IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., WARNER-LAMBERT COMPANY LLC, PF PRISM C.V., PFIZER MANUFACTURING HOLDINGS LLC and PFIZER PFE IRELAND PHARMACEUTICALS HOLDING 1 B.V.,	)	C.A. No. 19-753-CFC
Plaintiffs,	)	
v.	)	
NATCO PHARMA, INC. and NATCO PHARMA, LTD.,	)	
Defendants.	)	

DEFENDANTS NATCO PHARMA INC.'S AND NATCO PHARMA LTD'S ANSWER AND AFFIRMATIVE DEFENSES

Defendants Natco Pharma, Inc. and Natco Pharma, Ltd. (collectively "Natco" or "Defendants"), by and through its undersigned counsel, hereby responds to the separately numbered paragraphs of the complaint filed by Plaintiffs 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" or "Plaintiffs") against Natco as follows:

1. Natco admits that this action purports to be an action for patent infringement, and that the recited ANDA application seeks FDA approval to market a generic version of IBRANCE®, but denies any patent infringement as alleged by Plaintiffs.

2. Admitted.

PARTIES

3. Admitted.

4. Admitted.

5. Admitted.

6. Admitted.

7. Admitted.

8. Admitted.

9. Admitted.

10. Natco denies the allegations of Paragraph 10 of the Complaint as phrased.

11. Natco denies the allegations of Paragraph 11 of the Complaint as phrased, but does not contest subject matter jurisdiction or venue in this Court solely for purposes of the claims asserted against Natco in this case.

12. Natco denies the allegations of Paragraph 12 of the Complaint as phrased, but does not contest subject matter jurisdiction or venue in this Court solely for purposes of the claims asserted against Natco in this case.

JURISDICTION AND VENUE

13. Paragraph 13 of the Complaint contains legal conclusions to which no response is required. To the extent that an answer is required, Natco does not contest subject matter jurisdiction or venue in this Court solely for purposes of the claims asserted against Natco in this case.

14. Paragraph 14 of the Complaint contains legal conclusions to which no response is required. To the extent that an answer is required, Natco does not contest personal jurisdiction in this Court solely for purposes of the claims asserted against Natco in this case.

15. Paragraph 15 of the Complaint contains legal conclusions to which no response is required. To the extent that an answer is required, Natco does not contest personal jurisdiction in this Court solely for purposes of the claims asserted against Natcoin this case.

16. Natco denies the allegations of Paragraph 16 of the Complaint as phrased, but does not contest subject matter jurisdiction or venue in this Court solely for purposes of the claims asserted against Natoc in this case.

17. Natco denies the allegations of Paragraph 17 of the Complaint as phrased, but does not contest subject matter jurisdiction or venue in this Court solely for purposes of the claims asserted against Natco in this case.

18. Paragraph 18 of the Complaint contains legal conclusions to which no response is required. To the extent that an answer is required, Natco does not contest subject matter jurisdiction or venue in this Court solely for purposes of the claims asserted against Natco in this case.

19. Paragraph 19 of the Complaint contains legal conclusions to which no response is required. To the extent that an answer is required, Natco does not contest subject matter jurisdiction or venue in this Court solely for purposes of the claims asserted against Natco in this case.

20. Natco denies the allegations of Paragraph 20 of the Complaint as phrased, but does not contest subject matter jurisdiction or venue in this Court solely for purposes of the claims asserted against Natco in this case.

21. Paragraph 21 of the Complaint contains legal conclusions to which no response is required. To the extent that an answer is required, Natco does not contest venue in this Court solely for purposes of the claims asserted against Natco in this case.

22. Paragraph 22 of the Complaint contains legal conclusions to which no response is required. To the extent that an answer is required, Natco does not contest venue in this Court solely for purposes of the claims asserted against Natco in this case.

