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UNITED STATES DISTRICT COURT
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.,

Plaintiffs,

v.

EUGIA PHARMA SPECIALITIES LTD., EUGIA US LLC, AUROBINDO PHARMA USA, INC., AUROBINDO PHARMA LIMITED, MANKIND PHARMA LTD., LIFESTAR PHARMA LLC, ACCORD HEALTHCARE, INC., MEDICHEM S.A., MEDICHEM MANUFACTURING (MALTA) LTD., MEDICHEM USA, LLC, LUPIN INC., LUPIN PHARMACEUTICALS, INC., ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED, CIPLA LIMITED, and CIPLA USA, INC.,

Defendants.

Case No. 1:23-cv-00926-KMW-AMD
(consolidated)

ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT

Document Electronically Filed

Defendants Cipla Limited and Cipla USA, Inc. (collectively, "Cipla"), 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 No. 12,048,692 (the "'692 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. 218128, filed by Eugia; ANDA No. 218089, filed by Mankind; 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®.

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 U.S. Food and Drug Administration ("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 date listed in the FDA's electronic *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for the '692 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 '692 patent. Theravance Biopharma R&D IP, LLC is a wholly owned subsidiary of Theravance Biopharma Ireland Limited.

ANSWER: Cipla admits that the face of the '692 patent lists Theravance Biopharma R&D IP, LLC as the assignee of the '692 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 '692 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 admits that FDA's Orange Book lists Mylan Ireland Limited as the holder of New Drug Application No. 210598. 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 #2, Ameerpet, Hyderabad, Telangana 500038, India ("Maitrivihar" address) or its corporate office at Galaxy, Floors: 22-24, Plot No.1, Sy No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Hyderabad, Telangana 500032, India ("Galaxy" address).

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."; principal place of business at the "Maitrivihar" address); Medicure Int'l, Inc. v. Aurobindo Pharma Ltd. et al., No. 2:21-cv-17534, Answer (D.N.J. Feb. 16, 2022) ("Eugia Pharma Specialties Limited"; principal place of business at the "Galaxy" address); Amgen Inc. et al. v. Aurobindo Pharma Ltd. et al., No. 22-cv-00227, Answer (D. Del. Mar 17, 2022) ("Eugia Pharma Specialties Limited"; principal place of business at the "Maitrivihar" address); 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"; principal place of business at the "Maitrivihar" or "Galaxy" address).

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 '692 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 '692 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.

Cipla

27. 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.

28. 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.

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

ANSWER: Admitted.

30. 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 '692 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 remaining allegations and characterizations contained in Paragraph 30 of the Complaint.

31. 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 31 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

JURISDICTION AND VENUE

32. 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.

33. 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.

34. 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. *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)." (citation omitted)).

ANSWER: Paragraph 34 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 '692 patent for the limited purposes of this litigation. Cipla denies the remaining allegations of Paragraph 34.

Eugia

35. 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 35 of the Complaint, and therefore denies them.

36. 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 36 of the Complaint, and therefore denies them.

37. 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 37 of the Complaint, and therefore denies them.

38. 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 38 of the Complaint, and therefore denies them.

39. 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 39 of the Complaint, and therefore denies them.

40. 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 40 of the Complaint, and therefore denies them.

41. 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 41 of the Complaint, and therefore denies them.

42. 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 42 of the Complaint, and therefore denies them.

43. 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 43 of the Complaint, and therefore denies them.

44. 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 44 of the Complaint, and therefore denies them.

45. On information and belief, Aurobindo USA is registered as a "Manufacturer and 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 45 of the Complaint, and therefore denies them.

46. 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 46 of the Complaint, and therefore denies them.

47. 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 47 of the Complaint, and therefore denies them.

48. 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 '692 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 48 of the Complaint, and therefore denies them.

49. 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 '692 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 49 of the Complaint, and therefore denies them.

50. 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 50 of the Complaint, and therefore denies them.

51. Eugia did not contest jurisdiction and venue in patent infringement litigations 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 Ltd. et al.*, No. 1-23-cv-06667-KMW-AMD (D.N.J. Aug. 21, 2023); *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Ltd. et al.*, No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023); *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-24-cv-00150-KMW-AMD (D.N.J. Jan. 9, 2024).

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 51 of the Complaint, and therefore denies them.

52. 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. 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 Int'l, 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 52 of the Complaint, and therefore denies them.

Mankind

53. 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 53 of the Complaint, and therefore denies them.

54. 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 54 of the Complaint, and therefore denies them.

55. 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 55 of the Complaint, and therefore denies them.

56. 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 56 of the Complaint, and therefore denies them.

57. 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 57 of the Complaint, and therefore denies them.

58. 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 58 of the Complaint, and therefore denies them.

59. 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 59 of the Complaint, and therefore denies them.

60. 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 60 of the Complaint, and therefore denies them.

61. 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 '692 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 61 of the Complaint, and therefore denies them.

62. Mankind did not contest jurisdiction and venue in patent infringement litigations 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 Ltd. et al.*, No. 1-23-cv-06667-KMW-AMD (D.N.J. Aug. 21, 2023); *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Ltd. et al.*, No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023); *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-24-cv-00150-KMW-AMD (D.N.J. Jan. 9, 2024).

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. 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 Intell. Prop. 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 63 of the Complaint, and therefore denies them.

Cipla

64. 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 64 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.

65. 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 65 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 65.

66. 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 66 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 66.

67. 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 67 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 purpose 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 67.

68. 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 68 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 68.

69. 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.

70. 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.

71. 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 71 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 71.

72. 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 '692 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 72 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 New Jersey. Cipla denies the remaining allegations of Paragraph 72.

73. Cipla did not contest jurisdiction and venue, and filed counterclaims, in patent infringement litigations 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 Ltd. et al.*, No. 1-23-cv-06667-KMW-AMD (D.N.J. Aug. 21, 2023); *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Ltd. et al.*, No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023); *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-24-cv-00150-KMW-AMD (D.N.J. Jan. 9, 2024).

ANSWER: Admitted.

74. 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 Ltd.) (also filed a counterclaim).

ANSWER: Admitted.

THE PATENT-IN-SUIT

The ’692 Patent

75. The ’692 patent titled “Methods for Treating Chronic Obstructive Pulmonary Disease,” was duly and legally issued by the United States Patent and Trademark Office on July 30, 2024. A true and correct copy of the ’692 patent is attached as Exhibit A.

ANSWER: Cipla admits that Exhibit A to the Complaint purports to be a copy of the ’692 patent. Cipla admits that the ’692 patent is entitled “Methods for Treating Chronic Obstructive Pulmonary Disease” and lists July 30, 2024 as an issue date. Cipla denies the remaining allegations in Paragraph 75.

