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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.)
C.A. No. _____

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

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 against Defendants Mankind Pharma Ltd. (“Mankind Pharma”), Lifestar Pharma LLC (“Lifestar”) (collectively, “Mankind”); Teva Pharmaceuticals, Inc. (“Teva Pharmaceuticals”), Teva Pharmaceuticals USA, Inc. (“Teva USA”), Teva Pharmaceutical Industries Ltd. (“Teva Industries”) (collectively, “Teva”); Accord Healthcare, Inc. (“Accord Inc.”), Accord Healthcare, Ltd. (“Accord Ltd.”), Intas Pharmaceuticals Ltd. (“Intas”) (collectively, “Accord”); Eugia Pharma Specialties Ltd. (“Eugia Pharma”), Eugia US LLC (“Eugia US”), Aurobindo Pharma USA, Inc. (“Aurobindo USA”), Aurobindo Pharma Limited (“Aurobindo Ltd.”) (collectively, “Eugia”); Lupin Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc. (“Lupin Pharmaceuticals”) (collectively, “Lupin”); Orbicular Pharmaceutical Technologies Private Limited (“Orbicular”); and Cipla Limited (“Cipla Ltd.”), and

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 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”) (collectively, the “Patents-in-Suit”) arising under the Patent Laws of the United States, Title 35, United States Code, Section 1 *et seq.* This action relates to Abbreviated New Drug Application (“ANDA”) No. 218089, filed by Mankind; ANDA No. 217015, filed by Teva; ANDA No. 218100, filed by Accord; ANDA No. 218128, filed by Eugia; ANDA No. 218088, filed by Lupin; ANDA No. 217868, filed by Orbicular; and ANDA No. 217958, filed by Cipla, with the United States Food and Drug Administration (“FDA”) for approval to market generic versions of YUPELRI® (revefenacin) inhalation solution, for oral inhalation, prior to the expiration of patents listed in FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “Orange Book”) for YUPELRI®.

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 Patents-in-Suit. 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 Patents-in-Suit. 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 Maitrивihar, Plot #2, Ameerpet, Hyderabad, Telangana 500038, India (“Maitrивihar” 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 “Maitrивihar” address); *Medicure International, Inc. v. Aurobindo Pharma Ltd. et al.*, No. 2:21-cv-17534, Answer (D.N.J. Feb. 16, 2022) (“Eugia Pharma Specialties Limited;” 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 “Maitrивihar” 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 Specialties Limited;” principal place of business at the “Maitrивihar” 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® (reverfenacin) inhalation solution (the “Eugia ANDA Product”), for oral inhalation, prior to the expiration of the Patents-in-Suit.

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 Patents-in-Suit.

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.

Teva

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

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

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

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

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

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

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

Accord

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

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

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

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

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

39. On information and belief, Accord Inc., Accord Ltd., and Intas acted in concert to prepare and submit ANDA No. 218100 (the “Accord ANDA”) to FDA to engage in the

commercial manufacture, use, sale or offer for sale within or importation into, the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (reverfenacin) inhalation solution (the “Accord ANDA Product”), for oral inhalation, prior to the expiration of the Patents-in-Suit.

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

Lupin

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

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

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

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

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

46. On information and belief, Lupin Inc., Lupin Ltd., and Lupin Pharmaceuticals acted in concert to prepare and submit ANDA No. 218088 (the “Lupin ANDA”) to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into, the United

States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the “Lupin ANDA Product”), for oral inhalation, prior to the expiration of the Patents-in-Suit.

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

Orbicular

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

49. On information and belief, Orbicular prepared and submitted ANDA No. 217868 (the “Orbicular ANDA”) to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the “Orbicular ANDA Product”), for oral inhalation, prior to the expiration of the ’451 patent, the ’028 patent, the ’081 patent, and the ’289 patent.

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

Cipla

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

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

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

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

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

JURISDICTION AND VENUE

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

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

58. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 28 U.S.C. §§ 2201 and 2202.

