiaries of Sun Pharmaceutical Industries Ltd. Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. are collectively referred to herein as "Sun Pharmaceutical."

11. Upon information and belief, Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. acted in concert to prepare and submit Sun Pharmaceutical's ANDA to the FDA.

12. On information and belief Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd. know and intend that upon approval of Sun Pharmaceutical's ANDAs, Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd. will manufacture, market, sell, and distribute Sun Pharmaceutical's ANDA Products throughout the United States, including in New Jersey. On information and belief, Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Sun Pharmaceutical's ANDA Products, and enter into agreements that are nearer than arm's length. On information and belief, Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. participated, assisted, and cooperated in carrying out the acts complained of herein.

13. Upon information and belief, following any FDA approval of Sun Pharmaceutical's ANDA, Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. will act in concert to distribute and sell Sun Pharmaceutical's ANDA Product throughout the United States, including within New Jersey.

JURISDICTION AND VENUE

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

15. Sun Pharmaceutical Industries Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Sun Pharmaceutical Industries Ltd., itself and through its wholly-owned subsidiaries Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE, has

purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Sun Pharmaceutical Industries Ltd., itself and through its subsidiaries Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey and therefore transacts business within the State of New Jersey, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, Sun Pharmaceutical Industries Ltd. is subject to personal jurisdiction in New Jersey because, upon information and belief, it controls Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE, and therefore the activities of Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE in this jurisdiction are attributed to Sun Pharmaceutical Industries Ltd.

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

17. Sun Pharmaceutical Industries, Inc. is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Upon

information and belief, Sun Pharmaceutical Industries, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey and therefore transacts business within the State of New Jersey related to Pfizer's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

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

19. Upon information and belief, Sun Pharmaceutical derives substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and which

are manufactured by Sun Pharmaceutical and/or for which Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE or Sun Pharmaceutical Industries, Inc. is the named applicant on approved ANDAs. Upon information and belief, various products for which Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, or Sun Pharmaceutical Industries, Inc. is the named applicant on approved ANDAs are available at retail pharmacies in New Jersey.

20. Venue is proper in this district as to Sun Pharmaceutical Industries, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, inter alia, Sun Pharmaceutical Industries, Inc. has its principal place of business in New Jersey.

21. Venue is proper in this district as to Sun Pharmaceutical Industries, Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, inter alia, Sun Pharmaceutical Industries, Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

22. Venue is proper in this district as to Sun Pharma Global FZE pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, inter alia, Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates and is subject to personal jurisdiction in this judicial district.

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 Sun Pharmaceutical’s Notice Letter, Sun Pharmaceutical notified Pfizer of the submission of Sun Pharmaceutical’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 Sun Pharmaceutical’s ANDA Product prior to the expiration of the ’612 patent.

31. In Sun Pharmaceutical’s Notice Letter, Sun Pharmaceutical also notified Pfizer that, as part of Sun Pharmaceutical’s ANDA, Sun Pharmaceutical 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, Sun Pharmaceutical 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 Sun Pharmaceutical’s ANDA Product.

32. Sun Pharmaceutical’s ANDA Product and the use of Sun Pharmaceutical’s ANDA Product are covered by claims 1 and 2 of the ’612 patent.

33. In Sun Pharmaceutical’s Notice Letter, Sun Pharmaceutical 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. Sun Pharmaceutical’s submission of Sun Pharmaceutical’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun Pharmaceutical’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, Sun Pharmaceutical will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun Pharmaceutical’s ANDA Product immediately and imminently upon approval of Sun Pharmaceutical’s ANDA.

36. The manufacture, use, sale, offer for sale, or importation of Sun Pharmaceutical’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 Sun Pharmaceutical’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, Sun Pharmaceutical plans and intends to, and will, actively induce infringement of the ’612 patent when Sun Pharmaceutical’s ANDA is approved,

and plans and intends to, and will, do so immediately and imminently upon approval. Sun Pharmaceutical's activities will be done with knowledge of the '612 patent and specific intent to infringe that patent.

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

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

41. The foregoing actions by Sun Pharmaceutical 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, Sun Pharmaceutical 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 Sun Pharmaceutical's infringement of the '612 patent.

44. Unless Sun Pharmaceutical 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 Sun Pharmaceutical on the other regarding Sun Pharmaceutical's infringement, active inducement of infringement, and contribution to the infringement by others of the '612 patent, and/or 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 Sun Pharmaceutical's Notice Letter, Sun Pharmaceutical notified Pfizer of the submission of Sun Pharmaceutical'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 Sun Pharmaceutical's ANDA Product prior to the expiration of the '612 patent.

50. In Sun Pharmaceutical's Notice Letter, Sun Pharmaceutical also notified Pfizer that, as part of Sun Pharmaceutical's ANDA, Sun Pharmaceutical 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, Sun Pharmaceutical submitted Sun Pharmaceutical's 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 Sun Pharmaceutical's ANDA Product.