76. Theravance Biopharma R&D IP, LLC is the assignee of the ’692 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the ’692 patent. Mylan Ireland Limited is the exclusive sub-licensee of the ’692 patent from Theravance Biopharma Ireland Limited.

ANSWER: Cipla admits that Theravance Biopharma R&D IP, LLC is listed as the assignee on the face of the ’692 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in Paragraph 76 of the Complaint, and therefore denies them.

77. The ’692 patent is listed in the Orange Book as covering YUPELRI® and its approved uses.

ANSWER: Cipla admits that the '692 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 77 of the Complaint, and therefore denies them.

YUPELRI®

78. 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 78 of the Complaint, and therefore denies them.

79. 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 (revised 5/2022) recites that "YUPELRI is indicated for the maintenance treatment of patients 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 YUPELRI® label (revised 5/2022) 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 79 of the Complaint, and therefore denies them.

80. 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 80 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 80.

81. 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 81 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 81.

82. 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 82 of the Complaint, and therefore denies them.

83. YUPELRI® is indicated for the maintenance treatment of patients with COPD. (Exhibit 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 83 contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies the remaining allegations of Paragraph 83.

84. YUPELRI® was studied in two 12-week replicate placebo-controlled trials in patients with moderate to very severe COPD. The population had COPD with a mean post-bronchodilator forced expiratory volume in one second (FEV1) percent predicted of 55% (range: 10% to 90%). (Exhibit B at § 14.2).

ANSWER: Cipla admits that the YUPELRI® label (revised 5/2022) recites that "[t]he clinical development program for YUPELRI included two 12-week, randomized, double-blind, placebo-controlled, multiple-dose, parallel-group, confirmatory trials in subjects with moderate to very severe COPD." Cipla further admits the YUPELRI® label (revised 5/2022) recites "[a]t

screening, the mean post-bronchodilator percent predicted FEV_1 was 55% (range: 10% to 90%)."

Cipla denies the remaining allegations of Paragraph 84.

COPD

85. COPD is a chronic inflammatory lung disease characterized by progressive persistent airflow obstruction. Bronchodilators, such as muscarinic receptor antagonists and β-adrenergic agonists, are used to treat COPD. Such bronchodilators are typically delivered to a patient in need of treatment using an inhalation delivery device, such as a dry powder inhaler, a metered dose inhaler or a nebulizer.

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. Healthcare providers use guidelines from the Global Initiative for Chronic Obstructive Lung Disease, commonly known as the GOLD guidelines, to determine treatment algorithms for COPD patients. The GOLD guidelines are regularly updated, most recently for 2024.

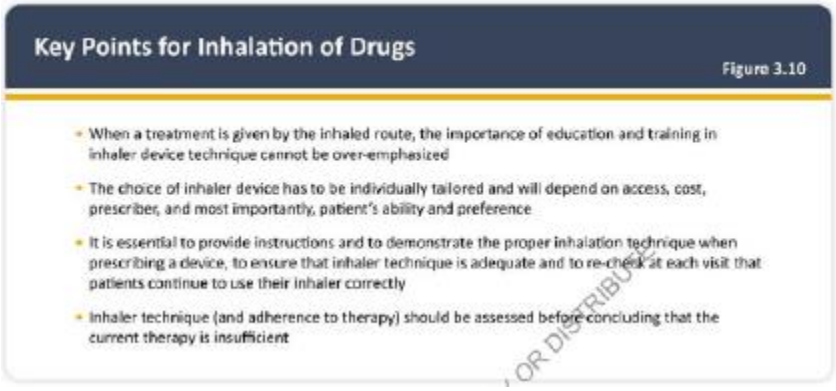
ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 86 of the Complaint, and therefore denies them.

87. The GOLD guidelines grade COPD into mild, moderate, severe, and very severe classifications based on the severity of airflow obstruction. Airflow obstruction is measured as forced expiratory volume in one second (FEV1). According to the GOLD guidelines, severe includes patients with a percent predicted FEV1 of equal to or greater than 30% and less than 50%. According to the GOLD guidelines, very severe includes patients with a percent predicted FEV1 of less than 30%.

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.

88. The GOLD guidelines also call for healthcare providers to match therapies more closely to each patient's needs. This involves, among other things, "ensur[ing] that inhaler technique is adequate and to re-check at each visit that patients continue to use their inhaler correctly." Inspiratory flow is also recognized as an important factor for patients to successfully

inhale drug particles from handheld inhalers. The GOLD guidelines state that each dry powder inhaler has a unique internal resistance, and patients must create turbulent energy within the device during inhalation to disaggregate the powder into fine particles. The GOLD guidelines continue by instructing healthcare providers to check visually that the patient can inhale forcefully through the device. These concepts are reflected in, for example, Figure 3.10 of the GOLD guidelines:



GOLD guidelines, at 53-55.

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. For many patients, any type of inhalation delivery device can be used to deliver an adequate dose of a bronchodilator. However, for COPD patients having a lower than normal inspiratory flow rate, nebulizers are sometimes recommended since these patients may be unable to generate a peak inspiratory flow rate ("PIFR") sufficient for proper use of a dry powder inhaler. *See, e.g.*, Mahler, D.A., *Peak Inspiratory Flow Rate as a Criterion for Dry Powder Inhaler Use in Chronic Obstructive Pulmonary Disease*, 14(7) ANN. AM. THORAC. SOC. 1103-07 (Jul. 2017) ("Mahler 2017"); Mahler, D.A. et al., *Comparison of dry powder versus nebulized beta-agonist in patients with COPD who have suboptimal peak inspiratory flow rate*, 27(2) J. AEROSOL MED. PULM. DRUG DELIV. 103-09 (Apr. 2014) ("Mahler 2014"). Accordingly, use of a nebulizer for delivery of a bronchodilator has been suggested for COPD patients having a low PIFR.

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.

90. Low PIFR is also referred to as suboptimal PIFR. Low or suboptimal PIFR can be readily established, for example, using the IN-CHECK DIAL® device which can, for example, simulate the resistance of a dry powder inhaler such as the DISKUS® device.

ANSWER: Paragraph 90 contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies the remaining allegations of Paragraph 90.

91. If the PIFR value is less than about 60 L/min, the patient may not achieve optimal clinical benefit from a dry powder inhaler. A PIFR of less than 30 L/min is insufficient for a dry powder inhaler.

ANSWER: Paragraph 91 contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies the remaining allegations of Paragraph 91.

ACTS GIVING RISE TO THIS ACTION

Eugia

92. 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 92 of the Complaint, and therefore denies them.