Eugia

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

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

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

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

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

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

65. This Court has personal jurisdiction over Eugia Pharma, Eugia US, Aurobindo USA, and Aurobindo Ltd. at least because, *inter alia*, on information and belief, (1) Eugia Pharma

itself, and/or in concert with Eugia US, Aurobindo Ltd. and/or Aurobindo USA, has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Eugia ANDA Product in the United States, including the State of New Jersey; and (2) Eugia Pharma itself, and/or in concert with Eugia US, Aurobindo Ltd. and/or Aurobindo USA, will market, distribute, offer for sale, and/or sell the Eugia ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 218128, and Eugia will derive substantial revenue from the use or consumption of the Eugia ANDA Product in the State of New Jersey.

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

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

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

69. 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.

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

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

72. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Eugia US at least because, on information and belief, Eugia US has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Eugia US has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the Patents-in-Suit 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.

73. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Aurobindo USA at least because, on information and belief, Aurobindo USA has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Aurobindo USA has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the Patents-in-Suit 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.

74. Venue is proper in this district for Aurobindo Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Aurobindo Ltd. is a foreign

corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

75. On information and belief, Eugia Pharma, Aurobindo USA, and Aurobindo Ltd. have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and have not contested jurisdiction and venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See, e.g., Eisai Co., Ltd. et al. v. Aurobindo Pharma Ltd. et al.*, No. 1-22-cv-03610 (D.N.J. June 8, 2022) (Aurobindo USA and Aurobindo Ltd.); *Aragon Pharms., Inc. et al. v. Eugia Pharma Specialities Ltd. et al.*, No. 2-22-cv-03186 (D.N.J. May 26, 2022) (Eugia Pharma and Aurobindo USA); *Medicure International, Inc. v. Aurobindo Pharma Ltd. et al.*, No. 2-21-cv-17534 (D.N.J. Sept. 24, 2021) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim); *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 2-21-cv-00624 (D.N.J. Jan. 12, 2021) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim); *Merck Sharp & Dohme BV et al. v. Aurobindo Pharma USA, Inc. et al.*, No. 2-20-cv-02576 (D.N.J. Mar. 10, 2020) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.); *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 2-20-cv-00315 (D.N.J. Jan. 8, 2020) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim); *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 2-19-cv-05799 (D.N.J. Feb. 14, 2019) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim); *Boehringer Ingelheim Pharms., Inc. et al. v. Aurobindo Pharma USA Inc. et al.*, No. 3-17-cv-07887 (D.N.J. Oct. 4, 2017) (Eugia Pharma and Aurobindo USA) (also filed a counterclaim); *Celgene Corp. v. Hetero Labs Ltd. et al.*, No. 2-17-cv-03387 (D.N.J. May 11, 2017) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim).

Mankind

76. 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.

77. 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.

78. 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.

79. 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.

80. 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).*

81. 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.

82. 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.

83. 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.

84. 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 Patents-in Suit 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.

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

Teva

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

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

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

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

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

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

and (2) Teva Pharmaceuticals itself, and/or in concert with Teva USA and/or Teva Industries, will market, distribute, offer for sale, and/or sell the Teva ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 217015, and Teva will derive substantial revenue from the use or consumption of the Teva ANDA Product in the State of New Jersey.

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

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

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

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

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

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

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

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

TherapeuticsMD, Inc. v. Teva Pharms. USA, Inc. et al., No. 2-20-cv-11087 (D.N.J. Aug. 21, 2020) (Teva USA); *TherapeuticsMD, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 2-20-cv-08809 (D.N.J. Jul. 13, 2020) (Teva USA) (also filed a counterclaim); *TherapeuticsMD, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 2-20-cv-03485 (D.N.J. Apr. 1, 2020) (Teva USA) (also filed a counterclaim); *Horizon Medicines LLC v. Teva Pharms. USA, Inc.*, No. 2-20-cv-08188 (D.N.J. Jul. 2, 2020) (Teva USA) (also filed a counterclaim); *Tris Pharma, Inc. v. Teva Pharms. USA, Inc.*, No. 2-20-cv-05212 (D.N.J. Apr. 28, 2020) (Teva USA) (also filed a counterclaim); *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 2-19-cv-21384 (D.N.J. Dec. 13, 2019) (Teva USA).

