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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

THERAVANCE BIOPHARMA R&D IP, LLC, THERAVANCE BIOPHARMA US, INC., THERAVANCE BIOPHARMA IRELAND LIMITED, MYLAN	1:23-cv-06667-KMW-AMD

IRELAND LIMITED, and MYLAN SPECIALTY L.P.,

Plaintiffs,

v.

EUGIA PHARMA SPECIALTIES LTD., EUGIA US LLC, AUROBINDO PHARMA USA, INC., AUROBINDO PHARMA LIMITED, MANKIND PHARMA LTD., LIFESTAR PHARMA LLC, TEVA PHARMACEUTICALS, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC., ACCORD HEALTHCARE, INC., ACCORD HEALTHCARE, LTD., INTAS PHARMACEUTICALS LTD., LUPIN INC., LUPIN LTD., LUPIN PHARMACEUTICALS, INC., ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED, CIPLA LIMITED, CIPLA USA, INC.,

Defendants.

Hon. Karen M. Williams, U.S.D.J
Hon. Ann Marie Donio, U.S.M.J.

ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS

Document Electronically Filed

Defendants Cipla Limited and Cipla USA Inc. (collectively, "Cipla" or "Defendants"), by and through their attorneys, respond to each of the numbered paragraphs in the Complaint for Patent Infringement by Plaintiffs Theravance Biopharma R&D IP, LLC, Theravance Biopharma Ireland Limited, Theravance Biopharma US, Inc., Mylan Ireland Limited, and Mylan Specialty L.P. (collectively, "Plaintiffs") as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 11,691,948 (the "'948 patent") arising under the Patent Laws of the United States, Title 35, United States Code, Section 1 et seq. This action relates to Abbreviated New Drug Application ("ANDA") No. 218089, filed by Mankind; ANDA No. 217015, filed by Teva; ANDA No. 218100, filed by Accord; ANDA No. 218128, filed by Eugia; ANDA No. 218088, filed by Lupin; ANDA No. 217868, filed by Orbicular; and ANDA No. 217958, filed by Cipla, with the United States Food and Drug

Administration ("FDA") for approval to market generic versions of YUPELRI® (revefenacin) inhalation solution, for oral inhalation, prior to the expiration of patents listed in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") for YUPELRI®, including the '948 patent.

ANSWER: Cipla admits that the Complaint purports to be based upon the patent laws of the United States, 35 U.S.C. § 1, *et seq.* Cipla admits that Cipla Ltd. prepared and submitted Abbreviated New Drug Application No. 217958 ("Cipla's ANDA") with the FDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or import of the product described in Cipla's ANDA ("Cipla's ANDA Product") before the expiration dates listed in the FDA's Orange Book for the '948 patent. Cipla denies the remaining allegations in Paragraph 1 of the Complaint.

THE PARTIES

Plaintiffs

2. Plaintiff Theravance Biopharma R&D IP, LLC is a Delaware limited liability company having a principal place of business at 901 Gateway Boulevard, South San Francisco, CA, 94080.

ANSWER: Upon information and belief, Cipla admits that Theravance Biopharma R&D IP, LLC has a place of business at 901 Gateway Boulevard, South San Francisco, CA, 94080. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 2 of the Complaint, and therefore denies them.

3. Plaintiff Theravance Biopharma US, Inc. is a Delaware corporation having a principal place of business at 901 Gateway Boulevard, South San Francisco, CA, 94080.

ANSWER: Upon information and belief, Cipla admits that Theravance Biopharma US, Inc. has a place of business at 901 Gateway Boulevard, South San Francisco, CA, 94080. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining

allegations and characterizations contained in Paragraph 3 of the Complaint, and therefore denies them.

4. Plaintiff Theravance Biopharma Ireland Limited is an Irish company having a registered office at Ten Earlsfort Terrace, Dublin 2, D02 T380, Ireland.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 4 of the Complaint, and therefore denies them.

5. Plaintiff Mylan Ireland Limited is a company having a principal place of business at Newenham Court, Northern Cross, Malahide Road, Dublin 17, Ireland; and a registered office at Unit 35/36, Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 5 of the Complaint, and therefore denies them.

6. Plaintiff Mylan Specialty L.P. is a company having a principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia, 26505.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 6 of the Complaint, and therefore denies them.

7. Plaintiff Mylan Specialty L.P. sells YUPELRI® in this judicial district and throughout the United States.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 7 of the Complaint, and therefore denies them.

8. Plaintiffs Mylan Specialty L.P. and Theravance Biopharma US, Inc. promote and market YUPELRI® in the United States.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 8 of the Complaint, and therefore denies them.

9. Theravance Biopharma R&D IP, LLC is the assignee of the '948 patent. Theravance Biopharma R&D IP, LLC is a wholly owned subsidiary of Theravance Biopharma Ireland Limited.

ANSWER: Cipla admits that the U.S. Patent and Trademark Office assignment database lists Theravance Biopharma R&D IP, LLC as the assignee of the '948 patent. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 9 of the Complaint, and therefore denies them.

10. Theravance Biopharma Ireland Limited is the exclusive licensee, and Mylan Ireland Limited is the exclusive sub-licensee, of the '948 patent. Mylan Ireland Limited is also the holder of approved New Drug Application No. 210598 for YUPELRI® (revefenacin) inhalation solution, for oral inhalation (the "YUPELRI® NDA").

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 10 of the Complaint, and therefore denies them.

Eugia

11. On information and belief, Defendant Eugia Pharma is a company organized and existing under the laws of India, with its principal place of business at either its registered office at Maitrivihar, Plot No. 2, Maitrivihar, Ameerpet, Hyderabad, Telangana , India, 500038.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 11 of the Complaint, and therefore denies them.

12. On information and belief, Eugia Pharma has on some occasions identified itself as Eugia Pharma "Specialities," and on other occasions as Eugia Pharma "Specialties," including, for

example, in Answers that Eugia Pharma filed in the following cases: *Pfizer Inc. et al. v. Aurobindo Pharma, Ltd. et al.*, No. 20-cv-01528, Answer (D. Del. Dec 4, 2020) ("Eugia Pharma Specialities Ltd."); *Medicure International, Inc. v. Aurobindo Pharma Ltd. et al.*, No. 2:21-cv-17534, Answer (D.N.J. Feb. 16, 2022) ("Eugia Pharma Specialties Limited"); *Amgen Inc. et al. v. Aurobindo Pharma Ltd. et al.*, No. 22-cv-00227, Answer (D. Del. Mar 17, 2022) ("Eugia Pharma Specialties Limited"); and *Aragon Pharms., Inc. et al. v. Eugia Pharma Specialities Ltd. et al.*, No. 2-22-cv-03186, Answer (D.N.J. May 26, 2022) ("Eugia Pharma Specialities Limited").

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 12 of the Complaint, and therefore denies them.

13. On information and belief, Defendant Eugia US is a company organized and existing under the laws of Delaware, with its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 13 of the Complaint, and therefore denies them.

14. On information and belief, Eugia US is formerly known as AuroMedics Pharma LLC.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 14 of the Complaint, and therefore denies them.

15. On information and belief, Defendant Aurobindo USA is a company organized and existing under the laws of Delaware, with its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 15 of the Complaint, and therefore denies them.

16. On information and belief, Defendant Aurobindo Ltd. is a company organized and existing under the laws of India, with its principal place of business at Plot No. 11, Survey No. 9, Water Mark Building, Kondapur, Hitech City, Hyderabad 500 084, Telangana, India.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 16 of the Complaint, and therefore denies them.

17. On information and belief, Eugia Pharma is a wholly owned subsidiary of Aurobindo Ltd.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 17 of the Complaint, and therefore denies them.

18. On information and belief, Eugia US is a wholly owned subsidiary of Aurobindo Ltd.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 18 of the Complaint, and therefore denies them.

19. On information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Ltd.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 19 of the Complaint, and therefore denies them.

20. On information and belief, Eugia Pharma, Eugia US, Aurobindo USA, and Aurobindo Ltd. acted in concert to prepare and submit ANDA No. 218128 (the "Eugia ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Eugia ANDA Product"), for oral inhalation, prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 20 of the Complaint, and therefore denies them.

21. On information and belief, following any FDA approval of the Eugia ANDA, Eugia Pharma, Eugia US, Aurobindo USA, and Aurobindo Ltd. will act in concert to commercially manufacture, import, market, offer for sale, distribute, and/or sell the Eugia ANDA Product throughout the United States, including within the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 21 of the Complaint, and therefore denies them.

Mankind

22. On information and belief, Defendant Mankind Pharma is a company organized and existing under the laws of India, with its principal place of business at 208, Okhla Industrial Estate, Phase III, New Delhi, 110020 India.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 22 of the Complaint, and therefore denies them.

23. On information and belief, Defendant Lifestar is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 1200 MacArthur Blvd., Mahwah, New Jersey 07430.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 23 of the Complaint, and therefore denies them.

24. On information and belief, Lifestar is a wholly owned subsidiary of Mankind Pharma.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 24 of the Complaint, and therefore denies them.

25. On information and belief, Mankind Pharma and Lifestar acted in concert to prepare and submit ANDA No. 218089 (the "Mankind ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into, the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Mankind ANDA Product"), for oral inhalation, prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 25 of the Complaint, and therefore denies them.

26. On information and belief, following any FDA approval of the Mankind ANDA, Mankind Pharma and Lifestar will act in concert to commercially manufacture, import, market, offer for sale, distribute, and/or sell the Mankind ANDA Product throughout the United States, including within the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 26 of the Complaint, and therefore denies them.

Teva

27. On information and belief, Defendant Teva Pharmaceuticals is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, New Jersey 07054.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 27 of the Complaint, and therefore denies them.

28. On information and belief, Defendant Teva USA is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, New Jersey 07054.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 28 of the Complaint, and therefore denies them.

29. On information and belief, Defendant Teva Industries is a company organized and existing under the laws of Israel, with its principal place of business at 5 Basel Street, Petach Tikva 49131 Israel.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 29 of the Complaint, and therefore denies them.

30. On information and belief, Teva Pharmaceuticals is a wholly owned subsidiary of Teva Industries.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 30 of the Complaint, and therefore denies them.

31. On information and belief, Teva USA is a wholly owned subsidiary of Teva Industries.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 31 of the Complaint, and therefore denies them.

32. On information and belief, Teva Pharmaceuticals, Teva USA, and Teva Industries acted in concert to prepare and submit ANDA No. 217015 (the "Teva ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into, the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Teva ANDA Product"), for oral inhalation, prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 32 of the Complaint, and therefore denies them.

33. On information and belief, following any FDA approval of the Teva ANDA, Teva Pharmaceuticals, Teva USA, and Teva Industries will act in concert to commercially manufacture, import, market, offer for sale, distribute, and/or sell the Teva ANDA Product throughout the United States, including within the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 33 of the Complaint, and therefore denies them.

Accord

34. On information and belief, Defendant Accord Inc. is a company organized and existing under the laws of the State of North Carolina, with its principal place of business at 1009 Slater Road, Suite 210B, Durham, North Carolina 27703.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 34 of the Complaint, and therefore denies them.

35. On information and belief, Defendant Accord Ltd. is a company organized and existing under the laws of India, with its principal place of business at Near Sola Bridge, Sarkhej – Gandhinagar Highway, Thaltej, Ahmedabad, Gujarat 380054, India.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 35 of the Complaint, and therefore denies them.

36. On information and belief, Defendant Intas is a company organized and existing under the laws of India, with its principal place of business at Near Sola Bridge, Sarkhej – Gandhinagar Highway, Thaltej, Ahmedabad, Gujarat 380054, India.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 36 of the Complaint, and therefore denies them.

37. On information and belief, Accord Inc. is a wholly owned subsidiary of Intas.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 37 of the Complaint, and therefore denies them.

38. On information and belief, Accord Ltd. is a wholly owned subsidiary of Intas.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 38 of the Complaint, and therefore denies them.

39. On information and belief, Accord Inc., Accord Ltd., and Intas acted in concert to prepare and submit ANDA No. 218100 (the "Accord ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into, the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Accord ANDA Product"), for oral inhalation, prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 39 of the Complaint, and therefore denies them.