COUNT I – INFRINGEMENT OF THE '612 PATENT

23. Natco incorporates its responses to Paragraphs 1-22 as if fully set forth herein.

24. Natco admits that the inventors listed on the front of the '612 patent are as noted in paragraph 24.

25. Natco admits that what purports to be a copy of the '612 patent is attached to the Complaint as Exhibit A. Natco admits that Exhibit A recites the title and issue date as alleged. Natco denies the '612 patent was duly and legally issued.

26. Natco admits that according to the records of the USPTO Pfizer appears to be the assignee of the '612 patent to Pfizer.

27. Natco admits that what purports to be a copy of the '612 patent is attached to the Complaint as Exhibit A. Natco admits that Exhibit A recites Claim 1 as noted in paragraph 27.

28. Natco admits that what purports to be a copy of the '612 patent is attached to the Complaint as Exhibit A. Natco admits that Exhibit A recites Claim 2 as noted in paragraph 28.

29. Natco lacks sufficient information or knowledge to admit or deny the allegations pertaining to the IBRANCE® product being covered by claims 1 and 2 of the '612 patent and therefore denies the same, but admits that the '612 patent has been listed in connection with IBRANCE® in the FDA's Orange Book.

30. Admitted.

31. Admitted.

32. Natco admits that filing its ANDA with a Paragraph IV certification to the '612 patent is a technical act of infringement under 35 U.S.C. § 271(e). Defendant otherwise denies the balance of the allegations of Paragraph 32 of the Complaint.

33. Admitted.

34. Natco admits that filing its ANDA with a Paragraph IV certification to the '612 patent is a technical act of infringement under 35 U.S.C. § 271(e).

35. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '612 patent. Natco denies the remaining allegations of Paragraph 35 of the Complaint as phrased, and affirmatively states that it will decide when and whether to market its product only upon FDA approval.

36. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '612 patent. Natco denies the remaining allegations of Paragraph 36 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

37. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '612 patent. Natco denies the remaining allegations of Paragraph 37 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

38. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '612 patent. Natco denies the remaining allegations of Paragraph 38 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

39. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '612 patent. Natco denies the

remaining allegations of Paragraph 39 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

40. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the ’612 patent. Natco denies the remaining allegations of Paragraph 40 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

41. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the ’612 patent. Natco denies the remaining allegations of Paragraph 41 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

42. Natco admits that it had knowledge of the ‘612 patent when it filed its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell its generic palbociclib products in the United States. Natco denies all other allegations in paragraph 42 of the Complaint.

43. Denied.

44. Denied.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’612 PATENT

45. Natco incorporates its responses to Paragraphs 1-44 as if fully set forth herein.

46. Paragraph 46 of the Complaint contains legal conclusions to which no response is required.

47. Natco admits that what purports to be a copy of the '612 patent is attached to the Complaint as Exhibit A. Natco admits that Exhibit A recites Claim 1 as noted in paragraph 47.

48. Natco admits that what purports to be a copy of the '612 patent is attached to the Complaint as Exhibit A. Natco admits that Exhibit A recites Claim 2 as noted in paragraph 48.

49. Admitted.

50. Admitted.

51. Natco admits that filing its ANDA with a Paragraph IV certification to the '612 patent is a technical act of infringement under 35 U.S.C. § 271(e). Defendant otherwise denies the balance of the allegations of Paragraph 51 of the Complaint.

52. Admitted.

53. Denied as phrased. Natco will decide when and whether to market its product in the United States only upon FDA approval.

54. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '612 patent. Natco denies the remaining allegations of Paragraph 54 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

55. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '612 patent. Natco denies the remaining allegations of Paragraph 55 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

56. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '612 patent. Natco denies the remaining allegations of Paragraph 56 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

57. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '612 patent. Natco denies the remaining allegations of Paragraph 57 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

58. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '612 patent. Natco denies the remaining allegations of Paragraph 58 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

59. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '612 patent. Natco denies the remaining allegations of Paragraph 59 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

60. Natco admits that it had knowledge of the '612 patent when it filed its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell its generic

palbociclib products in the United States. Natco denies all other allegations in paragraph 60 of the Complaint.

