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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	C.A. No. _____ *Document Filed Electronically*

USA, INC., AUROBINDO PHARMA LIMITED, MANKIND PHARMA LTD., LIFESTAR PHARMA LLC, CIPLA LIMITED, and CIPLA USA, INC.,	)
Defendants.	)

COMPLAINT FOR PATENT INFRINGEMENT

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"), by their attorneys, for their Complaint ("Complaint") against Defendants Eugia Pharma Specialities Ltd. ("Eugia Pharma"), Eugia US LLC ("Eugia US"), Aurobindo Pharma USA, Inc. ("Aurobindo USA"), Aurobindo Pharma Limited ("Aurobindo Ltd.") (collectively, "Eugia"); Mankind Pharma Ltd. ("Mankind Pharma"), Lifestar Pharma LLC ("Lifestar") (collectively, "Mankind"); and Cipla Limited ("Cipla Ltd."), Cipla USA, Inc. ("Cipla USA") (collectively, "Cipla") (all named defendants, collectively, "Defendants"), hereby allege 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®.

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.

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.

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

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.

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

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

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

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.

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").

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).

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).

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.

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

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.

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.

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

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

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

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.

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.

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.

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.

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

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.

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.

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.

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.

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

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.

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.

JURISDICTION AND VENUE

32. Plaintiffs incorporate by reference the prior paragraphs of this 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.

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)).

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.

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.

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.

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.

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.

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.

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.

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).

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).

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.

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.

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.

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.

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.

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.

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.

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).

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).

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.

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.

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.

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.

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).

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.

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.

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.

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.

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).

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).

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.

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.

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.

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.

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).

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.

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.

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.

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.

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).

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).

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.

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.

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

YUPELRI®

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

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.

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).

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®.

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.

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

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 (FEV_1) percent predicted of 55% (range: 10% to 90%). (Exhibit B at § 14.2).

COPD

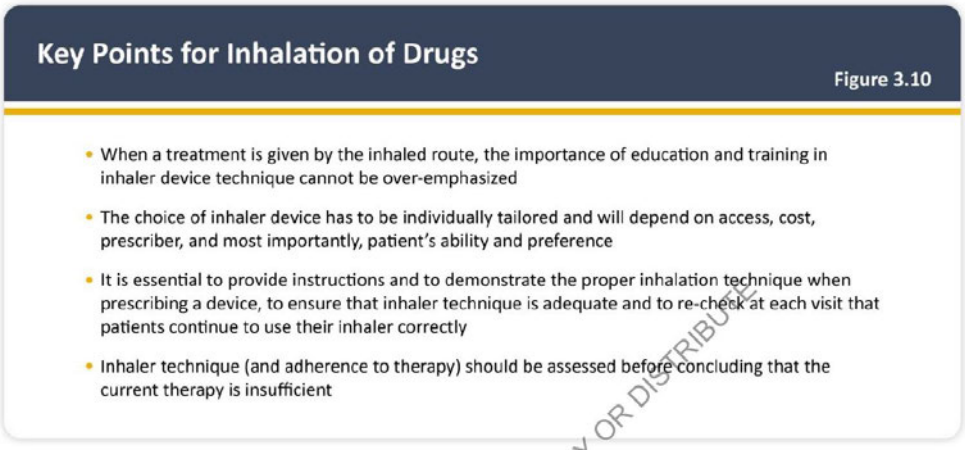
85. COPD is a chronic inflammatory lung disease characterized by progressive persistent airflow obstruction. Bronchodilators, such as muscarinic receptor antagonists and β-adrenergic agonists, are used to treat COPD. Such bronchodilators are typically delivered to a patient in need of treatment using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

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.

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 (FEV_1). According to the GOLD guidelines, severe includes patients with a percent predicted FEV_1 of equal to or greater than 30% and less than 50%. According to the GOLD guidelines, very severe includes patients with a percent predicted FEV_1 of less than 30%.

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.

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.

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.

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.

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").

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.

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").

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.

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”).

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.

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).

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.

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®.

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

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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).

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.

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)."