93. Plaintiffs filed a complaint for infringement of the '451 patent, '028 patent, '081 patent, '289 patent, and '531 patent against Eugia, *inter alia*, 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*¸ Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma USA, Inc., Aurobindo Pharma Limited (collectively, "Eugia"), in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD. Cipla denies the remaining allegations of Paragraph 93.

94. 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) 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 United States Patent No. 11,691,948 ("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 94 of the Complaint, and therefore denies them.

95. Plaintiffs filed a complaint for infringement of the '948 patent against Eugia, *inter alia*, in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with Civil Action No. 23-00926-KMW-AMD on September 29, 2023.

ANSWER: Cipla admits that Plaintiffs filed a complaint for infringement of the '948 patent against, *inter alia*, Eugia in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with Civil Action No. 23-00926-KMW-AMD on September 29, 2023. Cipla denies the remaining allegations of Paragraph 95.

96. On December 4, 2023, Plaintiffs filed a First Amended Consolidated Complaint for Patent Infringement against Eugia, *inter alia*, in Civil Action No. 23-00926-KMW-AMD, which included additional claims for infringement of U.S. Patent Nos. 8,017,783 (the "'783 patent"), 9,249,099 (the "'099 patent"), 10,100,013 (the "'013 patent"), and 11,649,209 (the "'209 patent").

ANSWER: Cipla admits that Plaintiffs filed a First Amended Consolidated Complaint for Patent Infringement of the '451 patent, '028 patent, '081 patent, the '289 patent, the '531 patent, the '948 patent, the '783 patent, the '099 patent, the '013 patent, and the '209 patent against, *inter alia*¸ Eugia, in this jurisdiction on December 4, 2023, in Civil Action No. 23-00926-KMW-AMD. Cipla denies the remaining allegations of Paragraph 96.

97. Plaintiffs filed a complaint for infringement of U.S. Patent No. 11,858,898 (the "'898 patent") against Eugia, *inter alia*, in this jurisdiction on January 9, 2024, which was assigned Civil Action No. 24-00150-KMW-AMD, and which was consolidated with Civil Action No. 23-00926-KMW-AMD on February 1, 2024.

ANSWER: Cipla admits that Plaintiffs filed a complaint for infringement of the '898 patent against, *inter alia*, Eugia in this jurisdiction on January 9, 2024, which was assigned Civil Action No. 24-00150-KMW-AMD, and which was consolidated with Civil Action No. 23-00926-KMW-AMD on February 1, 2024. Cipla denies the remaining allegations of Paragraph 97.

98. Eugia's filing of its ANDA No. 218128 constitutes infringement of the '692 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 98 of the Complaint, and therefore denies them.

99. 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 and methods of treatment described and claimed in one or more claims of the '692 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 99 of the Complaint, and therefore denies them.

100. 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 100 of the Complaint, and therefore denies them.

101. 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 101 of the Complaint, and therefore denies them.

102. 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 102 of the Complaint, and therefore denies them.

103. On information and belief, Eugia has actual knowledge as of the date of this Complaint of the '692 patent, at least because Plaintiffs have identified the '692 patent to Eugia as part of this Action.

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. On information and belief, Eugia intends to and will infringe, actively induce infringement, and/or contribute to infringement of one or more claims of the '692 patent upon receiving FDA approval of ANDA No. 218128 and prior to the expiration of the '692 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 104 of the Complaint, and therefore denies them.

105. On information and belief, Eugia will commercially manufacture, use, offer for sale, and/or sell the Eugia ANDA Product throughout the United States, and/or 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 '692 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 105 of the Complaint, and therefore denies them.

106. On information and belief, Eugia knows that the Eugia ANDA Product is especially made or adapted for use in a way that would infringe the '692 patent, and is not suitable for substantial non-infringing use. On information and belief, Eugia knowingly has taken and intends to take active steps to, and will, induce and/or contribute to infringement of one or more claims of the '692 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 106 of the Complaint, and therefore denies them.

107. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Eugia with respect to infringement of the '692 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 107 of the Complaint, and therefore denies them.

Mankind

108. 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 and Theravance Biopharma US, Inc. that it had submitted the Mankind 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 Mankind ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, '028 patent, '081 patent, '289 patent, and '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 108 of the Complaint, and therefore denies them.

109. Plaintiffs filed a complaint for infringement of the '451 patent, '028 patent, '081 patent, '289 patent, and '531 patent against Mankind, inter alia, 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 (collectively, "Mankind"), in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD. Cipla denies the remaining allegations of Paragraph 109.

110. 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) 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 110 of the Complaint, and therefore denies them.

111. Plaintiffs filed a complaint for infringement of the '948 patent against Mankind, inter alia, in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with Civil Action No. 23-00926-KMW-AMD on September 29, 2023.

ANSWER: Cipla admits that Plaintiffs filed a complaint for infringement of the '948 patent against, *inter alia*¸ Mankind in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with Civil Action No. 23-00926-KMW-AMD on September 29, 2023. Cipla denies the remaining allegations of Paragraph 111.

112. On December 4, 2023, Plaintiffs filed a First Amended Consolidated Complaint for Patent Infringement against Mankind, inter alia, in Civil Action No. 23-00926-KMW-AMD, which included additional claims for infringement of the '783 patent, the '099 patent, the '013 patent, and the '209 patent.

ANSWER: Cipla admits that Plaintiffs filed an amended complaint for infringement of the '451 patent, '028 patent, '081 patent, the '289 patent, the '531 patent, the '948 patent, the '783 patent, the '099 patent, the '013 patent, and the '209 patent against, *inter alia*¸ Mankind in this jurisdiction on December 4, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD. Cipla denies the remaining allegations of Paragraph 112.

113. Plaintiffs filed a complaint for infringement of the '898 patent against Mankind, *inter alia*, in this jurisdiction on January 9, 2024, which was assigned Civil Action No. 24-00150-KMW-AMD, and which was consolidated with Civil Action No. 23-00926-KMW-AMD on February 1, 2024.

ANSWER: Cipla admits that Plaintiffs filed a complaint for infringement of the '898 patent against, *inter alia*, Mankind in this jurisdiction on January 9, 2024, which was assigned Civil Action No. 24-00150-KMW-AMD, and which was consolidated with Civil Action No. 23-00926-KMW-AMD on February 1, 2024. Cipla denies the remaining allegations of Paragraph 113.

114. In a letter dated August 8, 2024, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Mankind Third Notice Letter"), Mankind notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that the Mankind ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Mankind '692 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 '692 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 114 of the Complaint, and therefore denies them.