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

52. In Sun Pharmaceutical's Notice Letter, Sun Pharmaceutical 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, Sun Pharmaceutical will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun Pharmaceutical's ANDA Product immediately and imminently upon approval of Sun Pharmaceutical's ANDA.

54. The manufacture, use, sale, offer for sale, or importation of Sun Pharmaceutical'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 Sun Pharmaceutical'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, Sun Pharmaceutical plans and intends to, and will, actively induce infringement of the '612 patent when Sun Pharmaceutical's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun Pharmaceutical's activities will be done with knowledge of the '612 patent and specific intent to infringe that patent.

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

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

59. The foregoing actions by Sun Pharmaceutical 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, Sun Pharmaceutical 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 Sun Pharmaceutical’s ANDA Product with its proposed labeling, or any other Sun Pharmaceutical 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 Sun Pharmaceutical’s Notice Letter, Sun Pharmaceutical notified Pfizer of the submission of Sun Pharmaceutical’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 Sun Pharmaceutical’s ANDA Product prior to the expiration of the ’489 patent.

70. In Sun Pharmaceutical’s Notice Letter, Sun Pharmaceutical also notified Pfizer that, as part of Sun Pharmaceutical’s ANDA, Sun Pharmaceutical 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, Sun Pharmaceutical submitted Sun Pharmaceutical’s 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 Sun Pharmaceutical’s ANDA Product.

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

72. In Sun Pharmaceutical’s Notice Letter, Sun Pharmaceutical 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. Sun Pharmaceutical's submission of Sun Pharmaceutical's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun Pharmaceutical'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, Sun Pharmaceutical will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun Pharmaceutical's ANDA Product immediately and imminently upon approval of Sun Pharmaceutical's ANDA.

75. The manufacture, use, sale, offer for sale, or importation of Sun Pharmaceutical'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 Sun Pharmaceutical'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, Sun Pharmaceutical plans and intends to, and will, actively induce infringement of the '489 patent when Sun Pharmaceutical's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun Pharmaceutical's activities will be done with knowledge of the '489 patent and specific intent to infringe that patent.

78. On information and belief, Sun Pharmaceutical knows that Sun Pharmaceutical's

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

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

80. The foregoing actions by Sun Pharmaceutical 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, Sun Pharmaceutical 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 Sun Pharmaceutical's infringement of the '489 patent.

83. Unless Sun Pharmaceutical 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 Sun Pharmaceutical on the other regarding Sun Pharmaceutical's infringement, active inducement of infringement, and contribution to the infringement by others of the '489 patent, and/or 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 Sun Pharmaceutical's Notice Letter, Sun Pharmaceutical notified Pfizer of the submission of Sun Pharmaceutical'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 Sun Pharmaceutical's ANDA Product prior to the expiration of the '489 patent.

88. In Sun Pharmaceutical's Notice Letter, Sun Pharmaceutical also notified Pfizer that, as part of Sun Pharmaceutical's ANDA, Sun Pharmaceutical 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, Sun Pharmaceutical submitted Sun Pharmaceutical's 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 Sun Pharmaceutical's ANDA Product.

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

90. In Sun Pharmaceutical's Notice Letter, Sun Pharmaceutical 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. Sun Pharmaceutical's submission of Sun Pharmaceutical's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun Pharmaceutical'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, Sun Pharmaceutical will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun Pharmaceutical's ANDA Product immediately and imminently upon approval of Sun Pharmaceutical's ANDA.

93. The manufacture, use, sale, offer for sale, or importation of Sun Pharmaceutical'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 Sun Pharmaceutical'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, Sun Pharmaceutical plans and intends to, and will, actively induce infringement of the ’489 patent when Sun Pharmaceutical’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun Pharmaceutical’s activities will be done with knowledge of the ’489 patent and specific intent to infringe that patent.

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

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

98. The foregoing actions by Sun Pharmaceutical 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, Sun Pharmaceutical 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 Sun Pharmaceutical’s ANDA Product with its proposed labeling, or any other Sun Pharmaceutical 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.

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 Sun Pharmaceutical’s submission to the FDA of Sun Pharmaceutical’s ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Sun Pharmaceutical’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 Sun Pharmaceutical,

and all persons acting in concert with Sun Pharmaceutical, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sun Pharmaceutical'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 Sun Pharmaceutical'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.

Dated: April 29, 2019

By: s/ Charles H. Chevalier
Charles H. Chevalier
Gibbons P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Phone: (973) 596-4500
cchevalier@gibbonslaw.com

OF COUNSEL:
David I. Berl

Christopher J. Mandernach
Michael Xun Liu
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000

Attorneys for Plaintiffs