IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., WARNER-LAMBERT COMPANY LLC, and PF PRISM IMB B.V.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
NATCO PHARMA, INC. and NATCO PHARMA, LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Pfizer Inc.; Warner-Lambert Company LLC; and PF PRISM IMB B.V. (collectively, "Pfizer") file this Complaint for patent infringement against Natco Pharma, Inc. and Natco Pharma, Ltd. (collectively, "Natco"), and by their attorneys, hereby alleges 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 Natco'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. RE47,739 ("the '739 patent") and U.S. Patent No. 10,723,730 ("the '730 patent"). These two patents are referred to collectively herein as "the patents-in-suit."

2. Natco Pharma, Ltd. notified Pfizer by letter dated July 13, 2021 ("Natco's Notice Letter") that it had submitted to the FDA ANDA No. 216173 ("Natco's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of generic palbociclib

tablets, 75 mg, 100 mg, and 125 mg ("Natco'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 IMB B.V. is a private limited 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.

6. Upon information and belief, defendant Natco Pharma, Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Natco House, Road No-2, Banjara Hills, Hyderabad 500034, India. Upon information and belief, Natco Pharma, Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products through various operating subsidiaries, including Natco Pharma, Inc.

7. Upon information and belief, defendant Natco Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business

at 241 West Roseville Road, Lancaster, PA 17601. Upon information and belief, Natco Pharma, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

8. Upon information and belief, Natco Pharma, Inc. is a wholly owned subsidiary of Natco Pharma, Ltd.

9. Upon information and belief, Natco Pharma, Inc. is the designated U.S. agent for Natco Pharma, Ltd. in connection with Natco's ANDA.

10. Upon information and belief, Natco Pharma, Ltd. and Natco Pharma, Inc. acted in concert to prepare and submit Natco's ANDA to the FDA.

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

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

13. Natco Pharma, Ltd. is subject to personal jurisdiction in Delaware because, among other things, Natco Pharma, Ltd., itself and through its wholly-owned subsidiary Natco Pharma,

Inc., 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, Natco Pharma, Ltd., itself and through its subsidiary Natco Pharma, 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. In addition, Natco Pharma, Ltd. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Natco Pharma, Inc. and therefore the activities of Natco Pharma, Inc. in this jurisdiction are attributed to Natco Pharma, Ltd.

14. Natco Pharma, 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. Natco Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, upon information and belief, Natco Pharma, 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.

15. Natco has previously used the process contemplated by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"),

21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

16. Upon information and belief, Natco, with knowledge of the Hatch-Waxman Act process, directed Natco's Notice Letter to, *inter alia*, Pfizer Inc., an entity incorporated in Delaware, and alleged in Natco's Notice Letter that the patents-in-suit are invalid. Upon information and belief, Natco 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.

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

18. Upon information and belief, if Natco's ANDA is approved, Natco will directly or indirectly manufacture, market, sell, and/or distribute Natco's ANDA Products within the United States, including in Delaware, consistent with Natco's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Natco 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, Natco's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon

information and belief, Natco'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 Natco's ANDA Products are approved before the patents-in-suit expire.

19. Upon information and belief, Natco derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Natco and/or for which Natco Pharma, Inc. or Natco Pharma, Ltd. is the named applicant on approved ANDAs. Upon information and belief, various products for which Natco Pharma, Ltd. and/or Natco Pharma, Inc. is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

20. Venue is proper in this district as to Natco Pharma, Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Natco Pharma, 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.

21. Venue is proper in this district as to Natco Pharma, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Natco Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

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

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

24. Natco's Notice Letter purported to include an "Offer of Confidential Access" to Pfizer to Natco's ANDA. The offer, however, was subject to various unreasonably restrictive conditions. Rather than engage in protracted negotiations regarding access to Natco's confidential information prior to filing of a complaint for infringement of the patents-in-suit, and in order to better align the schedule in this action with that of other already-pending actions, Pfizer and Natco agreed through counsel to proceed to file this Complaint and handle the production of Natco's confidential information in post-filing discovery.

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

COUNT I - INFRINGEMENT OF THE '739 PATENT

26. Pfizer incorporates each of the preceding paragraphs 1–25 as if fully set forth herein.

27. 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.