118. The Mankind Third Notice Letter does not provide a substantive unenforceability defense to the '692 patent in the "Detailed Statement."

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).

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.

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®.

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

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

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.

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.

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.

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.

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.

129. This action is being commenced within 45 days of receipt of the Mankind Third Notice Letter.

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.

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.

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.

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.

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.

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.

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).

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.

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®.

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

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

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.

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.

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.

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.

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.

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.

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).

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).

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.

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.

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.

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.

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).

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®.

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

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

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

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).

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).

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).

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%.

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

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

164. According to the YUPELRI® package insert, in Section 14.2, the clinical trials enrolled patients with mean percent predicted FEV_1 of 55%. (*Id.*)

165. The GOLD guidelines, Figure 2.7, categorize severe COPD based on FEV_1 of equal to or greater than 30% and less than 50%.

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.

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

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

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

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.

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 FEV_1 of less than 50%, using a nebulizer.

172. On information and belief, Eugia knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a FEV_1 of less than 50%, and that many of those patients will have a low PIFR.

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 FEV_1 of less than 50%, and that many of those patients will have a low PIFR.

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

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

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.

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).

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).

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.

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.

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.

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.

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).

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®.

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

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

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

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).

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).

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).

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%.

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

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

194. According to the YUPELRI® package insert, in Section 14.2, the clinical trials enrolled patients with mean percent predicted FEV_1 of 55%. (*Id.*)

195. The GOLD guidelines, Figure 2.7, categorize severe COPD based on FEV_1 of equal to or greater than 30% and less than 50%.

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.

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

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

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

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.

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 FEV_1 of less than 50%, using a nebulizer.

202. On information and belief, Mankind knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a FEV_1 of less than 50%, and that many of those patients will have a low PIFR.

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 FEV_1 of less than 50%, and that many of those patients will have a low PIFR.

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

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

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.

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).

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).

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.

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.

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.

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.

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).

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®.

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

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

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

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).

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).

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).

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%.

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

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

224. According to the YUPELRI® package insert, in Section 14.2, the clinical trials enrolled patients with mean percent predicted FEV_1 of 55%. (*Id.*)

225. The GOLD guidelines, Figure 2.7, categorize severe COPD based on FEV_1 of equal to or greater than 30% and less than 50%.

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.

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

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

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

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.

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 FEV_1 of less than 50%, using a nebulizer.

232. On information and belief, Cipla knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a FEV_1 of less than 50%, and that many of those patients will have a low PIFR.

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 FEV_1 of less than 50%, and that many of those patients will have a low PIFR.

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

Eugia

(a) A judgment under 35 U.S.C. § 271(e)(2)(A) that Eugia has infringed one or more claims of the '692 patent by the filing of its ANDA No. 218128;

(b) A judgment that Eugia's manufacturing, using, selling, offering for sale, and/or importing the Eugia ANDA Product in/into the United States will infringe one or more claims of the '692 patent under 35 U.S.C. § 271(b);

(c) A declaration under 28 U.S.C. §§ 2201-02 that if Eugia, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of the Eugia ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(b);

(d) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 218128 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date not earlier than the latest expiration date of the '692 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(e) A judgment under 35 U.S.C. §§ 271(e)(4)(B) and 283 providing injunctive relief against Eugia, whether alone or in concert with a subsidiary company, to prevent the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of the Eugia ANDA Product before the expiration of the '692 patent, inclusive of any extension(s) to patent term;

(f) A permanent injunction restraining and enjoining Eugia, whether alone or in concert with a subsidiary company, from making, using, selling, offering for sale, and/or importing

the Eugia ANDA Product or any pharmaceutical composition as claimed in the '692 patent in/into the United States, or practicing any processes or methods as claimed in the '692 patent, or from actively inducing to the infringement of any claim of the '692 patent, before the expiration of the '692 patent, respectively, inclusive of any extension(s) to patent term in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(g) Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, and damages under 35 U.S.C. § 271(e)(4)(C), to Plaintiffs if Eugia engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Eugia ANDA Product prior to the expiration date of the '692 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

(h) To the extent the facts show that this is an exceptional case, an award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(i) An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4);

(j) Costs and expenses in this action; and

(k) Such further and other relief as this Court may deem just and proper.