40. On information and belief, following any FDA approval of the Accord ANDA, Accord Inc., Accord Ltd., and Intas will act in concert to commercially manufacture, import, market, offer for sale, distribute, and/or sell the Accord ANDA Product throughout the United States, including within the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 40 of the Complaint, and therefore denies them.

Lupin

41. On information and belief, Defendant Lupin Inc. is a company organized and existing under the laws of the State of Delaware, with a place of business at 400 Campus Drive, Somerset, New Jersey 08873.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 41 of the Complaint, and therefore denies them.

42. On information and belief, Defendant Lupin Ltd. is a company organized and existing under the laws of India, with its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex Bandra (E), Mumbai, 400051, India.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 42 of the Complaint, and therefore denies them.

43. On information and belief, Defendant Lupin Pharmaceuticals is a company organized and existing under the laws of Delaware, with a place of business at 400 Campus Drive, Somerset, New Jersey 08873.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 43 of the Complaint, and therefore denies them.

44. On information and belief, Lupin Inc. is a wholly owned subsidiary of Lupin Ltd.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 44 of the Complaint, and therefore denies them.

45. On information and belief, Lupin Pharmaceuticals is a wholly owned subsidiary of Lupin Ltd.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 45 of the Complaint, and therefore denies them.

46. On information and belief, Lupin Inc., Lupin Ltd., and Lupin Pharmaceuticals acted in concert to prepare and submit ANDA No. 218088 (the "Lupin ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into, the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Lupin ANDA Product"), for oral inhalation, prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 46 of the Complaint, and therefore denies them.

47. On information and belief, following any FDA approval of the Lupin ANDA, Lupin Inc., Lupin Ltd., and Lupin Pharmaceuticals will act in concert to commercially manufacture, import, market, offer for sale, distribute, and/or sell the Lupin ANDA Product throughout the United States, including within the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 47 of the Complaint, and therefore denies them.

Orbicular

48. On information and belief, Defendant Orbicular is a company organized and existing under the laws of India, with its principal place of business at Plot No. 53, ALEAP Industrial Estate, Pragathi Nagar, Kukatpally, Hyderabad, 500090, India.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 48 of the Complaint, and therefore denies them.

49. On information and belief, Orbicular prepared and submitted ANDA No. 217868 (the "Orbicular ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into the United States, including, on information and belief, in the State

of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Orbicular ANDA Product"), for oral inhalation, prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 49 of the Complaint, and therefore denies them.

50. On information and belief, following any FDA approval of the Orbicular ANDA, Orbicular will commercially manufacture, import, market, offer for sale, distribute, and/or sell the Orbicular ANDA Product throughout the United States, including within the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 50 of the Complaint, and therefore denies them.

Cipla

51. On information and belief, Defendant Cipla Ltd. is a company organized and existing under the laws of India, with its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai Maharashtra 400013, India.

ANSWER: Admitted.

52. On information and belief, Defendant Cipla USA is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059.

ANSWER: Admitted.

53. On information and belief, Cipla USA is a wholly owned subsidiary of Cipla Ltd.

ANSWER: Admitted.

54. On information and belief, Cipla Ltd. and Cipla USA acted in concert to prepare and submit ANDA No. 217958 (the "Cipla ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into, the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Cipla ANDA Product"), for oral inhalation, prior to the expiration of the '948 patent.

ANSWER: Cipla admits that Cipla Ltd. prepared and submitted Cipla's ANDA with the FDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or import of Cipla's ANDA Product. Cipla denies the remaning allegations and characterizations contained in Paragraph 54 of the Complaint

55. On information and belief, following any FDA approval of the Cipla ANDA, Cipla Ltd. and Cipla USA will act in concert to commercially manufacture, import, market, offer for sale, distribute, and/or sell the Cipla ANDA Product throughout the United States, including within the State of New Jersey.

ANSWER: Cipla denies the allegations of Paragraph 55 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

JURISDICTION AND VENUE

56. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Cipla repeats and realleges its responses to the prior paragraphs of the Complaint as if fully set forth herein.

57. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271.

ANSWER: Cipla admits that the Complaint purports to be based upon the patent laws of the United States, 35 U.S.C. § 1, *et seq*., including 35 U.S.C. § 271.

58. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 28 U.S.C. §§ 2201 and 2202, regardless of whether the named defendants have submitted with their respective ANDAs a Paragraph IV certification to the '948 patent. *See Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1124 (Fed. Cir. 2018) ("Here, [Plaintiff's] complaint alleged that [Defendant] infringed the [] patent under 35 U.S.C. § 271(e)(2)(A) by filing the ANDA . . . Nothing more was required to establish the district court's subject matter jurisdiction pursuant to 28 U.S.C. § 1338(a)."

ANSWER: Paragraph 58 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest subject matter jurisdiction

over the '948 patent for the limited purposes of this litigation. Cipla denies the remaining allegations of Paragraph 58.

Eugia

59. This Court has personal jurisdiction over Eugia US at least because, on information and belief, Eugia US is a corporation with its principal place of business in the State of New Jersey, at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 59 of the Complaint, and therefore denies them.

60. This Court has personal jurisdiction over Aurobindo USA at least because, on information and belief, Aurobindo USA is a corporation with its principal place of business in the State of New Jersey, at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 60 of the Complaint, and therefore denies them.

61. This Court has personal jurisdiction over Eugia Pharma at least because, on information and belief, Eugia Pharma directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 61 of the Complaint, and therefore denies them.

62. This Court has personal jurisdiction over Eugia US at least because, on information and belief, Eugia US directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 62 of the Complaint, and therefore denies them.

63. This Court has personal jurisdiction over Aurobindo USA at least because, on information and belief, Aurobindo USA directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 63 of the Complaint, and therefore denies them.

64. This Court has personal jurisdiction over Aurobindo Ltd. at least because, on information and belief, Aurobindo Ltd. directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 64 of the Complaint, and therefore denies them.

65. This Court has personal jurisdiction over Eugia Pharma, Eugia US, Aurobindo USA, and Aurobindo Ltd. at least because, inter alia, on information and belief, (1) Eugia Pharma itself, and/or in concert with Eugia US, Aurobindo Ltd. and/or Aurobindo USA, has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Eugia ANDA Product in the United States, including the State of New Jersey; and (2) Eugia Pharma itself, and/or in concert with Eugia US, Aurobindo Ltd. and/or Aurobindo USA, will market, distribute, offer for sale, and/or sell the Eugia ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 218128, and Eugia will derive substantial revenue from the use or consumption of the Eugia ANDA Product in the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 65 of the Complaint, and therefore denies them.

66. If Eugia Pharma's connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Eugia Pharma is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Eugia Pharma in the State of New Jersey is consistent with the United States Constitution and laws. See Fed. R. Civ. P. 4(k)(2).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 66 of the Complaint, and therefore denies them.

67. If Aurobindo Ltd.'s connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Aurobindo Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Aurobindo Ltd. in the State of New Jersey is consistent with the United States Constitution and laws. See Fed. R. Civ. P. 4(k)(2).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 67 of the Complaint, and therefore denies them.

68. On information and belief, Eugia US is registered as a "Manufacturer and Wholesale" entity with the State of New Jersey's Department of Health under Registration No. 5004299.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 68 of the Complaint, and therefore denies them.

69. On information and belief, Aurobindo USA is registered as a "Wholesale" entity with the State of New Jersey's Department of Health under Registration Nos. 5003120 and 5005256.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 69 of the Complaint, and therefore denies them.

70. On information and belief, Aurobindo USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID No. 0100921223.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 70 of the Complaint, and therefore denies them.

71. Venue is proper in this district for Eugia Pharma pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Eugia Pharma is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 71 of the Complaint, and therefore denies them.

72. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Eugia US at least because, on information and belief, Eugia US has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Eugia US has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '948 patent that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Eugia ANDA in the State of New Jersey and/or with the intention of seeking to market the Eugia ANDA Product nationwide, including within the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 72 of the Complaint, and therefore denies them.

73. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Aurobindo USA at least because, on information and belief, Aurobindo USA has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Aurobindo USA has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '948 patent that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Eugia ANDA in the State of New Jersey and/or with the intention of seeking to market the Eugia ANDA Product nationwide, including within the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 73 of the Complaint, and therefore denies them.

74. Venue is proper in this district for Aurobindo Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Aurobindo Ltd. is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 74 of the Complaint, and therefore denies them.

75. Eugia did not contest jurisdiction and venue in a patent infringement litigation in the District of New Jersey related to the same Eugia ANDA No. 218128 for approval to market the same generic version of YUPELRI® (revefenacin) inhalation solution as in the instant case. *See, e.g.*, *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 75 of the Complaint, and therefore denies them.

76. On information and belief, Eugia Pharma, Aurobindo USA, and Aurobindo Ltd. have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and have not contested jurisdiction and venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See, e.g.*, *Eisai Co., Ltd. et al. v. Aurobindo Pharma Ltd. et al.*, No. 1-22-cv-03610 (D.N.J. June 8, 2022) (Aurobindo USA and Aurobindo Ltd.); *Aragon Pharms., Inc. et al. v. Eugia Pharma Specialities Ltd. et al.*, No. 2-22-cv-03186 (D.N.J. May 26, 2022) (Eugia Pharma and Aurobindo USA); *Medicure International, Inc. v. Aurobindo Pharma Ltd. et al.*, No. 2-21-cv-17534 (D.N.J. Sept. 24, 2021) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim); *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 2-21-cv-00624 (D.N.J. Jan. 12, 2021) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim); *Merck Sharp & Dohme BV et al. v. Aurobindo Pharma USA, Inc. et al.*, No. 2-20-cv-02576 (D.N.J. Mar. 10, 2020) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.); *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 2-20-cv-00315 (D.N.J. Jan. 8, 2020) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim); *Celgene Corp. v.*

Aurobindo Pharma Ltd. et al., No. 2-19-cv-05799 (D.N.J. Feb. 14, 2019) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim); *Boehringer Ingelheim Pharms., Inc. et al. v. Aurobindo Pharma USA Inc. et al.*, No. 3-17-cv-07887 (D.N.J. Oct. 4, 2017) (Eugia Pharma and Aurobindo USA) (also filed a counterclaim); *Celgene Corp. v. Hetero Labs Ltd. et al.*, No. 2-17-cv-03387 (D.N.J. May 11, 2017) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 76 of the Complaint, and therefore denies them.

Mankind

77. This Court has personal jurisdiction over Lifestar at least because, on information and belief, Lifestar is a corporation with its principal place of business in New Jersey, at 1200 MacArthur Blvd, Mahwah, New Jersey 07430.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 77 of the Complaint, and therefore denies them.

78. This Court has personal jurisdiction over Mankind Pharma at least because, on information and belief, Mankind Pharma directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 78 of the Complaint, and therefore denies them.

79. This Court has personal jurisdiction over Lifestar at least because, on information and belief, Lifestar directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 79 of the Complaint, and therefore denies them.

80. This Court has personal jurisdiction over Mankind Pharma and Lifestar at least because, *inter alia*, on information and belief, (1) Mankind Pharma itself, and/or in concert with its wholly owned subsidiary Lifestar, has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Mankind ANDA Product in the United States, including the State of New Jersey; and (2) Mankind Pharma itself, and/or in concert with its wholly owned subsidiary Lifestar, will market, distribute, offer for sale, and/or sell the Mankind ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 218089, and Mankind will derive substantial revenue from the use or consumption of the Mankind ANDA Product in the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 80 of the Complaint, and therefore denies them.

81. If Mankind Pharma's connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Mankind Pharma is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Mankind Pharma in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 81 of the Complaint, and therefore denies them.

82. On information and belief, Lifestar is registered as a "Manufacturer and Wholesale" entity with the State of New Jersey's Department of Health under Registration No. 5005074.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 82 of the Complaint, and therefore denies them.

83. On information and belief, Lifestar is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID No. 0450064472.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 83 of the Complaint, and therefore denies them.

84. Venue is proper in this district for Mankind Pharma pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, on information and belief, Mankind Pharma is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 84 of the Complaint, and therefore denies them.

85. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Lifestar at least because, on information and belief, Lifestar has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Lifestar has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '948 patent that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Mankind ANDA in the State of New Jersey and/or with the intention of seeking to market the Mankind ANDA Product nationwide, including within the State of New Jersey

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 85 of the Complaint, and therefore denies them.

86. Mankind did not contest jurisdiction and venue in a patent infringement litigation in the District of New Jersey related to the same Mankind ANDA No. 218089 for approval to market the same generic version of YUPELRI® (revefenacin) inhalation solution as in the instant case. *See, e.g., Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited, et al.*, No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 86 of the Complaint, and therefore denies them.

87. On information and belief, Mankind Pharma and Lifestar have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and did not contest jurisdiction and venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See, e.g.*, *Bayer Intellectual Property GmbH et al. v. Mankind Pharma Ltd.*, No. 22-cv-05599 (D.N.J. Sept. 16, 2022) (Mankind Pharma); *Merck Sharp & Dohme B.V. et al. v. Mankind Pharma Ltd. et al.*, No. 2:20-cv-02787 (D.N.J. Mar. 13, 2020) (Mankind Pharma and Lifestar); *Celgene Corp. v. Mankind Pharma Ltd. et al.*, No. 3:18-cv-11081 (D.N.J. June 26, 2018) (Mankind Pharma) (also filed a counterclaim).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 87 of the Complaint, and therefore denies them.

Teva

88. This Court has personal jurisdiction over Teva USA at least because, on information and belief, Teva USA is a corporation with its principal place of business in the State of New Jersey, at 400 Interpace Parkway, Suite A1, Parsippany, New Jersey 07054.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 88 of the Complaint, and therefore denies them.

89. This Court has personal jurisdiction over Teva Pharmaceuticals at least because, on information and belief, Teva Pharmaceuticals is a corporation with its principal place of business in the State of New Jersey, at 400 Interpace Parkway, Suite A1, Parsippany, New Jersey 07054.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 89 of the Complaint, and therefore denies them.

90. This Court has personal jurisdiction over Teva Pharmaceuticals at least because, on information and belief, Teva Pharmaceuticals directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 90 of the Complaint, and therefore denies them.

91. This Court has personal jurisdiction over Teva USA at least because, on information and belief, Teva USA directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 91 of the Complaint, and therefore denies them.

92. This Court has personal jurisdiction over Teva Industries at least because, on information and belief, Teva Industries directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 92 of the Complaint, and therefore denies them.

93. This Court has personal jurisdiction over Teva Pharmaceuticals, Teva USA, and Teva Industries at least because, *inter alia*, on information and belief, (1) Teva Pharmaceuticals itself, and/or in concert with Teva USA and/or Teva Industries, has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product in the United States, including the State of New Jersey; and (2) Teva Pharmaceuticals itself, and/or in concert with Teva USA and/or Teva Industries, will market, distribute, offer for sale, and/or sell the Teva ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 217015, and Teva will derive substantial revenue from the use or consumption of the Teva ANDA Product in the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 93 of the Complaint, and therefore denies them.

94. If Teva Industries' connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Teva Industries is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Teva Industries in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 94 of the Complaint, and therefore denies them.

95. On information and belief, Teva USA is registered as a "Manufacturer and Wholesale" entity with the State of New Jersey's Department of Health under Registration Nos. 5000583 and 5003436.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 95 of the Complaint, and therefore denies them.

96. On information and belief, Teva USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID. No. 0100250184.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 96 of the Complaint, and therefore denies them.

97. On information and belief, Teva Pharmaceuticals is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID No. 0450614134.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 97 of the Complaint, and therefore denies them.

98. Venue is proper in this district for Teva Industries pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Teva Industries is a foreign corporation organized and existing under the laws of Israel and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 98 of the Complaint, and therefore denies them.

99. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Teva Pharmaceuticals at least because, on information and belief, Teva Pharmaceuticals has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Teva Pharmaceuticals has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '948 patent that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Teva ANDA in the State of New Jersey and/or with the intention of seeking to market the Teva ANDA Product nationwide, including within the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 99 of the Complaint, and therefore denies them.

100. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Teva USA at least because, on information and belief, Teva USA has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Teva USA has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '948 patent that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Teva ANDA in the State of New Jersey and/or with the intention of seeking to market the Teva ANDA Product nationwide, including within the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 100 of the Complaint, and therefore denies them.

101. Teva Pharmaceuticals and Teva USA did not contest jurisdiction and venue, and filed counterclaims, in a patent infringement litigation in the District of New Jersey related to the same Teva ANDA No. 217015 for approval to market the same generic version of YUPELRI® (revefenacin) inhalation solution as in the instant case.[1] *See, e.g.*, *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 101 of the Complaint, and therefore denies them.

102. On information and belief, Teva Pharmaceuticals and/or Teva USA have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and have consented to jurisdiction and/or venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See, e.g.*, *Horizon Orphan LLC, et al. v. Teva Pharms., Inc.*, No. 1-22-cv-01382 (D.N.J. Mar. 15, 2022) (Teva Pharmaceuticals); *Evoke Pharma, Inc. v. Teva Pharms., Inc., et al.*, No. 1-22-cv-02019 (Apr. 7, 2022) (Teva Pharmaceuticals and Teva USA); *Merck Sharp & Dohme BV et al. v. Teva Pharm. Indus. Ltd. et al.*, No. 2-20-cv-18972 (D.N.J. Dec. 14, 2020) (Teva USA) (also filed a counterclaim); *TherapeuticsMD, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 2-20-cv-17496 (D.N.J. Nov. 30, 2020) (Teva USA) (also filed a counterclaim); *TherapeuticsMD, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 2-20-cv-11087 (D.N.J. Aug. 21, 2020) (Teva USA); *TherapeuticsMD, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 2-20-cv-08809 (D.N.J. Jul. 13, 2020) (Teva USA) (also filed a counterclaim); *TherapeuticsMD, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 2-20-cv-03485 (D.N.J. Apr. 1, 2020) (Teva USA) (also filed a counterclaim); *Horizon Medicines LLC v. Teva Pharms. USA, Inc.*, No. 2-20-cv-08188 (D.N.J. Jul. 2, 2020) (Teva USA) (also filed a counterclaim); *Tris Pharma, Inc. v. Teva Pharms. USA, Inc.*, No. 2-20-cv-05212 (D.N.J. Apr. 28, 2020) (Teva USA) (also filed a counterclaim); *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 2-19-cv-21384 (D.N.J. Dec. 13, 2019) (Teva USA).

[1] Defendant Teva Industries was dismissed from that action before answering the complaint. *See Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD, D.I. 21 (D.N.J. Feb. 16, 2023).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 102 of the Complaint, and therefore denies them.

Accord

103. This Court has personal jurisdiction over Accord Inc. at least because, on information and belief, Accord Inc. directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 103 of the Complaint, and therefore denies them.

104. This Court has personal jurisdiction over Accord Ltd. at least because, on information and belief, Accord Ltd. directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 104 of the Complaint, and therefore denies them.

105. This Court has personal jurisdiction over Intas at least because, on information and belief, Intas directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 105 of the Complaint, and therefore denies them.

106. This Court has personal jurisdiction over Accord Inc., Accord Ltd., and Intas at least because, *inter alia*, on information and belief, (1) Accord Inc. itself, and/or in concert with Intas and/or Accord Ltd., has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product in the United States, including the State of New Jersey; and (2) Accord Inc. itself, and/or in concert

with its wholly owned subsidiaries Intas and/or Accord Ltd., will market, distribute, offer for sale, and/or sell the Accord ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 218100, and Accord will derive substantial revenue from the use or consumption of the Accord ANDA Product in the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 106 of the Complaint, and therefore denies them.

107. If Accord Ltd.'s connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Accord Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Accord Ltd. in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 107 of the Complaint, and therefore denies them.

108. If Intas' connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Intas is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Intas in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 108 of the Complaint, and therefore denies them.

109. On information and belief, Intas, Accord Inc., and Accord Ltd. operate as a single integrated business. Accord Inc.'s website indicates that "Accord Healthcare, Inc., the US subsidiary of Intas Pharmaceuticals, is a leading generic pharmaceutical company . . . . Through its subsidiaries, Intas markets its products in 85 countries." *See* https://www.accordhealthcare.us/#:~:text=Accord%20Healthcare%2C%20Inc.%2C%20the,its20products%20in%2085%20countries. (Accessed August 21, 2023).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 109 of the Complaint, and therefore denies them.

110. Venue is proper as to Intas pursuant to 28 U.S.C. §§ 1391 and/or 1400(b) at least because, *inter alia*, on information and belief, Intas is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district..

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 110 of the Complaint, and therefore denies them.

111. Venue is proper in this district for Accord Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Accord Ltd. is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 111 of the Complaint, and therefore denies them.

112. Accord Inc. did not contest jurisdiction and venue, and filed counterclaims, in a patent infringement litigation in the District of New Jersey related to the same Accord ANDA No. 218100 for approval to market the same generic version of YUPELRI® (revefenacin) inhalation solution as in the instant case.[2] *See, e.g.*, *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 112 of the Complaint, and therefore denies them.

[2] Defendants Accord Ltd. and Intas were dismissed from that action before answering the complaint. *See Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD, D.I. 21 (D.N.J. Feb. 16, 2023).

113. On information and belief, Accord Inc. and Intas have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and have not contested jurisdiction and venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See, e.g.*, *Eagle Pharms., Inc., et al. v. Accord Healthcare Inc.*, No. 2-19-cv-09031 (D.N.J. Mar. 27, 2019) (Accord Inc.); *Sumitomo Dainippon Pharma Co., Ltd., et al. v. Aurobindo Pharma Ltd., et al.*, No. 2-18-cv-02620 (D.N.J. Feb. 23, 2018) (Accord Inc.); *Otsuka Pharms. Co., Ltd., v. Intas Pharms. Ltd., et al.*, No. 1:16-cv-05743 (D.N.J. Sept. 19, 2016) (Accord Inc. and Intas) (also filed a counterclaim); *Sanofi-Aventis US LLC v. Accord Healthcare, Inc.*, No. 3-14-cv-08079 (D.N.J. Dec. 29, 2014) (Accord Inc.) (also filed a counterclaim); *Otsuka Pharm. Co. v. Intas Pharms. Ltd., et al.*, No. 1-14-cv-03996 (D.N.J. Jun. 20, 2014) (Accord Inc. and Intas) (also filed a counterclaim).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 113 of the Complaint, and therefore denies them.

Lupin

114. This Court has personal jurisdiction over Lupin Inc. at least because, on information and belief, Lupin Inc. is a corporation with a place of business in the State of New Jersey, at 400 Campus Drive, Somerset, New Jersey 08873.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 114 of the Complaint, and therefore denies them.

115. This Court has personal jurisdiction over Lupin Pharmaceuticals at least because, on information and belief, Lupin Pharmaceuticals is a corporation with a place of business in the State of New Jersey, at 400 Campus Drive, Somerset, New Jersey 08873.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 115 of the Complaint, and therefore denies them.

116. This Court has personal jurisdiction over Lupin Inc. at least because, on information and belief, Lupin Inc. directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 116 of the Complaint, and therefore denies them.

117. This Court has personal jurisdiction over Lupin Ltd. at least because, on information and belief, Lupin Ltd. directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 117 of the Complaint, and therefore denies them.

118. This Court has personal jurisdiction over Lupin Pharmaceuticals at least because, on information and belief, Lupin Pharmaceuticals directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 118 of the Complaint, and therefore denies them.

119. This Court has personal jurisdiction over Lupin Inc., Lupin Ltd., and Lupin Pharmaceuticals at least because, *inter alia*, on information and belief, (1) Lupin Inc. itself, and/or in concert with Lupin Ltd. and/or Lupin Pharmaceuticals, has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Lupin ANDA Product in the United States, including the State of New Jersey; and (2) Lupin Inc. itself, and/or in concert with Lupin Ltd. and/or Lupin Pharmaceuticals, will market, distribute, offer for sale, and/or sell the Lupin ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 218088, and Lupin will derive substantial revenue from the use or consumption of the Lupin ANDA Product in the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 119 of the Complaint, and therefore denies them.