61. Denied.

62. Denied.

COUNT III - INFRINGEMENT OF THE '489 PATENT

63. Natco incorporates its responses to Paragraphs 1-62 as if fully set forth herein.

64. Natco admits that the inventors listed on the front of the '612 patent are as noted in paragraph 64.

65. Natco admits that what purports to be a copy of the '489 patent is attached to the Complaint as Exhibit B. Natco admits that Exhibit B recites the title and issue date as alleged. Natco denies the '489 patent was duly and legally issued.

66. Natco admits that according to the records of the USPTO Pfizer appears to be the assignee of the '612 patent to Pfizer.

67. Admitted.

68. Natco lacks sufficient information or knowledge to admit or deny the allegations pertaining to the whether the IBRANCE® product is covered by one or more claims of the '489 patent and therefore denies the same, but admits that the '489 patent has been listed in connection with IBRANCE® in the FDA's Orange Book.

69. Admitted

70. Admitted.

71. Natco admits that filing its ANDA with a Paragraph IV certification to the '489 patent is a technical act of infringement under 35 U.S.C. § 271(e). Defendant otherwise denies the balance of the allegations of Paragraph 71 of the Complaint.

72. Admitted.

73. Natco admits that filing its ANDA with a Paragraph IV certification to the '489 patent is a technical act of infringement under 35 U.S.C. § 271(e).

74. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '489 patent. Natco denies the remaining allegations of Paragraph 74 of the Complaint as phrased, and affirmatively states that it will decide whether and when to market its product only upon FDA approval.

75. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '489 patent. Natco denies the remaining allegations of Paragraph 75 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

76. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '489 patent. Natco denies the remaining allegations of Paragraph 76 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

77. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '489 patent. Natco denies the remaining allegations of Paragraph 77 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

78. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '489 patent. Natco denies the remaining allegations of Paragraph 78 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

79. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '489 patent. Natco denies the remaining allegations of Paragraph 79 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

80. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '489 patent. Natco denies the remaining allegations of Paragraph 80 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

81. Natco admits that it had knowledge of the '489 patent when it filed its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell its generic palbociclib products in the United States. Natco denies all other allegations in paragraph 81 of the Complaint.

82. Denied.

83. Denied.

COUNT IV - DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '489 PATENT

84. Natco incorporates its responses to Paragraphs 1-83 as if fully set forth herein.

85. Paragraph 85 of the Complaint contains legal conclusions to which no response is required.

86. Admitted. Natco admits that what purports to be a copy of the '489 patent is attached to the Complaint as Exhibit B. Natco admits that Exhibit B recites Claim 1 as noted in paragraph 86.

87. Admitted.

88. Admitted.

89. Natco admits that filing its ANDA with a Paragraph IV certification to the '489 patent is a technical act of infringement under 35 U.S.C. § 271(e). Defendant otherwise denies the balance of the allegations of Paragraph 89 of the Complaint.

90. Admitted.

91. Natco admits that filing its ANDA with a Paragraph IV certification to the '489 patent is a technical act of infringement under 35 U.S.C. § 271(e). Defendant otherwise denies the balance of the allegations of Paragraph 91 of the Complaint.

92. Denied as phrased. Natco will decide when and whether to market its product in the United States only upon FDA approval.

93. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '489 patent. Natco denies the remaining allegations of Paragraph 93 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

94. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of

its ANDA Product in the United States before expiration of the '489 patent. Natco denies the remaining allegations of Paragraph 94 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

95. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '489 patent. Natco denies the remaining allegations of Paragraph 95 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

96. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '489 patent. Natco denies the remaining allegations of Paragraph 96 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

97. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '489 patent. Natco denies the remaining allegations of Paragraph 97 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

98. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '489 patent. Natco denies the remaining allegations of Paragraph 98 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

99. Natco admits that it had knowledge of the '489 patent when it filed its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell its generic palbociclib products in the United States. Natco denies all other allegations in paragraph 99 of the Complaint.

