

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

PFIZER INC., WARNER-LAMBERT	)
COMPANY LLC, and PF PRISM	)
IMB B.V.,	)
	) C.A. No. 21-078-CFC
Plaintiffs,	)
	)
v.	)
	)
NATCO PHARMA, INC. and	)
NATCO PHARMA, LTD.,	)
	)
Defendants.	)

**DEFENDANTS NATCO PHARMA, INC. AND NATCO PHARMA, LTD.’S  
ANSWER AND AFFIRMATIVE DEFENSES**

Defendants Natco Pharma, Inc. and Natco Pharma, Ltd. (collectively, “Natco” or “Defendants”), by and through their undersigned counsel, hereby respond to the separately numbered paragraphs of the complaint filed by Plaintiffs Pfizer Inc., Warner-Lambert Company LLC, PF Prism IMB B.V. (collectively, “Pfizer” or “Plaintiffs”) against Natco as follows:

1.     **ANSWER:** 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.     **ANSWER:** Admitted.

## **PARTIES**

3. **ANSWER:** Admitted.

4. **ANSWER:** Admitted.

5. **ANSWER:** Admitted.

6. **ANSWER:** Admitted.

7. **ANSWER:** Admitted.

8. **ANSWER:** Admitted.

9. **ANSWER:** Natco denies the allegations of Paragraph 9 of the Complaint as phrased.

10. **ANSWER:** Natco denies the allegations of Paragraph 10 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.

11. **ANSWER:** 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.

## **JURISDICTION**

12. **ANSWER:** Paragraph 12 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.

13. **ANSWER:** 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 personal jurisdiction in this Court solely for purposes of the claims asserted against Natco in this case.

14. **ANSWER:** 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. **ANSWER:** Natco denies the allegations of Paragraph 15 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.

16. **ANSWER:** 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 Natco in this case.

17. **ANSWER:** Paragraph 17 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.

18. **ANSWER:** Natco denies the allegations of Paragraph 18 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.

19. **ANSWER:** Natco denies the allegations of Paragraph 19 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.

20. **ANSWER:** Paragraph 20 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.

21. **ANSWER:** 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.

### **FACTUAL BACKGROUND**

22. **ANSWER:** Denied as phrased. IBRANCE® is approved for the treatment of HRpositive, HER2-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine based therapy in postmenopausal women or in combination with fulvestrant in women with disease progression following endocrine therapy.

23. **ANSWER:** Natco admits that if approved, its ANDA Product will be approved as bioequivalent to IBRANCE®.

24. **ANSWER:** Natco admits that it included an “Offer of Confidential Access” to Pfizer in its notice letter to Natco’s ANDA, but denies it contained “various unreasonably restrictive conditions.”

25. **ANSWER:** Denied as phrased. Plaintiffs rejected Natco’s reasonable terms for access to Natco’s internal documents, and nothing in the governing statute requires an ANDA applicant to produce samples. Natco admits that it did not respond to Plaintiffs’ letter presenting unreasonable demands.

26. **ANSWER:** Admitted.

#### **COUNT I – INFRINGEMENT OF THE '730 PATENT**

27. **ANSWER:** Natco incorporates its responses to Paragraphs 1 - 26 as if fully set forth herein.

28. **ANSWER:** Natco admits that the inventors listed on the front of the '730 patent are as noted in paragraph 28.

29. **ANSWER:** Natco admits that what purports to be a copy of the '730 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 '730 patent was duly and legally issued.

30. **ANSWER:** Natco admits that according to the records of the USPTO Pfizer appears to be the assignee of the '730 patent to Pfizer.

31. **ANSWER:** Natco lacks sufficient information or knowledge to admit or deny the allegations pertaining to the IBRANCE® product being covered by one or more claims of the '730 patent and therefore denies the same, but admits that the '730 patent has been listed in connection with IBRANCE® in the FDA's Orange Book.

32. **ANSWER:** Natco admits that its Notice Letter notified Pfizer of the submission of Natco's ANDA to the FDA, and that the purpose of its ANDA submission is to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Natco's ANDA Product prior to the expiration of the '730 patent.

33. **ANSWER:** Admitted.

34. **ANSWER:** Natco admits that filing its ANDA with a Paragraph IV certification to the '730 patent is a technical act of infringement under 35 U.S.C. § 271(e). Natco otherwise denies the balance of the allegations of Paragraph 34 of the Complaint.