115. The Mankind Third Notice Letter states that "in its opinion, the '692 Patent is invalid and/or not infringed by" the Mankind ANDA Product. (Mankind 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 115 of the Complaint, and therefore denies them.

116. Mankind filed the Mankind '692 Patent Paragraph IV Certification without adequate justification for asserting that the '692 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 116 of the Complaint, and therefore denies them.

117. Mankind also attached to the Mankind Third Notice Letter a "Detailed Statement of the Factual and Legal Basis for its Opinion that U.S. Patent No. 12,048,692 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 117 of the Complaint, and therefore denies them.

118. The Mankind Third Notice Letter does not provide a substantive unenforceability defense to the '692 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 118 of the Complaint, and therefore denies them.

119. Mankind's filing of its ANDA No. 218089 constitutes infringement of the '692 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 119 of the Complaint, and therefore denies them.

120. 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 and methods of treatment described and claimed in one or more claims of the '692 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 120 of the Complaint, and therefore denies them.

121. 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 121 of the Complaint, and therefore denies them.

122. 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 122 of the Complaint, and therefore denies them.

123. 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 123 of the Complaint, and therefore denies them.

124. On information and belief, Mankind had knowledge of the '692 patent when it submitted and filed the Mankind '692 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 124 of the Complaint, and therefore denies them.

125. On information and belief, Mankind intends to and will infringe, actively induce infringement, and/or contribute to infringement of one or more claims of the '692 patent upon receiving FDA approval of ANDA No. 218089 and prior to the expiration of the '692 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 125 of the Complaint, and therefore denies them.

126. On information and belief, Mankind will commercially manufacture, use, offer for sale, and/or sell the Mankind ANDA Product throughout the United States, and/or 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 '692 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 126 of the Complaint, and therefore denies them.

127. On information and belief, Mankind knows that the Mankind ANDA Product is especially made or adapted for use in a way that would infringe the '692 patent, and is not suitable for substantial non-infringing use. On information and belief, Mankind knowingly has taken and intends to take active steps to, and will, induce and/or contribute to infringement of one or more claims of the '692 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 127 of the Complaint, and therefore denies them.

128. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Mankind with respect to infringement of the '692 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 128 of the Complaint, and therefore denies them.

129. This action is being commenced within 45 days of receipt of the Mankind 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 129 of the Complaint, and therefore denies them.

Cipla

130. 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 130.

131. Plaintiffs filed a complaint for infringement of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent against Cipla, *inter alia*, 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*, Cipla Limited and Cipla USA, 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 131.

132. Plaintiffs filed a complaint for infringement of the '948 patent against Cipla, *inter alia*, in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with Civil Action No. 23-00926-KMW-AMD on September 29, 2023.

ANSWER: Cipla admits that Plaintiffs filed a complaint for infringement of the '948 patent against, *inter alia*¸ Cipla Limited and Cipla USA, Inc., in this jurisdiction on August 21, 2023, which was assigned Civil Action No. 23-06667-KMW-AMD, and which was consolidated with Civil Action No. 23-00926-KMW-AMD on September 29, 2023. Cipla denies the remaining allegations of Paragraph 132.

133. In a letter dated August 24, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Cipla Second Notice Letter"), Cipla notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that the Cipla ANDA includes 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 Cipla ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '948 patent.

ANSWER: Cipla admits that in the Cipla Second Notice Letter, Cipla notified Plaintiffs that it had filed a Paragraph IV Certification with respect to the '948 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 that patent. Cipla denies the remaining allegations of Paragraph 133.

134. On December 4, 2023, Plaintiffs filed a First Amended Consolidated Complaint for Patent Infringement against Cipla, *inter alia*, in Civil Action No. 23-00926-KMW-AMD, which included additional claims for infringement of the '783 patent, the '099 patent, the '013 patent, and the '209 patent.

ANSWER: Cipla admits that Plaintiffs filed a First Amended Consolidated Complaint for Patent Infringement of the '451 patent, '028 patent, '081 patent, the '289 patent, the '531 patent, the '948 patent, the '783 patent, the '099 patent, the '013 patent, and the '209 patent against, *inter alia*¸ Cipla Limited and Cipla USA, Inc., in this jurisdiction on December 4, 2023, which was filed in Civil Action No. 23-00926-KMW-AMD. Cipla denies the remaining allegations of Paragraph 134.

135. Plaintiffs filed a complaint for infringement of the '898 patent against Cipla, *inter alia*, in this jurisdiction on January 9, 2024, which was assigned Civil Action No. 24-00150-KMW-AMD, and which was consolidated with Civil Action No. 23-00926-KMW-AMD on February 1, 2024.

ANSWER: Cipla admits that Plaintiffs filed a Complaint for Patent Infringement of the '898 patent against, *inter alia*¸ Cipla Limited and Cipla USA, Inc., in this jurisdiction on January 9, 2024, which was assigned as Civil Action No. 24-00150-KMW-AMD, and which was consolidated with Civil Action No. 23-00926-KMW-AMD on February 1, 2024. Cipla denies the remaining allegations of Paragraph 135.

136. Cipla's filing of its ANDA No. 217958 constitutes infringement of the '692 patent under at least 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

137. 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 and methods of treatment described and claimed in one or more claims of the '692 patent.

ANSWER: Denied.

138. 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 138 contains legal conclusions to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of Paragraph 138.

139. 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 139.

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

ANSWER: Admitted.

141. On information and belief, Cipla has actual knowledge as of the date of this Complaint of the '692 patent, at least because Plaintiffs have identified the '692 patent to Cipla as part of this Action.

ANSWER: Paragraph 138 contains legal conclusions to which no answer is required. To the extent that an answer is required, Cipla admits that Plaintiffs identified the '692 patent to Cipla as of the date of this Complaint. Cipla denies the remaining allegations of Paragraph 141.

142. On information and belief, Cipla intends to and will infringe, actively induce infringement, and/or contribute to infringement of one or more claims of the '692 patent upon receiving FDA approval of ANDA No. 217958 and prior to the expiration of the '692 patent.

ANSWER: Denied.

143. 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, and/or induce and/or contribute to such acts, promptly upon receiving FDA approval to do so and during the term of the '692 patent.

ANSWER: Cipla denies the allegations of Paragraph 143 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

144. On information and belief, Cipla knows that the Cipla ANDA Product is especially made or adapted for use in a way that would infringe the '692 patent, and is not suitable for substantial non-infringing use. On information and belief, Cipla knowingly has taken and intends

to take active steps to, and will, induce and/or contribute to infringement of one or more claims of the '692 patent.

ANSWER: Denied.

145. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Cipla with respect to infringement of the '692 patent.