Accord

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

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

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

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

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

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

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

106. On information and belief, Intas, Accord Inc., and Accord Ltd. operate as a single integrated business. Accord Inc.'s website indicates that "Accord Healthcare, Inc., the US subsidiary of Intas Pharmaceuticals, is a leading generic pharmaceutical company . . . In concert with its subsidiaries, Intas markets its products in 85 countries." *See* <https://www.accordhealthcare.us/#:~:text=Accord%20Healthcare%2C%20Inc.%2C%20the,its%20products%20in%2085%20countries>. (Accessed February 15, 2023).

107. Venue is proper as to Accord Inc. pursuant to 28 U.S.C. §§ 1391 and/or 1400(b). *See Eagle Pharms., Inc. et al. v. Accord Healthcare Inc.*, No. 2:19-cv-09031, Answer, Dkt. 11 at 4 (D.N.J. Mar. 27, 2019) ("Accord [Inc.] does not contest venue in this case.").

108. Venue is proper in this district for Intas pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Intas is a foreign corporation organized and

existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

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

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

Lupin

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

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

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

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

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

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

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

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

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

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

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

122. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Lupin Pharmaceuticals at least because, on information and belief, Lupin Pharmaceuticals has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Lupin Pharmaceuticals has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the Patents-in-Suit that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Lupin ANDA

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

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

Orbicular

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

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

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

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

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

Cipla

129. 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.

130. 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.

131. 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.

132. 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.

133. 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).*

134. 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.

135. 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.

136. 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.

137. 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 Patents-in Suit 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.

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

Pharms. LLC f/k/a Cubist Pharms., Inc. v. Cipla USA, Inc. et al., No. 3-19-cv-12920 (May 24, 2019) (Cipla Inc. and Cipla Ltd.) (also filed a counterclaim).

THE PATENTS-IN-SUIT

The '451 Patent

139. The '451 patent, titled “Crystalline Freebase Forms of a Biphenyl Compound,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on September 24, 2013. A true and correct copy of the '451 patent is attached as Exhibit A.

140. Theravance Biopharma R&D IP, LLC is the assignee of the '451 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the '451 patent. Mylan Ireland Limited is the exclusive sub-licensee of the '451 patent from Theravance Biopharma Ireland Limited.

141. The '451 patent is listed in the Orange Book as covering YUPELRI®.

The '028 Patent

142. The '028 patent, titled “Crystalline Freebase Forms of a Biphenyl Compound,” was duly and legally issued by the USPTO on September 19, 2017. A true and correct copy of the '028 patent is attached as Exhibit B.

143. Theravance Biopharma R&D IP, LLC is the assignee of the '028 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the '028 patent. Mylan Ireland Limited is the exclusive sub-licensee of the '028 patent from Theravance Biopharma Ireland Limited.

144. The '028 patent is listed in the Orange Book as covering YUPELRI®.

The '081 Patent

145. The '081 patent, titled "Crystalline Freebase Forms of a Biphenyl Compound," was duly and legally issued by the USPTO on February 4, 2020. A true and correct copy of the '081 patent is attached as Exhibit C.

146. Theravance Biopharma R&D IP, LLC is the assignee of the '081 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the '081 patent. Mylan Ireland Limited is the exclusive sub-licensee of the '081 patent from Theravance Biopharma Ireland Limited.

147. The '081 patent is listed in the Orange Book as covering YUPELRI®.

The '289 Patent

148. The '289 patent, titled "Crystalline Freebase Forms of a Biphenyl Compound," was duly and legally issued by the USPTO on May 18, 2021. A true and correct copy of the '289 patent is attached as Exhibit D.

149. Theravance Biopharma R&D IP, LLC is the assignee of the '289 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the '289 patent. Mylan Ireland Limited is the exclusive sub-licensee of the '289 patent from Theravance Biopharma Ireland Limited.

150. The '289 patent is listed in the Orange Book as covering YUPELRI® and its approved uses.

The '531 Patent

151. The '531 patent titled "Methods for Treating Chronic Obstructive Pulmonary Disease," was duly and legally issued by the USPTO on November 1, 2022. A true and correct copy of the '531 patent is attached as Exhibit E.

152. Theravance Biopharma R&D IP, LLC is the assignee of the '531 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the '531 patent. Mylan Ireland Limited is the exclusive sub-licensee of the '531 patent from Theravance Biopharma Ireland Limited.

153. The '531 patent is listed in the Orange Book as covering YUPELRI® and its approved uses.

YUPELRI®

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

155. 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.