35. **ANSWER:** Natco admits that claim 1 of the '730 patent is accurately recited in this paragraph, but otherwise denies the balance of the allegations of

Paragraph 35 of the Complaint to the extent it seeks to allege Natco's ANDA product, if approved, would be within the scope of this claim.

36. **ANSWER:** Denied.

37. **ANSWER:** Natco admits that claim 7 of the '730 patent is accurately recited in this paragraph, but otherwise denies the balance of the allegations of Paragraph 37 of the Complaint to the extent it seeks to allege Natco's ANDA product, if approved, would be within the scope of this claim.

38. **ANSWER:** Denied.

39. **ANSWER:** Natco admits that claim 15 of the '730 patent is accurately recited in this paragraph, but otherwise denies the balance of the allegations of Paragraph 39 of the Complaint to the extent it seeks to allege Natco's ANDA product, if approved, would be within the scope of this claim.

40. **ANSWER:** Denied.

41. **ANSWER:** Denied.

42. **ANSWER:** 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 '730 patent. Natco denies the remaining allegations of Paragraph 42 of the Complaint as phrased, and affirmatively states that it will decide when and whether to market its product only upon FDA approval.

43. **ANSWER:** Denied.

44. **ANSWER:** Denied.

45. **ANSWER:** Denied.

46. **ANSWER:** Denied.

47. **ANWSER:** Denied.

48. **ANSWER:** Denied.

49. **ANSWER:** Denied.

50. **ANSWER:** Denied.

51. **ANSWER:** Denied.

**COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '730 PATENT**

52. **ANSWER:** Natco incorporates its responses to Paragraphs 1 - 51 as if fully set forth herein.

53. **ANSWER:** Paragraph 53 of the Complaint contains legal conclusions to which no response is required.

54. **ANSWER:** Natco admits that its Notice Letter notified Pfizer of the submission of Natco's ANDA to the FDA, and that the purpose of its ANDA submission is to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Natco's ANDA Product prior to the expiration of the '730 patent.

55. **ANSWER:** Admitted.

56. **ANSWER:** Denied.

57. **ANSWER:** Natco admits that claim 1 of the '730 patent is accurately recited in this paragraph, but otherwise denies the balance of the allegations of Paragraph 57 of the Complaint to the extent it seeks to allege Natco's ANDA product, if approved, would be within the scope of this claim.

58. **ANSWER:** Denied.

59. **ANSWER:** Natco admits that claim 7 of the '730 patent is accurately recited in this paragraph, but otherwise denies the balance of the allegations of Paragraph 59 of the Complaint to the extent it seeks to allege Natco's ANDA product, if approved, would be within the scope of this claim.

60. **ANSWER:** Denied.

61. **ANSWER:** Natco admits that claim 15 of the '730 patent is accurately recited in this paragraph, but otherwise denies the balance of the allegations of Paragraph 61 of the Complaint to the extent it seeks to allege Natco's ANDA product, if approved, would be within the scope of this claim..

62. **ANSWER:** Denied.

63. **ANSWER:** 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 '730 patent. Natco denies the remaining allegations of Paragraph

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

64. **ANSWER:** Denied.

65. **ANSWER:** Denied.

66. **ANSWER:** Denied.

67. **ANSWER:** Denied.

68. **ANSWER:** Denied.

69. **ANSWER:** Denied.

70. **ANSWER:** Denied.

71. **ANSWER:** Denied.

72. **ANSWER:** 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**  
**(Non-Infringement of the '730 Patent)**

For the reasons stated in 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 2 of this Complaint, no claim of the '730 patent would be infringed upon approval of Natco's ANDA Product.

**SECOND DEFENSE**  
**(Invalidity of the '730 Patent Based on Title 35 of the U.S. Code)**

Based on information and belief based on investigation to date, one or more claims of the '730 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**  
**(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.

**FOURTH 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.

**PRAAYER FOR RELIEF**

WHEREFORE, Natco respectfully requests that this Court enter a judgment in its favor and against Plaintiffs as follows:

- (a) Dismissing the Complaint with prejudice and entering judgment for Natco;
- (b) Enjoining Plaintiffs, their officers, agents, servants, employees, attorneys and any person who acts in concert or participation with Plaintiffs from threatening to assert or otherwise attempting to enforce the '730 patent against Natco, its customers, suppliers, or anyone in privity with Natco;

- (c) Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Natco its reasonable attorneys' fees and costs incurred in this action;
- (d) Awarding Natco its costs and expenses incurred in this action; and
- (e) Awarding Natco such other and further relief as this Court may deem proper.

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