100. Denied.

101. Denied.

COUNT V - INFRINGEMENT OF THE '168 PATENT

102. Natco incorporates its responses to Paragraphs 1 - 101 as if fully set forth herein.

103. Natco admits that the inventors listed on the front of the '168 patent are as noted in paragraph 102.

104. Natco admits that what purports to be a copy of the '612 patent is attached to the Complaint as Exhibit C. Natco admits that Exhibit C recites the title and issue date as alleged. Natco denies the '168 patent was duly and legally issued.

105. Natco admits that according to the records of the USPTO Pfizer appears to be the assignee of the '168 patent to Pfizer.

106. Natco admits that what purports to be a copy of the '168 patent is attached to the Complaint as Exhibit C. Natco admits that Exhibit C recites Claim 1 as noted in paragraph 106.

107. Natco lacks sufficient information or knowledge to admit or deny the allegations pertaining to the whether the IBRANCE® product is covered by claims 1-7 and 9 of the '168 patent and therefore denies the same, but admits that the '168 patent has been listed in connection with IBRANCE® in the FDA's Orange Book.

108. Admitted.

109. Admitted.

110. Natco admits that filing its ANDA with a Paragraph IV certification to the '168 patent is a technical act of infringement under 35 U.S.C. § 271(e). Defendant otherwise denies the balance of the allegations of Paragraph 110 of the Complaint.

111. Admitted.

112. Natco admits that filing its ANDA with a Paragraph IV certification to the '168 patent is a technical act of infringement under 35 U.S.C. § 271(e).

113. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '168 patent. Natco denies the remaining allegations of Paragraph 113 of the Complaint as phrased, and affirmatively states that it will decide when and whether to market its product only upon FDA approval.

114. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '168 patent. Natco denies the remaining allegations of Paragraph 114 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

115. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '168 patent. Natco denies the remaining allegations of Paragraph 115 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

116. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of

its ANDA Product in the United States before expiration of the '168 patent. Natco denies the remaining allegations of Paragraph 116 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

117. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '168 patent. Natco denies the remaining allegations of Paragraph 117 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

118. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '168 patent. Natco denies the remaining allegations of Paragraph 118 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

119. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '168 patent. Natco denies the remaining allegations of Paragraph 119 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

120. Natco admits that it had knowledge of the '168 patent when it filed its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell its generic palbociclib products in the United States. Natco denies all other allegations in paragraph 120 of the Complaint.

121. Denied.

122. Denied.

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

123. Natco incorporates its responses to Paragraphs 1-122 as if fully set forth herein.

124. Paragraph 124 of the Complaint contains legal conclusions to which no response is required.

125. Natco admits that what purports to be a copy of the '168 patent is attached to the Complaint as Exhibit C. Natco admits that Exhibit C recites Claim 1 as noted in paragraph 125.

126. Admitted.

127. Admitted.

128. Natco admits that filing its ANDA with a Paragraph IV certification to the '168 patent is a technical act of infringement under 35 U.S.C. § 271(e). Defendant otherwise denies the balance of the allegations of Paragraph 128 of the Complaint.

129. Admitted.

130. Natco admits that filing its ANDA with a Paragraph IV certification to the '168 patent is a technical act of infringement under 35 U.S.C. § 271(e). Defendant otherwise denies the balance of the allegations of Paragraph 130 of the Complaint.

131. Denied as phrased. Natco will decide whether to market its product in the United States only upon FDA approval.

132. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '168 patent. Natco denies the remaining allegations of Paragraph 132 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

133. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '168 patent. Natco denies the remaining allegations of Paragraph 133 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

134. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '168 patent. Natco denies the remaining allegations of Paragraph 134 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

135. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '168 patent. Natco denies the remaining allegations of Paragraph 135 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

136. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '168 patent. Natco denies the remaining allegations of Paragraph 136 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

137. Natco admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its ANDA Product in the United States before expiration of the '168 patent. Natco denies the

remaining allegations of Paragraph 137 of the Complaint as phrased, and affirmatively states that it will decide whether to market its product only upon FDA approval.