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

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

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

31. 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.

32. In Natco's Notice Letter, Natco notified Pfizer of the submission of Natco's ANDA to the FDA. The purpose of this submission was to obtain, *inter alia*, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Natco's ANDA Products prior to the expiration of the '739 patent.

33. In Natco's Notice Letter, Natco also notified Pfizer that, as part of its ANDA, Natco 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. Upon information and belief, Natco 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 Natco's ANDA Products.

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

35. In Natco's Notice Letter, Natco 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.

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

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

38. The manufacture, use, sale, offer for sale, or importation of Natco'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.

39. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Natco'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.

40. Upon information and belief, Natco plans and intends to, and will, actively induce infringement of the '739 patent when Natco's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Natco's activities will be done with knowledge of the '739 patent and specific intent to infringe that patent.

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

42. Notwithstanding Natco's knowledge of the claims of the '739 patent, Natco has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Natco's

ANDA Products with their product labeling following FDA approval of Natco's ANDA prior to the expiration of the '739 patent.

43. The foregoing actions by Natco 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.

44. Upon information and belief, Natco 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.

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

46. Unless Natco 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 II - DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '739 PATENT

47. Pfizer incorporates each of the preceding paragraphs 1–46 as if fully set forth herein.

48. 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 Natco on the other regarding Natco'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.

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

50. In Natco's Notice Letter, Natco notified Pfizer of the submission of Natco's ANDA to the FDA. The purpose of this submission was to obtain, *inter alia*, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Natco's ANDA Products prior to the expiration of the '739 patent.

51. In Natco's Notice Letter, Natco also notified Pfizer that, as part of its ANDA, Natco 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. Upon information and belief, Natco 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 Natco's ANDA Products.

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

53. In Natco's Notice Letter, Natco 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.

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

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

56. The manufacture, use, sale, offer for sale, or importation of Natco'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.

57. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Natco'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.

58. Upon information and belief, Natco plans and intends to, and will, actively induce infringement of the '739 patent when Natco's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Natco's activities will be done with knowledge of the '739 patent and specific intent to infringe that patent.

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

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

61. The foregoing actions by Natco 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.

62. Upon information and belief, Natco 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.

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

64. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Natco's ANDA Products with its proposed labeling, or any other Natco 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 III – INFRINGEMENT OF THE '730 PATENT

65. Pfizer incorporates each of the preceding paragraphs 1–64 as if fully set forth herein.

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

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

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

69. 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").

70. In Natco's Notice Letter, Natco notified Pfizer of the submission of Natco's ANDA to the FDA. The purpose of this submission was to obtain, *inter alia*, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Natco's ANDA Products prior to the expiration of the '730 patent.

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

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

73. 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.

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

75. 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.

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

77. 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.

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

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

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

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

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

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

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

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

86. The foregoing actions by Natco 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.

87. Upon information and belief, Natco 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.

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

89. Unless Natco 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 IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’730 PATENT

90. Pfizer incorporates each of the preceding paragraphs 1–89 as if fully set forth herein.

91. 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 Natco on the other regarding Natco’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.

92. In Natco’s Notice Letter, Natco notified Pfizer of the submission of Natco’s ANDA to the FDA. The purpose of this submission was to obtain, *inter alia*, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Natco’s ANDA Products prior to the expiration of the ’730 patent.

93. In Natco’s Notice Letter, Natco also notified Pfizer that, as part of its ANDA, Natco 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, Natco 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 Natco's ANDA Products.

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

95. 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.

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

97. 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.

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

99. 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.

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

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

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

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

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

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

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

107. The foregoing actions by Natco 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.

108. Upon information and belief, Natco 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.

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

110. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of Natco's ANDA Products with their proposed labeling, or any other Natco 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 Natco's submission to the FDA of Natco's ANDA;

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

(c) A preliminary and permanent injunction enjoining Natco, and all persons acting in concert with Natco, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Natco's ANDA Products, or any other drug product covered by or whose use is covered by one or both 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 Natco's ANDA Products, or any other drug product which is covered by or whose use is covered by one or both 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 patent;

(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

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