156. 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).

157. 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®.

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

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

160. 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%). (Ex. F at § 14.2).

COPD

161. 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.

162. 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 2023.

163. 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%.

164. The GOLD guidelines also call for healthcare providers to assess patients' ability to use an inhaler regularly. Inspiratory flow is recognized as an important factor in successfully using 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.

165. 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.

166. 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.

167. 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

168. 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 ANDA No. 218128 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 revfenacin inhalation solution, for oral inhalation (the “Eugia 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.

169. On information and belief, Eugia included in the Eugia ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Eugia Paragraph IV Certification”) that, in its opinion and to the best of its knowledge, the ’451 patent, the ’028 patent, the ’081 patent, the ’289 patent, and the ’531 patent are invalid, unenforceable, and/or will not be infringed by the Eugia ANDA Product.

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

171. In the Notice Letter, Eugia offered confidential access to portions of its ANDA No. 218128, on terms and conditions set forth in the Eugia Notice Letter (“the Eugia Offer”). Eugia requested that Plaintiffs accept the Eugia Offer before receiving access to the Eugia ANDA. The Eugia Offer contained restrictions that contravene 21 U.S.C. § 355(j)(5)(C)(i)(III).

172. On information and belief, the active ingredient of the Eugia ANDA Product is revfenacin, which is the same active ingredient in YUPELRI® and the same active ingredient

used in the compositions, methods of use, and processes described and claimed in one or more claims of the Patents-in-Suit.

173. 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®.

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

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

176. On information and belief, Eugia had knowledge of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent when it submitted and filed ANDA No. 218128.

177. 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 Patents-in-Suit upon receiving FDA approval of ANDA No. 218128 and prior to the expiration of the Patents-in-Suit.

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

179. 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 Patents-in-Suit, 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 Patents-in-Suit.

180. On information and belief, Eugia uses processes covered by one or more claims of the Patents-in-Suit to prepare the Eugia ANDA Product.

181. On information and belief, the Eugia ANDA Product resulting from the processes claimed in one or more Patents-in-Suit is and/or is intended to be made, used, offered for sale, and/or sold without material change to the product resulting from the processes claimed by one or more Patents-in-Suit.

182. The Eugia ANDA Product resulting from the processes claimed by one or more Patents-in-Suit is not a nonessential and/or trivial component of another product.

183. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Eugia with respect to infringement of the Patents-in-Suit.

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

Mankind

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

186. On information and belief, Mankind included in the Mankind ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Mankind Paragraph IV Certification”) that, in its opinion and to the best of its knowledge, the ’451 patent, the ’028 patent, the ’081 patent, the ’289 patent, and the ’531 patent are invalid, unenforceable, and/or will not be infringed by the Mankind ANDA Product.

187. Mankind filed the Mankind Paragraph IV Certification without adequate justification for asserting that the Patents-in-Suit are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Mankind ANDA Product.

188. The Mankind Notice Letter states that Mankind has attached a “detailed statement of the factual and legal bases for Mankind’s Paragraph IV certifications that, in its opinion, the [Patents-in-Suit] are invalid and/or not infringed by Mankind’s revefenacin inhalation solution vials (175 mcg / 3 ml).” Mankind Notice Letter at 2. Neither the Mankind Notice Letter nor its attached “detailed statement” provide any substantive invalidity allegation with respect to the ’451 patent, ’028 patent, ’081 patent, and ’289 patent.

189. In the Notice Letter, Mankind offered confidential access to portions of its ANDA No. 218089, on terms and conditions set forth in the Mankind Notice Letter (“the Mankind Offer”). Mankind requested that Plaintiffs accept the Mankind Offer before receiving access to the Mankind ANDA. The Mankind Offer contained restrictions that contravene 21 U.S.C. § 355(j)(5)(C)(i)(III).

190. 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, methods of use, and processes described and claimed in one or more claims of the Patents-in-Suit.

191. 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®.

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

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

194. On information and belief, Mankind had knowledge of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent when it submitted and filed ANDA No. 218089.

195. 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 Patents-in-Suit upon receiving FDA approval of ANDA No. 218089 and prior to the expiration of the Patents-in-Suit.