120. If Lupin Ltd.'s connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Lupin Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Lupin Ltd. in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 120 of the Complaint, and therefore denies them.

121. On information and belief, Lupin Pharmaceuticals is registered as a "Manufacturer and Wholesale" entity with the State of New Jersey's Department of Health under Registration Nos. 5004060 and 5005159.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 121 of the Complaint, and therefore denies them.

122. On information and belief, Lupin Pharmaceuticals is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID Nos. 0100953673 and 0101043376.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 122 of the Complaint, and therefore denies them.

123. Venue is proper in this district for Lupin Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Lupin Ltd. is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 123 of the Complaint, and therefore denies them.

124. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Lupin Inc. at least because, on information and belief, Lupin Inc. has a regular and established place of

business in the State of New Jersey, and at least because, on information and belief, Lupin Inc. has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '948 patent that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Lupin ANDA in the State of New Jersey and/or with the intention of seeking to market the Lupin ANDA Product nationwide, including within the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 124 of the Complaint, and therefore denies them.

125. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Lupin Pharmaceuticals at least because, on information and belief, Lupin Pharmaceuticals has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Lupin Pharmaceuticals has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '948 patent that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Lupin ANDA in the State of New Jersey and/or with the intention of seeking to market the Lupin ANDA Product nationwide, including within the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 125 of the Complaint, and therefore denies them.

126. Lupin Inc. and Lupin Pharmaceuticals did not contest jurisdiction and venue, and filed counterclaims, in a patent infringement litigation in the District of New Jersey related to the same Lupin ANDA No. 218088 for approval to market the same generic version of YUPELRI® (revefenacin) inhalation solution as in the instant case.[3] *See, e.g.*, *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

[3] Defendant Lupin Ltd. was dismissed from that action before answering the complaint. *See Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD, D.I. 21 (D.N.J. Feb. 16, 2023).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 126 of the Complaint, and therefore denies them.

127. On information and belief, Lupin Inc., Lupin Ltd., and/or Lupin Pharmaceuticals have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and have not contested jurisdiction and venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See, e.g., Aragon Pharms., Inc. et al. v. Lupin Ltd. et al.*, No. 2-22-cv-02825 (D.N.J. May 13, 2022) (Lupin Ltd. and Lupin Pharmaceuticals) (also filed a counterclaim); *Jazz Pharm., Inc. v. Lupin Ltd.*, No. 2-22-cv-02773 (D.N.J. May 11, 2022) (Lupin Inc.) (also filed a counterclaim); *Bausch & Lomb, Inc. et al. v. Lupin Ltd. et al.*, No. 3-22-cv-00534 (D.N.J. Feb. 2, 2022) (Lupin Ltd.) (also filed a counterclaim); *Teva Branded Pharm. Prods. R&D, Inc. et al. v. Lupin Ltd. et al.*, No. 3-21-cv-13247 (D.N.J. Jul. 1, 2021) (Lupin Ltd.) (also filed a counterclaim); *Purple Biotech Ltd. v. Lupin Ltd. et al.*, No. 2-20-cv-12849 (D.N.J. Sept. 18, 2020) (Lupin Ltd.) (also filed a counterclaim); *Bausch Health Ireland Ltd. f/k/a Valeant Pharms. Ireland Ltd. et al. v. Lupin Ltd. et al.*, No. 1-20-cv-11039 (D.N.J. Aug. 21, 2020) (Lupin Inc.) (also filed a counterclaim); *Horizon Orphan LLC et al. v. Lupin Ltd. et al.*, No. 2-20-cv-10339 (D.N.J. Aug. 11, 2020) (Lupin Ltd. and Lupin Pharmaceuticals) (Lupin Ltd. also filed a counterclaim); *Celgene Corp. v. Lupin Ltd.*, No. 2-20-cv-08570 (D.N.J. Jul. 9, 2020) (Lupin Ltd.) (also filed a counterclaim); *Bristol-Myers Squibb Co. v. Lupin Ltd. et al.*, No. 3-20-cv-07810 (D.N.J. Jun. 25, 2020) (Lupin Inc.) (also filed a counterclaim); *Valeant Pharm. N. Am. LLC v. Lupin Ltd.*, No. 3-18-cv-13700 (Sept. 9, 2018) (Lupin Ltd.) (also filed a counterclaim).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 127 of the Complaint, and therefore denies them.

Orbicular

128. This Court has personal jurisdiction over Orbicular at least because, on information and belief, Orbicular directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 128 of the Complaint, and therefore denies them.

129. This Court has personal jurisdiction over Orbicular at least because, *inter alia*, on information and belief, (1) Orbicular filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Orbicular ANDA Product in the United States, including the State of New Jersey; and (2) Orbicular will market, distribute, offer for sale, and/or sell the Orbicular ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 217868, and Orbicular will derive substantial revenue from the use or consumption of the Orbicular ANDA Product in the State of New Jersey.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 129 of the Complaint, and therefore denies them.

130. If Orbicular's connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Orbicular is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Orbicular in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 130 of the Complaint, and therefore denies them.

131. Venue is proper in this district for Orbicular pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Orbicular is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 131 of the Complaint, and therefore denies them.

132. Orbicular did not contest jurisdiction and venue in patent infringement litigations in the District of New Jersey related to the same Orbicular ANDA No. 217868 for approval to market the same generic version of YUPELRI® (revefenacin) inhalation solution as in the instant case. *See, e.g., Theravance Biopharma R&D IP, LLC et al. v. Orbicular Pharmaceutical Technologies Private Ltd.*, No. 1:23-cv-02843-KMW-AMD (D.N.J. May 24, 2023); *Theravance*

Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al., No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 132 of the Complaint, and therefore denies them.

133. On information and belief, Orbicular has litigated a previous Hatch-Waxman patent infringement dispute in the District of New Jersey and did not contest jurisdiction and venue in the District of New Jersey in a prior case arising out of the filing of an ANDA filing. *See Aerie Pharm., Inc. et al. v. Orbicular Pharm. Techs.*, No. 3-22-cv-01364 (D.N.J. Mar. 14, 2022).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 133 of the Complaint, and therefore denies them.

Cipla

134. This Court has personal jurisdiction over Cipla USA at least because, on information and belief, Cipla USA is a corporation with its principal place of business in the State of New Jersey, at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059.

ANSWER: Paragraph 134 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest personal jurisdiction over Cipla USA in this Court for the limited purposes of this litigation. Cipla admits that Cipla USA has a principal place of business in the State of New Jersey, at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059.

135. This Court has personal jurisdiction over Cipla Ltd. at least because, on information and belief, Cipla Ltd. directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Paragraph 135 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest personal jurisdiction

over Cipla Ltd. in this Court for the limited purposes of this litigation. Cipla further admits that Cipla Ltd. is in the business of developing, manufacturing, and selling pharmaceutical drug products, including generic drug products, in the United States. Cipla denies the remaining allegations of Paragraph 135.

136. This Court has personal jurisdiction over Cipla USA at least because, on information and belief, Cipla USA directly or indirectly develops, manufacturers, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

ANSWER: Paragraph 136 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest personal jurisdiction in this Court for the limited purposes of this litigation. Cipla further admits that Cipla USA is in the business of marketing, and selling pharmaceutical drug products, including generic drug products, in the United States. Cipla denies the remaining allegations of Paragraph 136.

137. This Court has personal jurisdiction over Cipla Ltd. and Cipla USA at least because, *inter alia*, on information and belief, (1) Cipla Ltd. itself, and/or in concert with its wholly owned subsidiary and agent Cipla USA, has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Cipla ANDA Product in the United States, including the State of New Jersey; and (2) Cipla Ltd. itself, and/or in concert with its wholly owned subsidiary and agent Cipla USA, will market, distribute, offer for sale, and/or sell the Cipla ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 217958, and Cipla will derive substantial revenue from the use or consumption of the Cipla ANDA Product in the State of New Jersey.

ANSWER: Paragraph 137 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited or Cipla USA, Inc. for the limited purposes of this litigation. Cipla further admits that Cipla Limited prepared and submitted Cipla's ANDA seeking approval from the FDA to market and sell Cipla's ANDA Product in the United States. Cipla denies the remaining allegations of Paragraph 137.

138. If Cipla Ltd.'s connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Cipla Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Cipla Ltd. in the State of New Jersey is consistent with the United States Constitution and laws. See Fed. R. Civ. P. 4(k)(2).

ANSWER: Paragraph 138 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest this Court's jurisdiction over Cipla Ltd. for the limited purposes of this litigation. Cipla denies the remaining allegations of Paragraph 138.

139. On information and belief, Cipla USA is registered as a "Manufacturer and Wholesale" entity with the State of New Jersey's Department of Health under Registration No. 5005183.

ANSWER: Admitted.

140. On information and belief, Cipla USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID No. 0450318628.

ANSWER: Admitted.

141. Venue is proper in this district for Cipla Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Cipla Ltd. is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

ANSWER: Paragraph 141 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest venue in this Court for the limited purposes of this litigation. Cipla admits that Cipla Limited is a foreign corporation. Cipla denies the remaining allegations of Paragraph 141.

142. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Cipla USA at least because, on information and belief, Cipla USA has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Cipla USA has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '948 patent that will lead to foreseeable harm and injury to Plaintiffs by

preparing or assisting in preparing the Cipla ANDA in the State of New Jersey and/or with the intention of seeking to market the Cipla ANDA Product nationwide, including within the State of New Jersey.

ANSWER: Paragraph 142 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest venue in this Court for the limited purposes of this litigation. Cipla admits that Cipla USA is a corporation organized and existing under the laws of the State of Delaware. Cipla denies the remaining allegations of Paragraph 142.

143. Cipla did not contest jurisdiction and venue, and filed counterclaims, in a patent infringement litigation in the District of New Jersey related to the same Cipla ANDA No. 217958 for approval to market the same generic version of YUPELRI® (revefenacin) inhalation solution as in the instant case. *See, e.g., Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

ANSWER: Admitted.

144. On information and belief, Cipla Ltd. and Cipla USA have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and did not contest jurisdiction and venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See, e.g., Par Pharm., Inc. et al. v. Cipla Ltd. et al.*, No. 2-22-cv-02814 (D.N.J. May 13, 2022) (Cipla Ltd. and Cipla USA) (also filed a counterclaim); *Teva Branded Pharm. Prods. R&D, Inc. et al. v. Cipla Ltd.*, No. 2-20-cv-14890 (D.N.J. Oct. 23, 2020) (Cipla Ltd.) (also filed a counterclaim); *Teva Branded Pharm. Prods. R&D, Inc. et al. v. Cipla Ltd.*, No. 2-20-cv-10172 (D.N.J. Aug. 7, 2020) (Cipla Ltd.) (also filed a counterclaim); *Celgene Corp. v. Cipla Ltd.*, No. 2-20-cv-07759 (D.N.J. Jun. 24, 2020) (Cipla Ltd.) (also filed a counterclaim); *Celgene Corp. v. Cipla Ltd.*, No. 2-19-cv-14731 (D.N.J. Jul. 3, 2019) (Cipla Ltd.) (also filed a counterclaim); *Cubist Pharms. LLC f/k/a Cubist Pharms., Inc. v. Cipla USA, Inc. et al.*, No. 3-19-cv-12920 (May 24, 2019) (Cipla Inc. and Cipla Ltd.) (also filed a counterclaim).

ANSWER: Admitted.

THE PATENT-IN-SUIT

145. The ’948 patent, titled “Crystalline Freebase Forms of a Biphenyl Compound,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on July 4, 2023. A true and correct copy of the ’948 patent is attached as Exhibit A.

ANSWER: Cipla admits that Exhibit A to the Complaint purports to be a copy of the '948 patent. Cipla admits that the '948 patent is entitled "Crystalline Freebase Forms of a Biphenyl Compound" and lists July 4, 2023 as an issue date. Cipla denies the remaining allegations in Paragraph 145.

146. Theravance Biopharma R&D IP, LLC is the assignee of the '948 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the '948 patent. Mylan Ireland Limited is the exclusive sub-licensee of the '948 patent from Theravance Biopharma Ireland Limited.