Mankind

(a) A judgment under 35 U.S.C. § 271(e)(2)(A) that Mankind has infringed one or more claims of the '692 patent by the filing of its ANDA No. 218089;

(b) A judgment that Mankind's manufacturing, using, selling, offering for sale, and/or importing the Mankind ANDA Product in/into the United States will infringe one or more claims of the '692 patent under 35 U.S.C. § 271(b);

(c) A declaration under 28 U.S.C. §§ 2201-02 that if Mankind, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation

of the Mankind ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(b);

(d) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 218089 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date not earlier than the latest expiration date of the '692 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(e) A judgment under 35 U.S.C. §§ 271(e)(4)(B) and 283 providing injunctive relief against Mankind, whether alone or in concert with a subsidiary company, to prevent the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of the Mankind ANDA Product before the expiration of the '692 patent, inclusive of any extension(s) to patent term;

(f) A permanent injunction restraining and enjoining Mankind, whether alone or in concert with a subsidiary company, from making, using, selling, offering for sale, and/or importing the Mankind ANDA Product or any pharmaceutical composition as claimed in the '692 patent in/into the United States, or practicing any processes or methods as claimed in the '692 patent, or from actively inducing to the infringement of any claim of the '692 patent, before the expiration of the '692 patent, respectively, inclusive of any extension(s) to patent term in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(g) Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, and damages under 35 U.S.C. § 271(e)(4)(C), to Plaintiffs if Mankind engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Mankind ANDA Product prior to the expiration date of the '692 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

(h) To the extent the facts show that this is an exceptional case, an award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(i) An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4);

(j) Costs and expenses in this action; and

(k) Such further and other relief as this Court may deem just and proper.

Cipla

(a) A judgment under 35 U.S.C. § 271(e)(2)(A) that Cipla has infringed one or more claims of the '692 patent by the filing of its ANDA No. 217958;

(b) A judgment that Cipla's manufacturing, using, selling, offering for sale, and/or importing the Cipla ANDA Product in/into the United States will infringe one or more claims of the '692 patent under 35 U.S.C. § 271(b);

(c) A declaration under 28 U.S.C. §§ 2201-02 that if Cipla, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of the Cipla ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(b);

(d) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 217958 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date not earlier than the latest expiration date of the '692 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(e) A judgment under 35 U.S.C. §§ 271(e)(4)(B) and 283 providing injunctive relief against Cipla, whether alone or in concert with a subsidiary company, to prevent the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United

States of the Cipla ANDA Product before the expiration of the '692 patent, inclusive of any extension(s) to patent term;

(f) A permanent injunction restraining and enjoining Cipla, whether alone or in concert with a subsidiary company, from making, using, selling, offering for sale, and/or importing the Cipla ANDA Product or any pharmaceutical composition as claimed in the '692 patent in/into the United States, or practicing any processes or methods as claimed in the '692 patent, or from actively inducing to the infringement of any claim of the '692 patent, before the expiration of the '692 patent, respectively, inclusive of any extension(s) to patent term in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(g) Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, and damages under 35 U.S.C. § 271(e)(4)(C), to Plaintiffs if Cipla engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Cipla ANDA Product prior to the expiration date of the '692 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

(h) To the extent the facts show that this is an exceptional case, an award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(i) An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4);

(j) Costs and expenses in this action; and

(k) Such further and other relief as this Court may deem just and proper.

Dated: August 19, 2024

Respectfully submitted,

/s/ *Arnold B. Calmann*

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned counsel hereby certifies that this matter in controversy is the subject of the following litigation, pending in this District: *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Ltd. et al.*, Consolidated Case No. 1:23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

Dated: August 19, 2024

Respectfully submitted,

/s/ *Arnold B. Calmann*

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LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel hereby certifies that the within Complaint seeks injunctive and other equitable relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: August 19, 2024

Respectfully submitted,

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