ANSWER: Cipla admits that an actual, substantial, and continuing justiciable case or controversy exists between Cipla and Plaintiffs. Cipla denies the remaining allegations of Paragraph 145.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 12,048,692 BY EUGIA

146. 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.

147. Eugia's submission of ANDA No. 218128 containing a Paragraph IV Certification 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 '692 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '692 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 147 of the Complaint, and therefore denies them.

148. Unless enjoined, upon FDA approval of Eugia's ANDA No. 218128, Eugia will infringe one or more claims of the '692 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

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. On information and belief, upon FDA approval of Eugia's ANDA No. 218128, Eugia intends to manufacture, market, sell, and offer to sell Eugia's ANDA Product with an FDA-approved package insert that will direct healthcare providers and patients in the use of Eugia's 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 149 of the Complaint, and therefore denies them.

150. On information and belief, Eugia will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Eugia knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '692 patent by marketing Eugia's ANDA Product with the FDA-approved package insert.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 150 of the Complaint, and therefore denies them.

151. The '692 patent has one independent claim, claim 1, which states:

> 1. A method for treating chronic obstructive pulmonary disease (COPD) in a patient with severe to very severe COPD, the method comprising:
>
> (a) selecting a patient having a percent predicted forced expiratory volume in one second less than 50 percent; and
>
> (b) administering a pharmaceutical composition comprising an aqueous solution of revefenacin or a pharmaceutically acceptable salt thereof to the selected patient using a nebulizer;
>
> wherein the patient has a low peak inspiratory flow rate.

ANSWER: Cipla admits that the '692 patent has an independent claim 1 which states:

> 1. A method for treating chronic obstructive pulmonary disease (COPD) in a patient with severe to very severe COPD, the method comprising:
>
> (a) selecting a patient having a percent predicted forced expiratory volume in one second less than 50 percent; and

(b) administering a pharmaceutical composition comprising an aqueous solution of revefenacin or a pharmaceutically acceptable salt thereof to the selected patient using a nebulizer;

wherein the patient has a low peak inspiratory flow rate.

Cipla denies the remaining allegations of Paragraph 151.

152. A healthcare provider will directly infringe one of more of the claims of the '692 patent. Specifically, a healthcare provider administering Eugia's ANDA Product in accordance with Eugia's package insert will perform the steps of one or more claims of the '692 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 152 of the Complaint, and therefore denies them.

153. 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 153 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 153.

154. 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 154 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 154.

155. The package insert for Eugia's ANDA Product will be substantially similar to the package insert for YUPELRI® in all material respects.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 155 of the Complaint, and therefore denies them.

156. Providers of revefenacin review and follow the package inserts for the revefenacin products they use to treat their patients.

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. On information and belief, Eugia is seeking approval to market its 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 157 of the Complaint, and therefore denies them.

158. The YUPELRI® package insert instructs that YUPELRI® is "indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." (Exhibit B at § 1).

ANSWER: Cipla admits that the YUPELRI® package insert (revised 5/2022) recites that "YUPELRI is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 158 of the Complaint, and therefore denies them.

159. The "Dosage and Administration" section of the YUPELRI® package instructs that the recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." (*Id.* at § 2).

ANSWER: Cipla admits that the YUPELRI® package insert (revised 5/2022) recites that "[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 159 of the Complaint, and therefore denies them.

160. The "Dosage Forms and Strengths" section of the YUPELRI® package insert states that YUPELRI® is an "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." (*Id.* at § 3).

ANSWER: Cipla admits that the YUPELRI® package insert (revised 5/2022) recites, "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 160 of the Complaint, and therefore denies them.

161. A healthcare provider will select a patient having COPD for treatment with YUPELRI® based on the patient having a percent predicted force expiratory volume in one second less than about 50%.

ANSWER: Paragraph 161 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 161.

162. Many of those selected patients will have a low peak inspiratory flow rate.

ANSWER: Paragraph 162 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 162.

163. The YUPELRI® package insert describes the treatment of severe and very severe patients in Clinical Studies. (*Id.* at § 14.2).

ANSWER: Cipla admits that the YUPELRI® package insert (revised 5/2022) recites that "[t]he clinical development program for YUPELRI included two 12-week, randomized, double-blind, placebo-controlled, multiple-dose, parallel-group, confirmatory trials in subjects with moderate to very severe COPD designed to evaluate the efficacy of once-daily YUPELRI's effect on lung function." Cipla is without knowledge or information sufficient to form a belief as

to the truth of the remaining allegations and characterizations contained in Paragraph 163 of the Complaint, and therefore denies them.

164. According to the YUPELRI® package insert, in Section 14.2, the clinical trials enrolled patients with mean percent predicted FEV1 of 55%. (*Id*.)

ANSWER: Cipla admits the YUPELRI® package insert (revised 5/2022) recites "[a]t screening, the mean post-bronchodilator percent predicted FEV_1 was 55% (range: 10% to 90%)." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 164 of the Complaint, and therefore denies them.

165. The GOLD guidelines, Figure 2.7, categorize severe COPD based on FEV1 of equal to or greater than 30% and less than 50%.

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. A healthcare provider, or a patient at the direction of a healthcare provider, will administer Eugia's ANDA Product to the patient once daily using a nebulizer.

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. The YUPELRI® package insert, in Section 2, Dosing and Administration, instructs treating patients by administering YUPELRI® by nebulizer. (Exhibit B at § 2).

ANSWER: Cipla admits that the YUPELRI® package insert (revised 5/2022) recites, "The 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 167 of the Complaint, and therefore denies them.

168. The GOLD guidelines, such as at pages 53-55, advise healthcare providers to check the patient's ability to use an inhaler.

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. It is known that successful use of dry powder inhalers such as the HandiHaler® requires a PIFR of 60 L/min.

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. A healthcare provider will use a nebulizer for patients selected for treatment for having a percent predicted forced expiratory volume in one second less than 50 percent, and many of those patients will have a low PIFR. *See*, *e.g.*, Mahler 2017; Mahler 2014.

ANSWER: Paragraph 170 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 170.

171. On information and belief, Eugia specifically intends that its ANDA product, if marketed, would be administered to some patients with severe or very severe COPD having a PIFR of less than about 60 L/min and FEV1 of less than 50%, using a nebulizer.

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. On information and belief, Eugia knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a FEV1 of less than 50%, and that many of those patients will have a low PIFR.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 172 of the Complaint, and therefore denies them.

173. On information and belief, Eugia knows, and specifically intends, that some healthcare providers will select patients for treatment with its proposed ANDA product, if marketed, based on the patient having a FEV1 of less than 50%, and that many of those patients will have a low PIFR.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 173 of the Complaint, and therefore denies them.

174. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '692 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 174 of the Complaint, and therefore denies them.