ANSWER: Cipla admits that Theravance Biopharma R&D IP, LLC is listed as the assignee of the '948 patent in the U.S. Patent and Trademark Office assignment database. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in Paragraph 146 and therefore denies them.

147. The '948 patent is listed in the Orange Book as covering YUPELRI®.

ANSWER: Cipla admits that the '948 patent is listed in connection with YUPELRI® in the FDA's Orange Book. Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 147 of the Complaint, and therefore denies them.

YUPELRI®

148. Plaintiffs are engaged in the business of creating, developing, and bringing to market innovative pharmaceutical products for the treatment of diseases.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 148 of the Complaint, and therefore denies them.

149. Plaintiffs' YUPELRI® (revefenacin) is a prescription medicine indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease ("COPD"), a chronic inflammatory lung disease characterized by progressive persistent airflow obstruction.

Revefenacin is a long-acting muscarinic antagonist, which is often referred to as an anticholinergic. It is administered long-term as one vial of YUPELRI®, one time each day, by the orally inhaled route via a jet nebulizer.

ANSWER: Cipla admits that the YUPELRI® label recites that "YUPELRI is indicated for the maintenance treatment of patientis with chronic obstructive pulmonary disease (COPD)," and that "[r]evefenacin is a long-acting muscarinic antagonist, which is often referred to as an anticholinergic." Cipla further admits that the label states "[t]he recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 149 of the Complaint, and therefore denies them.

150. FDA regulations require that approved drug products include prescribing information reciting the FDA-approved indication(s) for the drug and related instructions for healthcare providers to safely and effectively administer the drug. *See* 21 C.F.R. § 201.56(a)(1)-(3), (d)(1); 21 C.F.R. § 201.57(a)-(c).

ANSWER: Paragraph 150 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 150.

151. Consistent with FDA regulations, the package insert for YUPELRI® includes prescribing information that recites the FDA-approved indication for YUPELRI® and provides instructions for healthcare providers and patients to safely and effectively administer YUPELRI®.

ANSWER: Paragraph 151 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 151.

152. Attached as Exhibit B is a true and correct copy of the May 2022 YUPELRI® package insert, which is the current version of the YUPELRI® package insert.

ANSWER: Cipla admits that Exhibit B to the Complaint purports to be a copy of the May 2022 YUPELRI® package insert. Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 152 of the Complaint, and therefore denies them.

153. YUPELRI® is indicated for the maintenance treatment of patients with COPD. (Ex. B at § 1).

ANSWER: Cipla admits that the YUPELRI® label recites that "YUPELRI is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." The remainder of Paragraph 153 contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies the remaining allegations of Paragraph 153.

ACTS GIVING RISE TO THIS ACTION

Eugia

154. In a letter dated January 9, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Eugia Notice Letter"), Eugia notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had submitted the Eugia ANDA to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of the Eugia ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of United States Patent Nos. 8,541,451 (the "'451 patent"), 9,765,028 (the "'028 patent"), 10,550,081 (the "'081 patent"), 11,008,289 (the "'289 patent"), and 11,484,531 (the "'531 patent").

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 154 of the Complaint, and therefore denies them.

155. Plaintiffs filed a complaint for infringement of the '451 patent, '028 patent, '081 patent, '289 patent, and '531 patent against, *inter alia*¸ Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma USA, Inc., and Aurobindo Pharma Limited, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD. On July 4, 2023, the '948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

ANSWER: Cipla admits that Plaintiffs filed a complaint for infringement of the '451 patent, '028 patent, '081 patent, '289 patent, and '531 patent against, *inter alia*¸ Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma USA, Inc., and Aurobindo Pharma Limited, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD. Cipla admits that the face of the '948 patent lists an issue date of July 4, 2023. Cipla admits that the FDA Orange Book database lists a "Submission Date" of July 5, 2023 for the '948 patent in connection with YUPELRI®. Cipla denies the remaining allegations of paragraph 155.

156. In a letter dated July 31, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Eugia Second Notice Letter"), Eugia notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that the Eugia ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Eugia '948 Patent Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or sale of the Eugia ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 156 of the Complaint, and therefore denies them.

157. The Eugia Second Notice Letter states that "in Eugia's opinion and to the best of its knowledge, the ['948] patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Eugia's ANDA." (Eugia Second Notice Letter at 3).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 157 of the Complaint, and therefore denies them.

158. Eugia filed the Eugia Paragraph IV Certification without adequate justification for asserting that the '948 patent are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Eugia ANDA Product.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 158 of the Complaint, and therefore denies them.

159. Eugia also attached to the Eugia Second Notice Letter a "Detailed Factual and Legal Basis for Eugia's Paragraph IV Certification Regarding [the '948 patent]."

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 159 of the Complaint, and therefore denies them.

160. The Eugia Second Notice Letter does not provide a substantive unenforceability defense to the '948 patent in the "Detailed Factual and Legal Basis."

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 160 of the Complaint, and therefore denies them.

161. Eugia's filing of its ANDA No. 218128 constitutes infringement of the '948 patent under at least 35 U.S.C. § 271(e)(2)(A).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 161 of the Complaint, and therefore denies them.

162. On information and belief, the active ingredient of the Eugia ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions described and claimed in one or more claims of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 162 of the Complaint, and therefore denies them.

163. On information and belief, Eugia asserts in ANDA No. 218128 that the Eugia ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA,

and contains data that, according to Eugia, demonstrate the bioequivalence of the Eugia ANDA Product to YUPELRI®.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 163 of the Complaint, and therefore denies them.

164. On information and belief, Eugia is seeking approval to market the Eugia ANDA Product for the same approved indication as YUPELRI®.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 164 of the Complaint, and therefore denies them.

165. On information and belief, Eugia is seeking approval to market the Eugia ANDA Product for maintenance treatment of patients with COPD.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 165 of the Complaint, and therefore denies them.

166. On information and belief, Eugia had knowledge of the '948 patent when it submitted and filed the Eugia '948 Patent Paragraph IV Certification to ANDA No. 218128.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 166 of the Complaint, and therefore denies them.

167. On information and belief, Eugia intends to and will infringe one or more claims of the '948 patent upon receiving FDA approval of ANDA No. 218128 and prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 167 of the Complaint, and therefore denies them.

168. On information and belief, Eugia will commercially manufacture, use, offer for sale, and/or sell the Eugia ANDA Product throughout the United States, import the Eugia ANDA Product into the United States, and/or induce and/or contribute to such acts promptly upon receiving FDA approval to do so and during the term of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 168 of the Complaint, and therefore denies them.

169. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Eugia with respect to infringement of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 169 of the Complaint, and therefore denies them.

170. This action is being commenced within 45 days of receipt of the Eugia Second Notice Letter.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 170 of the Complaint, and therefore denies them.

Mankind

171. In a letter dated January 5, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Mankind Notice Letter"), Mankind notified Mylan Ireland Limited that it had submitted ANDA No. 218089 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of its proposed revefenacin inhalation solution, for oral inhalation (the "Mankind ANDA Product"), as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 171 of the Complaint, and therefore denies them.

172. Plaintiffs filed a complaint for infringement of the ’451 patent, ’028 patent, ’081 patent, ’289 patent, and ’531 patent against, *inter alia*¸ Mankind Pharma and Lifestar, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

ANSWER: Cipla admits that Plaintiffs filed a complaint for infringement of the ’451 patent, ’028 patent, ’081 patent, ’289 patent, and ’531 patent against, *inter alia*¸ Mankind Pharma Ltd. and Lifestar Pharma LLC, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD. Cipla denies the remaining allegations of paragraph 172.

173. On July 4, 2023, the ’948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

ANSWER: Cipla admits that the face of the ’948 patent lists an issue date of July 4, 2023. Cipla admits that the FDA Orange Book database lists a “Submission Date” of July 5, 2023 for the ’948 patent in connection with YUPELRI®. Cipla denies the remaining allegations of paragraph 173.

174. In a letter dated July 10, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the “Mankind Second Notice Letter”), Mankind notified Mylan Ireland Limited and Theravance Biopharma US, Inc. that the Mankind ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the “Mankind ’948 Patent Paragraph IV Certification”) to obtain approval to engage in the commercial manufacture, use, or sale of the Mankind ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the ’948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 174 of the Complaint, and therefore denies them.

175. The Mankind Second Notice Letter states that “in its opinion, the ’948 patent is invalid and/or not infringed by” the Mankind ANDA Product. (Mankind Second Notice Letter at 2).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 175 of the Complaint, and therefore denies them.

176. Mankind filed the Mankind '948 Patent Paragraph IV Certification without adequate justification for asserting that the '948 patent is invalid and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Mankind ANDA Product.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 176 of the Complaint, and therefore denies them.

177. Mankind also attached to the Mankind Second Notice Letter a "Detailed Statement of the Factual and Legal Basis for its Opinion that U.S. Patent No. 11,691,948 is invalid, unenforceable and/or will not be infringed by Mankind's manufacture, use, offer for sale, or sale of Mankind's Revefenacin inhalation solution vials (175 mcg / 3 mL)."

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 177 of the Complaint, and therefore denies them.

178. The Mankind Second Notice Letter does not provide a substantive unenforceability defense to the '948 patent in the "Detailed Statement."

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 178 of the Complaint, and therefore denies them.

179. Mankind's filing of its ANDA No. 218089 constitutes infringement of the '948 patent under at least 35 U.S.C. § 271(e)(2)(A).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 179 of the Complaint, and therefore denies them.

180. On information and belief, the active ingredient of the Mankind ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions described and claimed in one or more claims of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 180 of the Complaint, and therefore denies them.

181. On information and belief, Mankind asserts in ANDA No. 218089 that the Mankind ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Mankind, demonstrate the bioequivalence of the Mankind ANDA Product to YUPELRI®.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 181 of the Complaint, and therefore denies them.

182. On information and belief, Mankind is seeking approval to market the Mankind ANDA Product for the same approved indication as YUPELRI®.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 182 of the Complaint, and therefore denies them.

183. On information and belief, Mankind is seeking approval to market the Mankind ANDA Product for maintenance treatment of patients with COPD.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 183 of the Complaint, and therefore denies them.

184. On information and belief, Mankind had knowledge of the '948 patent when it submitted and filed the Mankind '948 Patent Paragraph IV Certification to ANDA No. 218089.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 184 of the Complaint, and therefore denies them.

185. On information and belief, Mankind intends to and will infringe one or more claims of the ’948 patent upon receiving FDA approval of ANDA No. 218089 and prior to the expiration of the ’948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 185 of the Complaint, and therefore denies them.

186. On information and belief, Mankind will commercially manufacture, use, offer for sale, and/or sell the Mankind ANDA Product throughout the United States, import the Mankind ANDA Product into the United States, and/or induce and/or contribute to such acts promptly upon receiving FDA approval to do so and during the term of the ‘948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 186 of the Complaint, and therefore denies them.

187. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Mankind with respect to infringement of the ’948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 187 of the Complaint, and therefore denies them.

188. This action is being commenced within 45 days of receipt of the Mankind Second Notice Letter.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 188 of the Complaint, and therefore denies them.

Teva

189. In a letter dated January 5, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Teva Notice Letter"), Teva notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had submitted ANDA No. 217015 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of its proposed revefenacin inhalation solution, for oral inhalation (the "Teva ANDA Product"), as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 189 of the Complaint, and therefore denies them.

190. Plaintiffs filed a complaint for infringement of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent against, *inter alia*¸ Teva Pharmaceuticals, Teva USA, and Teva Industries, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

ANSWER: Cipla admits that Plaintiffs filed a complaint for infringement of the '451 patent, '028 patent, '081 patent, '289 patent, and '531 patent against, *inter alia*¸ Teva Pharmaceuticals, Inc., Teva Pharmaceutical Industries Ltd., and Teva Pharmaceuticals USA, Inc., in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

191. On July 4, 2023, the '948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

ANSWER: Cipla admits that the face of the '948 patent lists an issue date of July 4, 2023. Cipla admits that the FDA Orange Book database lists a "Submission Date" of July 5, 2023 for the '948 patent in connection with YUPELRI®. Cipla denies the remaining allegations of paragraph 191.