138. Natco admits that it had knowledge of the '168 patent when it filed its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell its generic palbociclib products in the United States. Natco denies all other allegations in paragraph 138 of the Complaint.

139. Denied.

140. Denied.

RESPONSE TO PRAYER FOR RELIEF

Natco denies that Plaintiffs are entitled to any of the relief requested by the Complaint, or any other relief whatsoever.

AFFIRMATIVE DEFENSES

Natco asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. Natco does not assume the burden of proof on any such defenses, except as required by the applicable law with respect to the particular defense asserted. Natco reserves the right to assert other defenses and/or to otherwise supplement or amend its Answer and Affirmative Defenses to the Complaint upon discovery of facts or evidence rendering such action appropriate.

FIRST DEFENSE
(Invalidity of the '612 Patent Based on Title 35 of the U.S. Code)

Based at least upon the prior art and arguments set forth in the detailed statement of the legal and factual basis for its Paragraph IV Certification, included with the letter that is the subject of paragraph 31 of this Complaint, one or more claims of the '612 patent are invalid to a person

having ordinary skill in the art, and for otherwise failing to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 103 and/or 112.

SECOND DEFENSE
(Invalidity of the '489 Patent Based on Title 35 of the U.S. Code)

Based at least upon the prior art and arguments set forth in the detailed statement of the legal and factual basis for its Paragraph IV Certification, included with the letter that is the subject of paragraph 69 of this Complaint, one or more claims of the '489 patent are invalid to a person having ordinary skill in the art, and for otherwise failing to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 103 and/or 112.

THIRD DEFENSE
(Invalidity of the '168 Patent Based on Title 35 of the U.S. Code)

Based at least upon the prior art and arguments set forth in the detailed statement of the legal and factual basis for its Paragraph IV Certification, included with the letter that is the subject of paragraph 108 of this Complaint, one or more claims of the '168 patent are invalid to a person having ordinary skill in the art, and for otherwise failing to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 103 and/or 112.

FOURTH DEFENSE
(Lack of Irreparable Harm)

Plaintiffs have planned for, and in fact anticipated, the filing of several ANDA applications with the FDA for the approval of generic forms of its IBRANCE® product for many years. Accordingly, should Natco's ANDA product be approved and should it further be sold in the United States market, Plaintiffs would not be irreparably harmed as a result of such anticipated competition. Further, should such sales occur, there are adequate remedies at law available, assuming such sales are found to infringe the patents in suit. Moreover, considering the balance of hardships between the parties, and the public interest in fostering the prompt introduction of

generic pharmaceuticals to the market, the equitable remedy of a permanent injunction is not warranted in any event.

FIFTH DEFENSE
(Additional Defenses or Counterclaims)

Natco reserves all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent laws and any additional defenses or counterclaims that discovery may reveal including that Plaintiffs have failed to state a claim upon which relief may be granted and that Plaintiffs have failed to aver any facts supporting that this is an exceptional case and an award of attorney's fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiff respectfully requests that this Court enter a judgment in its favor and against Counterclaim-Defendants as follows:

(a) Dismissing the Complaint with prejudice and entering judgment for Counterclaim-Plaintiff;

(b) Declaring that the claims of the '612, '489, and '168 patents are invalid;

(c) Enjoining Counterclaim-Defendants, their officers, agents, servants, employees, attorneys and any person who acts in concert or participation with Counterclaim-Defendants from threatening to assert or otherwise attempting to enforce the '612, '489, and '168 patents against Counterclaim-Plaintiff, its customers, suppliers, or anyone in privity with Counterclaim-Plaintiff;

(d) Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Counterclaim-Plaintiff its reasonable attorneys' fees and costs incurred in this action;

(e) Awarding Counterclaim-Plaintiff its costs and expenses incurred in this action; and

(f) Awarding Counterclaim-Plaintiff such other and further relief as this Court may deem proper.

/s/ Kelly E. Farnan

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