175. 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 175 of the Complaint, and therefore denies them.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 12,048,692 BY MANKIND

176. 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.

177. Mankind's submission of ANDA No. 218089 containing a Paragraph IV Certification 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 '692 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '692 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 177 of the Complaint, and therefore denies them.

178. Unless enjoined, upon FDA approval of Mankind's ANDA No. 218089, Mankind will infringe one or more claims of the '692 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

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. On information and belief, upon FDA approval of Mankind's ANDA No. 218089, Mankind intends to manufacture, market, sell, and offer to sell Mankind's ANDA Product with an FDA-approved package insert that will direct healthcare providers and patients in the use of Mankind's 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 179 of the Complaint, and therefore denies them.

180. On information and belief, Mankind will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Mankind knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '692 patent by marketing Mankind's ANDA Product with the FDA-approved package insert.

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. The '692 patent has one independent claim, claim 1, which states:

> 1. A method for treating chronic obstructive pulmonary disease (COPD) in a patient with severe to very severe COPD, the method comprising:
>
> (a) selecting a patient having a percent predicted forced expiratory volume in one second less than 50 percent; and

> (b) administering a pharmaceutical composition comprising an aqueous solution of revefenacin or a pharmaceutically acceptable salt thereof to the selected patient using a nebulizer;
>
> wherein the patient has a low peak inspiratory flow rate.

ANSWER: Cipla admits that the '692 has an independent claim 1 which states:

> 1. A method for treating chronic obstructive pulmonary disease (COPD) in a patient with severe to very severe COPD, the method comprising:
>
> (a) selecting a patient having a percent predicted forced expiratory volume in one second less than 50 percent; and
>
> (b) administering a pharmaceutical composition comprising an aqueous solution of revefenacin or a pharmaceutically acceptable salt thereof to the selected patient using a nebulizer;
>
> wherein the patient has a low peak inspiratory flow rate.

Cipla denies the remaining allegations of Paragraph 181.

182. A healthcare provider will directly infringe one of more of the claims of the '692 patent. Specifically, a healthcare provider administering Mankind's ANDA Product in accordance with Mankind's package insert will perform the steps of one or more claims of the '692 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 182 of the Complaint, and therefore denies them.

183. 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 183 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 183.

184. 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 184 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 184.

185. The package insert for Mankind's ANDA Product will be substantially similar to the package insert for YUPELRI® in all material respects.

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. Providers of revefenacin review and follow the package inserts for the revefenacin products they use to treat their patients.

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. On information and belief, Mankind is seeking approval to market its 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 187 of the Complaint, and therefore denies them.

188. The YUPELRI® package insert instructs that YUPELRI® is "indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." (Exhibit B at § 1).

ANSWER: Cipla admits that the YUPELRI® package insert (revised 5/2022) recites that "YUPELRI is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." Cipla is without knowledge or information sufficient to form a belief

as to the truth of the remaining allegations and characterizations contained in Paragraph 188 of the Complaint, and therefore denies them.

189. The "Dosage and Administration" section of the YUPELRI® package instructs that the "recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." (*Id.* at § 2).

ANSWER: Cipla admits that the YUPELRI® package insert (revised 5/2022) recites that "[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 189 of the Complaint, and therefore denies them.

190. The "Dosage Forms and Strengths" section of the YUPELRI® package insert states that YUPELRI® is an "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." (*Id.* at § 3).

ANSWER: Cipla admits that the YUPELRI® package insert (revised 5/2022) recites, "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 190 of the Complaint, and therefore denies them.

191. A healthcare provider will select a patient having COPD for treatment with YUPELRI® based on the patient having a percent predicted force expiratory volume in one second less than about 50%.

ANSWER: Paragraph 191 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 191.

192. Many of those selected patients will have a low peak inspiratory flow rate.

ANSWER: Paragraph 192 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 192.

193. The YUPELRI® package insert describes the treatment of severe and very severe patients in Clinical Studies. (*Id.* at § 14.2).

ANSWER: Cipla admits that the YUPELRI® package insert (revised 5/2022) recites that "[t]he clinical development program for YUPELRI included two 12-week, randomized, double-blind, placebo-controlled, multiple-dose, parallel-group, confirmatory trials in subjects with moderate to very severe COPD designed to evaluate the efficacy of once-daily YUPELRI's effect on lung function." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 193 of the Complaint, and therefore denies them.

194. According to the YUPELRI® package insert, in Section 14.2, the clinical trials enrolled patients with mean percent predicted FEV1 of 55%. (*Id.*).

ANSWER: Cipla admits the YUPELRI® package insert (revised 5/2022) recites "[a]t screening, the mean post-bronchodilator percent predicted FEV_1 was 55% (range: 10% to 90%)." Cipla is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and characterizations contained in Paragraph 194 of the Complaint, and therefore denies them.

195. The GOLD guidelines, Figure 2.7, categorize severe COPD based on FEV1 of equal to or greater than 30% and less than 50%.

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. A healthcare provider, or a patient at the direction of a healthcare provider, will administer Mankind's ANDA Product to the patient once daily using a nebulizer.

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. The YUPELRI® package insert, in the Section 2, Dosing and Administration, instructs treating patients by administering YUPELRI® by nebulizer. (Exhibit B at § 2).

ANSWER: Cipla admits that the YUPELRI® package insert (revised 5/2022) recites, "The 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 197 of the Complaint, and therefore denies them.

198. The GOLD guidelines, such as at pages 53-55, advise healthcare providers to check the patient's ability to use an inhaler.

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. It is known that successful use of dry powder inhalers such as the HandiHaler® requires a PIFR of 60 L/min.

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 healthcare provider will use a nebulizer for patients selected for treatment for having a percent predicted forced expiratory volume in one second less than 50 percent, and many of those patients will have a low PIFR. *See, e.g.*, Mahler 2017; Mahler 2014.

ANSWER: Paragraph 200 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 200.

201. On information and belief, Mankind specifically intends that its ANDA product, if marketed, would be administered to some patients with severe or very severe COPD having a PIFR of less than about 60 L/min and FEV1 of less than 50%, using a nebulizer.

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. On information and belief, Mankind knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a FEV1 of less than 50%, and that many of those patients will have a low PIFR.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 202 of the Complaint, and therefore denies them.

203. On information and belief, Mankind knows, and specifically intends, that some healthcare providers will select patients for treatment with its proposed ANDA product, if marketed, based on the patient having a FEV1 of less than 50%, and that many of those patients will have a low PIFR.

ANSWER: Cipla is without knowledge or information sufficient to form a belief as to the truth of the allegations and characterizations contained in Paragraph 203 of the Complaint, and therefore denies them.

204. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '692 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 204 of the Complaint, and therefore denies them.

205. 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 205 of the Complaint, and therefore denies them.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 12,048,692 BY CIPLA

206. 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.

207. Cipla's submission of ANDA No. 217958 containing a Paragraph IV Certification 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 '692 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '692 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

208. Unless enjoined, upon FDA approval of Cipla's ANDA No. 217958, Cipla will infringe one or more claims of the '692 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

ANSWER: Denied.

209. On information and belief, upon FDA approval of Cipla's ANDA No. 217958, Cipla intends to manufacture, market, sell, and offer to sell Cipla's ANDA Product with an FDA-approved package insert that will direct healthcare providers and patients in the use of Cipla's ANDA Product.

ANSWER: Denied.

210. On information and belief, Cipla will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Cipla knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '692 patent by marketing Cipla's ANDA Product with the FDA-approved package insert.

ANSWER: Denied.

211. The '692 patent has one independent claim, claim 1, which states:

> 1. A method for treating chronic obstructive pulmonary disease (COPD) in a patient with severe to very severe COPD, the method comprising:
>
> (a) selecting a patient having a percent predicted forced expiratory volume in one second less than 50 percent; and

> (b) administering a pharmaceutical composition comprising an aqueous solution of revefenacin or a pharmaceutically acceptable salt thereof to the selected patient using a nebulizer;
>
> wherein the patient has a low peak inspiratory flow rate.

ANSWER: Cipla admits that the '692 has an independent claim 1 which states:

> 1. A method for treating chronic obstructive pulmonary disease (COPD) in a patient with severe to very severe COPD, the method comprising:
>
> (a) selecting a patient having a percent predicted forced expiratory volume in one second less than 50 percent; and
>
> (b) administering a pharmaceutical composition comprising an aqueous solution of revefenacin or a pharmaceutically acceptable salt thereof to the selected patient using a nebulizer;
>
> wherein the patient has a low peak inspiratory flow rate.

Cipla denies the remaining allegations of Paragraph 211.

212. A healthcare provider will directly infringe one of more of the claims of the '692 patent. Specifically, a healthcare provider administering Cipla's ANDA Product in accordance with Cipla's package insert will perform the steps of one or more claims of the '692 patent.

ANSWER: Denied.

213. 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 213 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 213.

214. 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 214 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 214.

215. The package insert for Cipla's ANDA Product will be substantially similar to the package insert for YUPELRI® in all material respects.

ANSWER: Denied.

216. Providers of revefenacin review and follow the package inserts for the revefenacin products they use to treat their patients.

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. On information and belief, Cipla is seeking approval to market its 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 217.

218. The YUPELRI® package insert instructs that YUPELRI® is "indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." (Exhibit B at § 1).

ANSWER: Cipla admits that the YUPELRI® package insert (revised 5/2022) recites that "YUPELRI is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." Cipla denies the remaining allegations and characterizations contained in Paragraph 218 of the Complaint.

219. The "Dosage and Administration" section of the YUPELRI® package instructs that the "recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." (*Id.* at § 2).

ANSWER: Cipla admits that the YUPELRI® package insert (revised 5/2022) recites that "[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 denies the remaining allegations and characterizations contained in Paragraph 219 of the Complaint.

220. The "Dosage Forms and Strengths" section of the YUPELRI® package insert states that YUPELRI® is an "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." (*Id.* at § 3).

ANSWER: Cipla admits that the YUPELRI® package insert (revised 5/2022) recites, "Inhalation solution: 175 mcg of revefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials." Cipla denies the remaining allegations and characterizations contained in Paragraph 220 of the Complaint.

221. A healthcare provider will select a patient having COPD for treatment with YUPELRI® based on the patient having a percent predicted force expiratory volume in one second less than about 50%.

ANSWER: Paragraph 221 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 221.

222. Many of those selected patients will have a low peak inspiratory flow rate.

ANSWER: Paragraph 222 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 222.

223. The YUPELRI® package insert describes the treatment of severe and very severe patients in Clinical Studies. (*Id.* at § 14.2).

ANSWER: Cipla admits that the YUPELRI® package insert (revised 5/2022) recites that "[t]he clinical development program for YUPELRI included two 12-week, randomized, double-blind, placebo-controlled, multiple-dose, parallel-group, confirmatory trials in subjects with moderate to very severe COPD designed to evaluate the efficacy of once-daily YUPELRI's

effect on lung function." Cipla denies the remaining allegations and characterizations contained in Paragraph 223 of the Complaint.

224. According to the YUPELRI® package insert, in Section 14.2, the clinical trials enrolled patients with mean percent predicted FEV1 of 55%. (*Id.*).

ANSWER: Cipla admits the YUPELRI® package insert (revised 5/2022) recites "[a]t screening, the mean post-bronchodilator percent predicted FEV_1 was 55% (range: 10% to 90%)." Cipla denies the remaining allegations and characterizations contained in Paragraph 224 of the Complaint.

225. The GOLD guidelines, Figure 2.7, categorize severe COPD based on FEV1 of equal to or greater than 30% and less than 50%.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in Paragraph 225 of the Complaint, and therefore denies them.

226. A healthcare provider, or a patient at the direction of a healthcare provider, will administer Cipla's ANDA Product to the patient once daily using a nebulizer.

ANSWER: Denied.

227. The YUPELRI® package insert, in Section 2, Dosing and Administration, instructs treating patients by administering YUPELRI® by nebulizer. (Exhibit B at § 2).

ANSWER: Cipla admits that the YUPELRI® package insert (revised 5/2022) recites, "The recommended dosage is 175 mcg YUPELRI (one 175 mcg unit-dose vial) administered by oral inhalation once daily by nebulizer using a mouthpiece." Cipla denies the remaining allegations and characterizations contained in Paragraph 227 of the Complaint.

228. The GOLD guidelines, such as at pages 53-55, advise healthcare providers to check the patient's ability to use an inhaler.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in Paragraph 228 of the Complaint, and therefore denies them.

229. It is known that successful use of dry powder inhalers such as the HandiHaler® requires a PIFR of 60 L/min.

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.

230. A healthcare provider will use a nebulizer for patients selected for treatment for having a percent predicted forced expiratory volume in one second less than 50 percent, and many of those patients will have a low PIFR. *See, e.g.*, Mahler 2017; Mahler 2014.

ANSWER: Paragraph 230 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 230.

231. On information and belief, Cipla specifically intends that its ANDA product, if marketed, would be administered to some patients with severe or very severe COPD having a PIFR of less than about 60 L/min and FEV1 of less than 50%, using a nebulizer.