192. Teva's filing of its ANDA No. 217015 constitutes infringement of the '948 patent under at least 35 U.S.C. § 271(e)(2)(A).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 192 of the Complaint, and therefore denies them.

193. On information and belief, the active ingredient of the Teva ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions described and claimed in one or more claims of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 193 of the Complaint, and therefore denies them.

194. On information and belief, Teva asserts in ANDA No. 217015 that the Teva ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Teva, demonstrate the bioequivalence of the Teva ANDA Product to YUPELRI®.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 194 of the Complaint, and therefore denies them.

195. On information and belief, Teva is seeking approval to market the Teva ANDA Product for the same approved indication as YUPELRI®.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 195 of the Complaint, and therefore denies them.

196. On information and belief, Teva is seeking approval to market the Teva ANDA Product for maintenance treatment of patients with COPD.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 196 of the Complaint, and therefore denies them.

197. On information and belief, Teva has knowledge of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 197 of the Complaint, and therefore denies them.

198. On information and belief, Teva intends to and will infringe one or more claims of the '948 patent upon receiving FDA approval of ANDA No. 217015 and prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 198 of the Complaint, and therefore denies them.

199. On information and belief, Teva will commercially manufacture, use, offer for sale, and/or sell the Teva ANDA Product throughout the United States, import the Teva ANDA Product into the United States, and/or induce and/or contribute to such acts promptly upon receiving FDA approval to do so and during the term of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 199 of the Complaint, and therefore denies them.

200. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Teva with respect to infringement of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 200 of the Complaint, and therefore denies them.

Accord

201. In a letter dated January 6, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Accord Notice Letter"), Accord notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had submitted the Accord ANDA to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of its proposed revefenacin inhalation solution, for oral inhalation (the

"Accord ANDA Product"), as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 201 of the Complaint, and therefore denies them.

202. Plaintiffs filed a complaint for infringement of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent against, *inter alia*, Accord Inc., Accord Ltd., and Intas, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

ANSWER: Cipla admits that Plaintiffs filed a complaint for infringement of the '451 patent, '028 patent, '081 patent, '289 patent, and '531 patent against, *inter alia*, Accord Healthcare, Inc., Accord Healthcare Ltd., and Intas Pharmaceuticals Ltd., in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD. Cipla denies the remaining allegations of paragraph 202.

203. On July 4, 2023, the '948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

ANSWER: Cipla admits that the face of the '948 patent lists an issue date of July 4, 2023. Cipla admits that the FDA Orange Book database lists a "Submission Date" of July 5, 2023 for the '948 patent in connection with YUPELRI®. Cipla denies the remaining allegations of paragraph 203.

204. In a letter dated July 19, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Accord Second Notice Letter"), Accord notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that the Accord ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Accord '948 Patent Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or sale of the Accord ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 204 of the Complaint, and therefore denies them.

205. Accord's filing of its ANDA No. 218100 constitutes infringement of the '948 patent under at least 35 U.S.C. § 271(e)(2)(A).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 205 of the Complaint, and therefore denies them.

206. The Accord Second Notice Letter states that, in its opinion, the '948 patent is "invalid, unenforceable, and/or will not be infringed" by the Accord ANDA Product. (Accord Second Notice Letter at 1.)

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 206 of the Complaint, and therefore denies them.

207. Accord filed the Accord '948 Patent Paragraph IV Certification without adequate justification for asserting that the '948 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Accord ANDA Product.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 207 of the Complaint, and therefore denies them.

208. Accord also attached a "detailed statement of the factual and legal basis of Accord's opinion that U.S. Patent No. 11691948 is invalid, unenforceable, and/or will not be infringed."

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 208 of the Complaint, and therefore denies them.

209. The Accord Second Notice Letter does not provide a substantive invalidity and unenforceability defense to the '948 patent in the "Detailed Statement."

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 209 of the Complaint, and therefore denies them.

210. On information and belief, the active ingredient of the Accord ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions described and claimed in one or more claims of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 210 of the Complaint, and therefore denies them.

211. On information and belief, Accord asserts in ANDA No. 218100 that the Accord ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Accord, demonstrate the bioequivalence of the Accord ANDA Product to YUPELRI®.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 211 of the Complaint, and therefore denies them.

212. On information and belief, Accord is seeking approval to market the Accord ANDA Product for the same approved indication as YUPELRI®.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 212 of the Complaint, and therefore denies them.

213. On information and belief, Accord is seeking approval to market the Accord ANDA Product for maintenance treatment of patients with COPD.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 213 of the Complaint, and therefore denies them.

214. On information and belief, Accord had knowledge of the '948 patent when it submitted and filed the Accord '948 Patent Paragraph IV Certification to ANDA No. 218100.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 214 of the Complaint, and therefore denies them.

215. On information and belief, Accord intends to and will infringe one or more claims of the '948 patent upon receiving FDA approval of ANDA No. 218100 and prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 215 of the Complaint, and therefore denies them.

216. On information and belief, Accord will commercially manufacture, use, offer for sale, and/or sell the Accord ANDA Product throughout the United States, and/or import the Accord ANDA Product into the United States, promptly upon receiving FDA approval to do so and during the term of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 216 of the Complaint, and therefore denies them.

217. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Accord with respect to infringement of the '948 patent. This action is being commenced within 45 days of receipt of the Accord Second Notice Letter.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 217 of the Complaint, and therefore denies them.

Lupin

218. In a letter dated January 5, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Lupin Notice Letter"), Lupin notified Mylan Ireland Limited and Theravance Biopharma R&D IP LLC that it had submitted ANDA No. 218088 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of its proposed revefenacin inhalation solution, for oral inhalation (the "Lupin ANDA Product"), as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 218 of the Complaint, and therefore denies them.

219. Plaintiffs filed a complaint for infringement of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent against, *inter alia*¸ Lupin Inc., Lupin Ltd., Lupin Pharmaceuticals, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

ANSWER: Cipla admits that Plaintiffs filed a complaint for infringement of the '451 patent, '028 patent, '081 patent, '289 patent, and '531 patent against, *inter alia*¸ Lupin Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc., in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD. Cipla denies the remaining allegations of paragraph 219.

220. On July 4, 2023, the '948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

ANSWER: Cipla admits that the face of the '948 patent lists an issue date of July 4, 2023. Cipla admits that the FDA Orange Book database lists a "Submission Date" of July 5, 2023 for the '948 patent in connection with YUPELRI®. Cipla denies the remaining allegations of paragraph 220.

221. In a letter dated August 3, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Lupin Second Notice Letter"), Lupin notified Mylan

Ireland Limited, Mylan Pharmaceuticals Inc., Theravance Biopharma R&D IP LLC, and Theravance Biopharma Ireland Ltd. that the Lupin ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Lupin '948 Patent Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or sale of the Lupin ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 221 of the Complaint, and therefore denies them.

222. The Lupin Second Notice Letter states that "in its opinion and to the best of its knowledge, each claim of the '948 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Lupin's ANDA" (Lupin Second Notice Letter at 2).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 222 of the Complaint, and therefore denies them.

223. Lupin filed the Lupin '948 Patent Paragraph IV Certification without adequate justification for asserting that the '948 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Lupin ANDA Product.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 223 of the Complaint, and therefore denies them.

224. Lupin also attached to the Lupin Second Notice Letter a "Detailed Statement of the Factual and Legal Bases for Lupin 's ANDA Certification That the Claims of U.S. Patent No. 11,691,948 Will Not Be Infringed, Are Invalid, and/or Are Unenforceable."

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 224 of the Complaint, and therefore denies them.

225. The Lupin Second Notice Letter does not provide a substantive unenforceability defense to the '948 patent in the "Detailed Statement."

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 225 of the Complaint, and therefore denies them.

226. Lupin's filing of its ANDA No. 218088 constitutes infringement of the '948 patent under at least 35 U.S.C. § 271(e)(2)(A).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 226 of the Complaint, and therefore denies them.

227. On information and belief, the active ingredient of the Lupin ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions described and claimed in one or more claims of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 227 of the Complaint, and therefore denies them.

228. On information and belief, Lupin asserts in ANDA No. 218088 that the Lupin ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Lupin, demonstrate the bioequivalence of the Lupin ANDA Product to YUPELRI®.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 228 of the Complaint, and therefore denies them.

229. On information and belief, Lupin is seeking approval to market the Lupin ANDA Product for the same approved indication as YUPELRI®.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 229 of the Complaint, and therefore denies them.

230. On information and belief, Lupin is seeking approval to market the Lupin ANDA Product for maintenance treatment of patients with COPD.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 230 of the Complaint, and therefore denies them.

231. On information and belief, Lupin had knowledge of the '948 patent when it submitted and filed the Lupin '948 Patent Paragraph IV Certification to ANDA No. 218088.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 231 of the Complaint, and therefore denies them.

232. On information and belief, Lupin intends to and will infringe one or more claims of the '948 patent upon receiving FDA approval of ANDA No. 218088 and prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 232 of the Complaint, and therefore denies them.

233. On information and belief, Lupin will commercially manufacture, use, offer for sale, and/or sell the Lupin ANDA Product throughout the United States, and/or import the Lupin ANDA Product into the United States, promptly upon receiving FDA approval to do so and during the term of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 233 of the Complaint, and therefore denies them.

234. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Lupin with respect to infringement of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 234 of the Complaint, and therefore denies them.

235. This action is being commenced within 45 days of receipt of the Lupin Second Notice Letter.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 235 of the Complaint, and therefore denies them.

Orbicular

236. In a letter dated January 13, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Orbicular Notice Letter"), Orbicular notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had submitted ANDA No. 217868 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of its proposed revefenacin inhalation solution, for oral inhalation (the "Orbicular ANDA Product"), as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, the '028 patent, the '081 patent, and the '289 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 236 of the Complaint, and therefore denies them.

237. Plaintiffs filed a complaint for infringement of the '451 patent, the '028 patent, the '081 patent, and the '289 patent against, *inter alia*¸ Orbicular, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

ANSWER: Cipla admits that Plaintiffs filed a complaint for infringement of the '451 patent, '028 patent, '081 patent, '289 patent, and '531 patent against, *inter alia*¸ Orbicular Pharmaceutical Technologies Private Limited, in this jurisdiction on February 16, 2023, which

was assigned Civil Action No. 23-00926-KMW-AMD. Cipla denies the remaining allegations of paragraph 237.

238. In a letter dated April 12, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Orbicular Second Notice Letter"), Orbicular notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had amended the Orbicular ANDA to contain a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to obtain approval to engage in the commercial manufacture, use, or sale of the Orbicular ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '531 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 238 of the Complaint, and therefore denies them.

239. Plaintiffs filed a complaint for infringement of the '531 patent against Orbicular in this jurisdiction on May 24, 2023, which was assigned Civil Action No. 23-02843-KMW-AMD, and later consolidated into 23-00926-KMW-AMD.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 239 of the Complaint, and therefore denies them.

240. On July 4, 2023, the '948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

ANSWER: Cipla admits that the face of the '948 patent lists an issue date of July 4, 2023. Cipla admits that the FDA Orange Book database lists a "Submission Date" of July 5, 2023 for the '948 patent in connection with YUPELRI®. Cipla denies the remaining allegations of paragraph 240.

241. In a letter dated August 10, 2023, purporting to be notice under 21 U.S.C. §355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Orbicular Third Notice Letter"), Orbicular notified Mylan Ireland Limited, Viatris Inc., and Theravance Biopharma R&D IP, LLC that the Orbicular ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Orbicular '948 Patent Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or

sale of the Orbicular ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 241 of the Complaint, and therefore denies them.

242. The Orbicular Third Notice Letter states that the '948 patent "is invalid, unenforceable, and/or will not be infringed by" the Orbicular ANDA Product. (Orbicular Third Notice Letter at 2).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 242 of the Complaint, and therefore denies them.

243. Orbicular filed the Orbicular '948 Patent Paragraph IV Certification without adequate justification for asserting that the '948 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Orbicular ANDA Product.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 243 of the Complaint, and therefore denies them.

244. Orbicular also attached to the Orbicular Third Notice Letter a "Detailed Statement of the Factual and Legal Bases for Orbicular's Assertion of Invalidity, Unenforceability, and/or Noninfringement of U.S. Patent No. 11,691,948 Regarding Revefenacin Inhalation Solution, 175 mcg/3 mL."

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 244 of the Complaint, and therefore denies them.

245. The Orbicular Third Notice Letter does not provide a substantive invalidity and/or unenforceability defense to the '948 patent in the "Detailed Statement."

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 245 of the Complaint, and therefore denies them.

246. Orbicular's filing of its ANDA No. 217868 constitutes infringement of the '948 patent under at least 35 U.S.C. § 271(e)(2)(A).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 246 of the Complaint, and therefore denies them.

247. On information and belief, the active ingredient of the Orbicular ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions described and claimed in one or more claims of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 246 of the Complaint, and therefore denies them.

248. On information and belief, Orbicular asserts in ANDA No. 217868 that the Orbicular ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Orbicular, demonstrate the bioequivalence of the Orbicular ANDA Product to YUPELRI®.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 248 of the Complaint, and therefore denies them.

249. On information and belief, Orbicular is seeking approval to market the Orbicular ANDA Product for the same approved indication as YUPELRI®.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 249 of the Complaint, and therefore denies them.

250. On information and belief, Orbicular is seeking approval to market the Orbicular ANDA Product for maintenance treatment of patients with COPD.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 250 of the Complaint, and therefore denies them.

251. On information and belief, Orbicular had knowledge of the '948 patent when it submitted and filed the Orbicular '948 Patent Paragraph IV Certification to ANDA No. 217868.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 251 of the Complaint, and therefore denies them.

252. On information and belief, Orbicular intends to and will infringe one or more claims of the '948 patent upon receiving FDA approval of ANDA No. 217868 and prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 252 of the Complaint, and therefore denies them.

253. On information and belief, Orbicular will commercially manufacture, use, offer for sale, and/or sell the Orbicular ANDA Product throughout the United States, and/or import the Orbicular ANDA Product into the United States, promptly upon receiving FDA approval to do so and during the term of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 253 of the Complaint, and therefore denies them.

254. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Orbicular with respect to infringement of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 254 of the Complaint, and therefore denies them.

255. This action is being commenced within 45 days of receipt of the Orbicular Third Notice Letter.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 255 of the Complaint, and therefore denies them.

Cipla

256. In a letter dated January 17, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Cipla Notice Letter"), Cipla notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had submitted ANDA No. 217958 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of its proposed revefenacin inhalation solution, for oral inhalation (the "Cipla ANDA Product"), as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent.

ANSWER: Cipla admits that in the Cipla Notice Letter, Cipla notified Plaintiffs that it had filed a Paragraph IV Certification with respect to the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent, and was seeking approval from the FDA to engage in the commercial manufacture, use, or sale of Cipla's ANDA Product prior to the expiration of those patents. Cipla denies the remaining allegations of Paragraph 256.

257. Plaintiffs filed a complaint for infringement of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent against, *inter alia*¸ Cipla Ltd. and Cipla USA, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMWAMD.

ANSWER: Cipla admits that Plaintiffs filed a complaint for infringement of the '451 patent, '028 patent, '081 patent, '289 patent, and '531 patent against, *inter alia*¸ Cipla Limited and

Cipla USA, Inc., in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

258. On July 4, 2023, the ’948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

ANSWER: Cipla admits that the face of the ’948 patent lists an issue date of July 4, 2023. Cipla admits that the FDA Orange Book database lists a “Submission Date” of July 5, 2023 for the ’948 patent in connection with YUPELRI®. Cipla denies the remaining allegations of paragraph 258.

259. Cipla’s filing of its ANDA No. 217958 constitutes infringement of the ’948 patent under at least 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

260. On information and belief, the active ingredient of the Cipla ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions described and claimed in one or more claims of the ‘948 patent.

ANSWER: Cipla admits that the active ingredient in Cipla’s ANDA Product is revefenacin. Cipla denies the remaining allegations of Paragraph 260.

261. On information and belief, Cipla asserts in ANDA No. 217958 that the Cipla ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Cipla, demonstrate the bioequivalence of the Cipla ANDA Product to YUPELRI®.

ANSWER: Paragraph 261 contains legal conclusions to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 261.

262. On information and belief, Cipla is seeking approval to market the Cipla ANDA Product for the same approved indication as YUPELRI®.

ANSWER: Cipla admits that it is seeking approval to market the Cipla ANDA Product. Cipla denies the remaining allegations of Paragraph 262.

263. On information and belief, Cipla is seeking approval to market the Cipla ANDA Product for maintenance treatment of patients with COPD.

ANSWER: Admitted.

264. On information and belief, Cipla has knowledge of the '948 patent.

ANSWER: Admitted.

265. On information and belief, Cipla intends to and will infringe one or more claims of the '948 patent upon receiving FDA approval of ANDA No. 217958 and prior to the expiration of the '948 patent.

ANSWER: Denied.

266. On information and belief, Cipla will commercially manufacture, use, offer for sale, and/or sell the Cipla ANDA Product throughout the United States, and/or import the Cipla ANDA Product into the United States, promptly upon receiving FDA approval to do so and during the term of the '948 patent.

ANSWER: Cipla denies the allegations of Paragraph 266 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

267. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Cipla with respect to infringement of the '948 patent.

ANSWER: Cipla admits that actual, substantial, and continuing justiciable case or controversy exists between Cipla and Plaintiffs. Cipla denies the remaining allegations of Paragraph 267.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY EUGIA

268. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Cipla repeats and realleges its responses to the prior paragraphs of the Complaint as if fully set forth herein.

269. Eugia's submission of ANDA No. 218128 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Eugia

ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 269 of the Complaint, and therefore denies them.

270. Eugia's commercial manufacture, sale, offer for sale, or use of the Eugia ANDA Product within the United States, or importation of the Eugia ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 270 of the Complaint, and therefore denies them.

271. Eugia's commercial manufacture, sale, offer for sale, or use of the Eugia ANDA Product within the United States, or importation of the Eugia ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 271 of the Complaint, and therefore denies them.

272. On information and belief, Eugia intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Eugia ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218128 and any amendments thereto, i.e., prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 272 of the Complaint, and therefore denies them.

273. On information and belief, Eugia had knowledge of the '948 patent when it submitted ANDA No. 218128. Eugia's infringement has been, and continues to be, deliberate.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 273 of the Complaint, and therefore denies them.

274. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '948 patent is not enjoined.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 274 of the Complaint, and therefore denies them.

275. Plaintiffs do not have an adequate remedy at law.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 275 of the Complaint, and therefore denies them.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY MANKIND

276. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Cipla repeats and realleges its responses to the prior paragraphs of the Complaint as if fully set forth herein.

277. Mankind's submission of ANDA No. 218089 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Mankind ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 277 of the Complaint, and therefore denies them.

278. Mankind's commercial manufacture, sale, offer for sale, or use of the Mankind ANDA Product within the United States, or importation of the Mankind ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 278 of the Complaint, and therefore denies them.

279. Mankind's commercial manufacture, sale, offer for sale, or use of the Mankind ANDA Product within the United States, or importation of the Mankind ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 279 of the Complaint, and therefore denies them.

280. On information and belief, Mankind intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mankind ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218089 and any amendments thereto, i.e., prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 280 of the Complaint, and therefore denies them.

281. On information and belief, Mankind had knowledge of the '948 patent when it submitted the Mankind '948 Patent Paragraph IV Certification as part of ANDA No. 218089. Mankind's infringement has been, and continues to be, deliberate.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 281 of the Complaint, and therefore denies them.

282. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '948 patent is not enjoined.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 282 of the Complaint, and therefore denies them.

283. Plaintiffs do not have an adequate remedy at law.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 283 of the Complaint, and therefore denies them.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY TEVA

284. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Cipla repeats and realleges its responses to the prior paragraphs of the Complaint as if fully set forth herein.

285. Teva's submission of ANDA No. 217015 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Teva ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 285 of the Complaint, and therefore denies them.

286. Teva's commercial manufacture, sale, offer for sale, or use of the Teva ANDA Product within the United States, or importation of the Teva ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 286 of the Complaint, and therefore denies them.

287. Teva's commercial manufacture, sale, offer for sale, or use of the Teva ANDA Product within the United States, or importation of the Teva ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 287 of the Complaint, and therefore denies them.

288. On information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Teva ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217015 and any amendments thereto, i.e., prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 288 of the Complaint, and therefore denies them.

289. On information and belief, Teva has knowledge of the '948 patent. Teva's infringement has been, and continues to be, deliberate.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 289 of the Complaint, and therefore denies them.

290. Plaintiffs will be substantially and irreparably harmed if Teva's infringement of the '948 patent is not enjoined.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 290 of the Complaint, and therefore denies them.

291. Plaintiffs do not have an adequate remedy at law.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 291 of the Complaint, and therefore denies them.

COUNT IV
INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY ACCORD

292. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Cipla repeats and realleges its responses to the prior paragraphs of the Complaint as if fully set forth herein.

293. Accord's submission of ANDA No. 218100 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Accord ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 293 of the Complaint, and therefore denies them.

294. Accord's commercial manufacture, sale, offer for sale, or use of the Accord ANDA Product within the United States, or importation of the Accord ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 294 of the Complaint, and therefore denies them.

295. Accord's commercial manufacture, sale, offer for sale, or use of the Accord ANDA Product within the United States, or importation of the Accord ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 295 of the Complaint, and therefore denies them.

296. On information and belief, Accord intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218100 and any amendments thereto, i.e., prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 296 of the Complaint, and therefore denies them.

297. On information and belief, Accord had knowledge of the '948 patent when it submitted the Accord '948 Patent Paragraph IV Certification as part of ANDA No. 218100. Accord's infringement has been, and continues to be, deliberate.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 297 of the Complaint, and therefore denies them.

298. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '948 patent is not enjoined.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 298 of the Complaint, and therefore denies them.

299. Plaintiffs do not have an adequate remedy at law.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 299 of the Complaint, and therefore denies them.

COUNT V

INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY LUPIN

300. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Cipla repeats and realleges its responses to the prior paragraphs of the Complaint as if fully set forth herein.

301. Lupin's submission of ANDA No. 218088 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Lupin ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 301 of the Complaint, and therefore denies them.

302. Lupin's commercial manufacture, sale, offer for sale, or use of the Lupin ANDA Product within the United States, or importation of the Lupin ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 302 of the Complaint, and therefore denies them.

303. Lupin's commercial manufacture, sale, offer for sale, or use of the Lupin ANDA Product within the United States, or importation of the Lupin ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 303 of the Complaint, and therefore denies them.

304. On information and belief, Lupin intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product, and the

proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218088 and any amendments thereto, i.e., prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 304 of the Complaint, and therefore denies them.

305. On information and belief, Lupin had knowledge of the '948 patent when it submitted the Lupin '948 Patent Paragraph IV Certification as part of ANDA No. 218088. Lupin's infringement has been, and continues to be, deliberate.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 305 of the Complaint, and therefore denies them.

306. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '948 patent is not enjoined.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 306 of the Complaint, and therefore denies them.

307. Plaintiffs do not have an adequate remedy at law.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 307 of the Complaint, and therefore denies them.

COUNT VI
INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY ORBICULAR

308. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Cipla repeats and realleges its responses to the prior paragraphs of the Complaint as if fully set forth herein.

309. Orbicular's submission of ANDA No. 217868 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Orbicular ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 309 of the Complaint, and therefore denies them.

310. Orbicular's commercial manufacture, sale, offer for sale, or use of the Orbicular ANDA Product within the United States, or importation of the Orbicular ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 310 of the Complaint, and therefore denies them.

311. Orbicular's commercial manufacture, sale, offer for sale, or use of the Orbicular ANDA Product within the United States, or importation of the Orbicular ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 311 of the Complaint, and therefore denies them.

312. On information and belief, Orbicular intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Orbicular ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217868 and any amendments thereto, i.e., prior to the expiration of the '948 patent.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 312 of the Complaint, and therefore denies them.