ANSWER: Denied.

232. On information and belief, Cipla knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a FEV1 of less than 50%, and that many of those patients will have a low PIFR.

ANSWER: Denied.

233. On information and belief, Cipla knows, and specifically intends, that some healthcare providers will select patients for treatment with its proposed ANDA product, if marketed, based on the patient having a FEV1 of less than 50%, and that many of those patients will have a low PIFR.

ANSWER: Denied.

234. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '692 patent is not enjoined.

ANSWER: Denied.

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

ANSWER: Denied.

PRAYER FOR RELIEF

Cipla denies that Plaintiffs are entitled to the relief sought in paragraphs (a) through (k) on pages 41 through 45 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 235 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 '692 Patent)

Each claim of the '692 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 '692 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '692 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 '692 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 Letters and/or are estopped from contesting any alleged defect in service of Cipla's Notice Letters.

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 '692 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. 12,048,692 (the "'692 patent" or "Patent-in-Suit") 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-400013, 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, and August 21, 2023, Counterclaim Defendants filed civil actions in this judicial district against Cipla alleging infringement of certain patents (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"), 11,484,531 (the "'531 patent"), and 11,691,948 (the "'948 patent")). These actions were consolidated in Civil Action No. 23-00926-KMW-AMD. On or about December 4, 2023, Counterclaim Defendants added infringement allegations with respect to United States Patent Nos. 8,017,783 (the "'783 patent"),

9,249,099 (the "'099 patent"), 10,100,013 (the "'013 patent"), and 11,649,209 (the "'209 patent") with respect to Cipla in Civil Action No. 23-00926-KMW-AMD. On or about January 9, 2024, Counterclaim Defendants filed a civil action in this judicial district against Cipla alleging infringement of United States Patent No. 11,858,898 (the "'898 patent"). This action was consolidated with in Civil Action No. 23-00926-KMW-AMD.

14. On or about August 19, 2024, Counterclaim Defendants filed a civil action in this judicial district against Cipla alleging infringement of the '692 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 Patent-in-Suit.

The Patent-in-Suit

15. Based on the allegations in the Complaint, the '692 patent, entitled "Methods for Treating Chronic Obstructive Pulmonary Disease," was issued on July 30, 2024. Theravance Biopharma R&D IP, LLC is listed as the assignee on the face of the '692 patent.

16. The '692 patent is listed in the Orange Book in association with YUPELRI®.

17. On January 17, 2023, Cipla sent Counterclaim Defendants Mylan Ireland Ltd. and Theravance Biopharma R&D IP, LLC notification of Paragraph IV Certification for the '451 patent, '028 patent, '081 patent, '289 patent, and '531 patent with respect to Cipla's filing of ANDA No. 217958 ("Cipla's First Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), (iv) and 21 C.F.R. § 314.95(c)(1).

18. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), Cipla's First Notice Letter included, among other things, Cipla's detailed factual and legal basis for the Paragraph IV Certification regarding the '451 patent, '028 patent, '081 patent, '289 patent,

and ’531 patent as it pertains to Cipla’s ANDA Product and an Offer of Confidential Access to Cipla’s ANDA Product.

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 Second 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 Second 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.

21. On May 29, 2024, Cipla sent Counterclaim Defendants Mylan Ireland Ltd. and Theravance Biopharma R&D IP, LLC notification of Paragraph IV Certification for the ’898 patent with respect to Cipla’s filing of ANDA No. 217958 (“Cipla’s Third Notice Letter”), pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), (iv) and 21 C.F.R. § 314.95(c)(1).

22. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), Cipla’s Third Notice Letter included, among other things, Cipla’s detailed factual and legal basis for the Paragraph IV Certification regarding the ’898 patent as it pertains to Cipla’s ANDA Product and an Offer of Confidential Access to Cipla’s ANDA Product.

23. On or about August 19, 2024, Counterclaim Defendants filed the instant Complaint alleging infringement of the ’692 patent.

First Counterclaim
(Declaratory Judgment of Noninfringement of the ’692 Patent)

24. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 23 of the Counterclaims as if fully set forth herein.

25. Counterclaim Defendants have accused Cipla of infringing the '692 patent.

26. Cipla denies infringement of the '692 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 '692 patent.

27. 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 a declaratory judgment regarding infringement of any valid and enforceable claim of the '692 patent.

28. 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 '692 patent.

Second Counterclaim
(Declaratory Judgment of Invalidity of the '692 Patent)

29. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 28 of the Counterclaims as if fully set forth herein.

30. The claims of the '692 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.

31. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '692 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

32. 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 '692 patent.

33. Cipla is entitled to a judicial declaration that all claims of the '692 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 Patent-in-Suit, either literally or under the doctrine of equivalents;

B. Declaring that the claims of the Patent-in-Suit 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 Patent-in-Suit 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: October 17, 2024

K&L GATES LLP

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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, the following actions involve the same matter as the instant action:

- *Theravance Biopharma R&D IP, LLC et al v. Accord Healthcare, Inc. et al.*, 1-23-cv-00157 (MDNC) (Filed Feb. 17, 2023);
- *Theravance Biopharma R&D IP, LLC et al v. Lupin Inc. et al.*, 1-23-cv-00187 (DDE) (Filed Feb. 17, 2023);
- *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Ltd. et al.*, Consolidated Case No. 1:24-cv-08558-KMW-AMD (D.N.J. Aug. 19, 2024); and
- *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Ltd. Et al.*, 1:24-cv-00150-KMW-AMD (D.N.J. Jan. 1, 2024).

I further certify that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. I certify under penalty of perjury that the foregoing is true and correct.

Dated: October 17, 2024

/s/ Loly G. Tor
Loly G. 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: October 17, 2024

/s/ Loly G. Tor
Loly G. Tor

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

UNITED STATES DISTRICT COURT
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.,

Plaintiffs,

v.

EUGIA PHARMA SPECIALITIES LTD., EUGIA US LLC, AUROBINDO PHARMA USA, INC., AUROBINDO PHARMA LIMITED, MANKIND PHARMA LTD., LIFESTAR PHARMA LLC, ACCORD HEALTHCARE, INC., MEDICHEM S.A., MEDICHEM MANUFACTURING (MALTA) LTD., MEDICHEM USA, LLC, LUPIN INC., LUPIN PHARMACEUTICALS, INC., ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED, CIPLA LIMITED, and CIPLA USA, INC.,

Defendants.

Case No. 1:24-cv-08558-KMW-AMD

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

CERTIFICATE OF SERVICE

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 to Plaintiffs' Complaint, 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.

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

Dated: October 17, 2024

/s/ Loly G. Tor
Loly G. Tor