313. On information and belief, Orbicular had knowledge of the '948 patent when it submitted the Orbicular '948 Patent Paragraph IV Certification as part of ANDA No. 217868. Orbicular's infringement has been, and continues to be, deliberate.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 313 of the Complaint, and therefore denies them.

314. Plaintiffs will be substantially and irreparably harmed if Orbicular's infringement of the '948 patent is not enjoined.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 314 of the Complaint, and therefore denies them.

315. Plaintiffs do not have an adequate remedy at law.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 315 of the Complaint, and therefore denies them.

COUNT VII
INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY CIPLA

316. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Cipla repeats and realleges its responses to the prior paragraphs of the Complaint as if fully set forth herein.

317. Cipla's submission of ANDA No. 217958 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Cipla ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

318. Cipla's commercial manufacture, sale, offer for sale, or use of the Cipla ANDA Product within the United States, or importation of the Cipla ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

319. Cipla's commercial manufacture, sale, offer for sale, or use of the Cipla ANDA Product within the United States, or importation of the Cipla ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

ANSWER: Denied.

320. On information and belief, Cipla intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Cipla ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217958 and any amendments thereto, i.e., prior to the expiration of the '948 patent.

ANSWER: Cipla denies the allegations of Paragraph 320 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

321. On information and belief, Cipla has knowledge of the '948 patent. Cipla's infringement has been, and continues to be, deliberate.

ANSWER: Cipla admits that it had knowledge of the '948 patent when it submitted ANDA No. 217958. Cipla denies the remaining allegations in Paragraph 321 of the Complaint.

322. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '948 patent is not enjoined.

ANSWER: Denied.

323. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

REQUEST FOR RELIEF

Cipla denies that Plaintiffs are entitled to the relief sought in paragraphs (a) through (yyy) on pages 58 through 69 of the Complaint. Should Plaintiffs receive any of their requested relief,

no such relief should prevent Cipla from obtaining a Pre-Launch Activities Importation Request from the FDA, or acting under it, in connection with Cipla's ANDA Product.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its responses to paragraphs 1 through 323 of the Complaint, Cipla alleges the following Separate Defenses to the Complaint. Cipla expressly reserves the right to allege additional defenses as they become known through the course of discovery or other factual investigation. Cipla does not intend to hereby assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

First Defense
(Invalidity of the '948 Patent)

Each claim of the '948 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Second Defense
(Noninfringement of the '948 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '948 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '948 patent, either literally or under the doctrine of equivalents.

Third Defense
(Waiver)

Plaintiffs have waived any defect in the manner in which Cipla served Cipla's Notice Letter and/or are estopped from contesting any alleged defect in service of Cipla's Notice Letter.

Fourth Defense
(Estoppel)

Plaintiffs are estopped from asserting infringement by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

Fifth Defense
(Failure to State a Claim)

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

Sixth Defense
(No Exceptional Case)

Cipla's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Seventh Defense
(No Willful Infringement)

Cipla has not willfully infringed any claim of the '948 patent.

COUNTERCLAIMS

Without admitting the allegations of Plaintiffs Theravance Biopharma R&D IP, LLC, Theravance Biopharma Ireland Limited, Theravance Biopharma US, Inc., Mylan Ireland Limited, and Mylan Specialty L.P. (collectively, "Plaintiffs" or "Counterclaim Defendants") other than those expressly admitted herein, Defendants Cipla Limited and Cipla USA Inc. (collectively, "Cipla" or "Defendants" or "Counterclaim Plaintiffs") bring the following Counterclaims against Plaintiffs/Counterclaim Defendants for declaratory judgment that United States Patent No. 11,691,948 (the "'948 patent") is invalid and/or not infringed by Cipla and the product as described in Cipla's Abbreviated New Drug Application No. 217958 ("Cipla's ANDA Product").

The Parties

1. Counterclaim Plaintiff Cipla Limited is an entity organized and existing under the laws of India, having a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400 013, India.

2. Counterclaim Plaintiff Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 10 Independence Boulevard, Suite 300, Warren, NJ 07059.

3. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Theravance Biopharma R&D IP, LLC is a Delaware limited liability company having a principal place of business at 901 Gateway Boulevard, South San Francisco, CA, 94080.

4. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Theravance Biopharma Ireland Limited is an Irish company having a registered office at Ten Earlsfort Terrace, Dublin 2, D02 T380, Ireland.

5. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Theravance Biopharma US, Inc. is a Delaware corporation having a principal place of business at 901 Gateway Boulevard, South San Francisco, CA, 94080.

6. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Mylan Ireland Limited is a company having a principal place of business at Newenham Court, Northern Cross, Malahide Road, Dublin 17, Ireland; and a registered office at Unit 35/36, Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland.

7. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Mylan Specialty L.P. is a company having a principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia, 26505.

8. Upon information and belief, Counterclaim Defendant Mylan Ireland Limited is also the holder of approved New Drug Application No. 210598 for YUPELRI® (revefenacin).

9. Upon information and belief, Counterclaim Defendants Mylan Specialty L.P. and Theravance Biopharma US, Inc. currently promote and market YUPELRI® in the United States.

Jurisdiction and Venue

10. This court has subject matter jurisdiction over the Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a), and 1367, based on an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*

11. This Court has personal jurisdiction over Counterclaim Defendants because Counterclaim Defendants have availed themselves of the rights and privileges and subjected themselves to the jurisdiction of this forum by suing Cipla in this judicial district.

12. Venue is proper in this district for the purposes of these Counterclaims because Counterclaim Defendants filed the present action in this district.

13. On or about February 16, 2023, Counterclaim Defendants filed a civil action in this judicial district against Cipla relating to Cipla's ANDA No. 217958 and alleging infringement of United States Patent Nos. 8,541,451, 9,765,028, 10,550,081, 11,008,289, and 11,484,531, which, like the '948 patent, are listed in the Orange Book in association with YUPELRI®.

14. There is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Cipla and Cipla's ANDA Product's non-infringement of the Patents-in-Suit.

15. On or about August 21, 2023, Counterclaim Defendants filed a civil action in this judicial district against Cipla alleging infringement of the '948 patent. There is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the

issuance of a declaratory judgment regarding Cipla and Cipla's ANDA Product's non-infringement of the '948 patent.

The '948 patent

16. Based on the allegations in the Complaint, the '948 patent, entitled "Crystalline Freebase Forms of a Biphenyl Compound," was issued on July 4, 2023. The U.S. Patent and Trademark Office lists Theravance Biopharma R&D IP, LLC as the assignee of the '948 patent.

17. The '948 patent is listed in the Orange Book in association with YUPELRI®.

18. On or about August 21, 2023, Counterclaim Defendants brought this present action alleging infringement of the '948 patent.

19. On August 24, 2023, Cipla sent Counterclaim Defendants Mylan Ireland Ltd. and Theravance Biopharma R&D IP, LLC notification of Paragraph IV Certification for the '948 patent with respect to Cipla's filing of ANDA No. 217958 ("Cipla's Notice Letter "), pursuant to 21 U.S.C. §355(j)(2)(B)(ii), (iv) and 21 C.F.R. § 314.95(c)(1).

20. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), Cipla's Notice Letter included, among other things, Cipla's detailed factual and legal basis for the Paragraph IV Certification regarding the '948 patent as it pertains to Cipla's ANDA Product and an Offer of Confidential Access to Cipla's ANDA Product.

First Counterclaim
(Declaratory Judgment of Noninfringement of the '948 Patent)

21. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 20 of the Counterclaims as if fully set forth herein.

22. Counterclaim Defendants have accused Cipla of infringing the '948 patent.

23. Cipla denies infringement of the '948 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if

marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’948 patent.

24. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the ’948 patent.

25. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of Cipla’s ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the ’948 patent.

Second Counterclaim
(Declaratory Judgment of Invalidity of the ’948 Patent)

26. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 25 of the Counterclaims as if fully set forth herein.

27. The claims of the ’948 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

28. For at least the reasons stated in Cipla’s Notice Letter , which is hereby incorporated by reference in its entirety, the claims of the ’948 patent are not infringed by Cipla’s ANDA Product and/or are invalid.

29. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla’s ANDA Product is infringing the claims of the ’948 patent and will continue to try to interfere with Cipla’s business with respect to Cipla’s ANDA Product.

30. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the ’948 patent.

31. Cipla is entitled to a judicial declaration that all claims of the ’948 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Request for Relief

WHEREFORE, Cipla requests that this Court enter judgment against Counterclaim Defendants:

A. Declaring that the manufacture, use, sale, offer for sale, and/or importation of Cipla’s ANDA Product does not and will not directly or indirectly infringe any claim of the ‘948 patent, either literally or under the doctrine of equivalents;

B. Declaring that the claims of the ‘948 patent are invalid and/or unenforceable;

C. Ordering that Counterclaim Defendants’ Complaint be dismissed with prejudice and judgment entered in favor of Cipla;

D. Preliminarily and permanently enjoining Counterclaim Defendants, its employees and agents, and any other person acting in concert with any of them, from asserting or threatening to assert any alleged rights arising under the ‘948 patent against Cipla or any person or entity working in concert with Cipla;

E. Awarding Cipla its costs and expenses incurred in this action;

F. Declaring that this is an exceptional case in favor of Cipla and awarding Cipla its reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

G. Awarding Cipla such other and further relief as the Court may deem proper.

DATED: September 22, 2023

Respectfully submitted,

K&L Gates LLP

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Attorneys for Defendants/Counterclaim-Plaintiffs Cipla Ltd. and Cipla USA, Inc.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Cipla Ltd. and Cipla USA, Inc. hereby certifies that, to the best of my knowledge, this matter in controversy is also the subject of the following litigation, pending in this District:

- *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Ltd. et al.*, Consolidated Case No. 2:23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023)

I also hereby certify that, to the best of my knowledge, no other actions currently involve the same U.S. Patent No. as the instant action.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: September 22, 2023

s/ *Loly Tor*
Loly Tor

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Cipla Limited and Cipla USA, Inc. hereby certifies that this action involves a request for injunctive relief and therefore is not appropriate for compulsory arbitration.

Dated: September 22, 2023

s/ *Loly Tor*
Loly Tor

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

THERAVANCE BIOPHARMA R&D IP, LLC, THERAVANCE BIOPHARMA US, INC., THERAVANCE BIOPHARMA IRELAND LIMITED, MYLAN IRELAND LIMITED, and MYLAN SPECIALTY L.P.,	1:23-cv-06667-KMW-AMD Hon. Karen M. Williams, U.S.D.J Hon. Ann Marie Donio, U.S.M.J.

Plaintiffs, v. EUGIA PHARMA SPECIALTIES LTD., EUGIA US LLC, AUROBINDO PHARMA USA, INC., AUROBINDO PHARMA LIMITED, MANKIND PHARMA LTD., LIFESTAR PHARMA LLC, TEVA PHARMACEUTICALS, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC., ACCORD HEALTHCARE, INC., ACCORD HEALTHCARE, LTD., INTAS PHARMACEUTICALS LTD., LUPIN INC., LUPIN LTD., LUPIN PHARMACEUTICALS, INC., ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED, CIPLA LIMITED, CIPLA USA, INC., Defendants.	**ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS** ***Document Electronically Filed***

LOLY G. TOR, of full age, hereby certifies as follows:

1. I am an attorney-at-law of the State of New Jersey and admitted to practice before the United States District Court for the District of New Jersey and partner with the law firm of K&L Gates LLP, attorneys for Defendants/Counterclaim-Plaintiffs Cipla Limited and Cipla USA, Inc.

2. I hereby certify that on the date indicated below, I caused a copy of Defendants/Counterclaim-Plaintiffs Cipla Limited and Cipla USA, Inc.'s Answer, Separate Defenses, and Counterclaims, Fed. R. Civ. P. 7.1 Corporate Disclosure Statement, and this certificate of service to be served upon all counsel of record by CM/ECF and e-mail.

3. I certify under penalty of perjury that the foregoing is true and correct.

Dated: Septmber 22, 2023

s/ Loly Tor
Loly Tor