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

197. 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 Patents-in-Suit, 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 Patents-in-Suit.

198. On information and belief, Mankind uses processes covered by one or more claims of the Patents-in-Suit to prepare the Mankind ANDA Product.

199. On information and belief, the Mankind ANDA Product resulting from the processes claimed in one or more Patents-in-Suit is and/or is intended to be made, used, offered for sale, and/or sold without material change to the product resulting from the processes claimed by one or more Patents-in-Suit.

200. The Mankind ANDA Product resulting from the processes claimed by one or more Patents-in-Suit is not a nonessential and/or trivial component of another product.

201. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Mankind with respect to infringement of the Patents-in-Suit.

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

Teva

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

204. On information and belief, Teva included in the Teva ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Teva Paragraph IV Certification”) that, in its opinion and to the best of its knowledge, the ’451 patent, the ’028 patent, the ’081 patent, the ’289 patent, and the ’531 patent are invalid, unenforceable, and/or will not be infringed by the Teva ANDA Product.

205. Teva filed the Teva Paragraph IV Certification without adequate justification for asserting that the Patents-in-Suit are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Teva ANDA Product.

206. The Teva Notice Letter states that Teva has attached a “detailed statement of the legal and factual basis for the Paragraph IV certification” “that in Teva’s opinion and to the best of its knowledge, the claims of the ’451; ’028; ’081; ’289 and ’531 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Teva’s ANDA.” Teva Notice Letter at 2. Neither the Teva Notice Letter nor its attached “detailed statement” provide any substantive invalidity allegation with respect to any of the Patents-in-Suit.

207. In the Notice Letter, Teva offered confidential access to portions of its ANDA No. 217015, on terms and conditions set forth in the Teva Notice Letter (“the Teva Offer”). Teva requested that Plaintiffs accept the Teva Offer before receiving access to the Teva ANDA. The Teva Offer contained restrictions that contravene 21 U.S.C. § 355(j)(5)(C)(i)(III).

208. On information and belief, the active ingredient of the Teva ANDA Product is revfenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions, methods of use, and processes described and claimed in one or more claims of the Patents-in-Suit.

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

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

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

212. On information and belief, Teva had knowledge of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent when it submitted and filed ANDA No. 217015.

213. On information and belief, Teva intends to and will infringe, actively induce infringement, and/or contribute to infringement of one or more claims of the Patents-in-Suit upon receiving FDA approval of ANDA No. 217015 and prior to the expiration of the Patents-in-Suit.

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

215. On information and belief, Teva knows that the Teva ANDA Product is especially made or adapted for use in a way that would infringe the Patents-in-Suit, and is not suitable for substantial non-infringing use. On information and belief, Teva 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 Patents-in-Suit.

216. On information and belief, Teva uses processes covered by one or more claims of the Patents-in-Suit to prepare the Teva ANDA Product.

217. On information and belief, the Teva ANDA Product resulting from the processes claimed in one or more Patents-in-Suit is and/or is intended to be made, used, offered for sale, and/or sold without material change to the product resulting from the processes claimed by one or more Patents-in-Suit.

218. The Teva ANDA Product resulting from the processes claimed by one or more Patents-in-Suit is not a nonessential and/or trivial component of another product.

219. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Teva with respect to infringement of the Patents-in-Suit.

220. This action is being commenced within 45 days of receipt of the Teva Notice Letter.

Accord

221. In a letter dated January 6, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the “Accord Notice Letter”), Accord notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had submitted ANDA No. 218100 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 refefenacin inhalation solution, for oral inhalation (the “Accord ANDA Product”), as a generic version of YUPELRI® in/into the United States, prior to the expiration of the ’451 patent, the ’028 patent, the ’081 patent, the ’289 patent, and the ’531 patent.

222. On information and belief, Accord included in the Accord ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Accord Paragraph IV Certification”) that, in its opinion and to the best of its knowledge, the ’451 patent, the ’028 patent, the ’081 patent, the ’289 patent,

and the '531 patent are invalid, unenforceable, and/or will not be infringed by the Accord ANDA Product.

223. Accord filed the Accord Paragraph IV Certification without adequate justification for asserting that the Patents-in-Suit are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Accord ANDA Product.

224. The Accord Notice Letter states that Accord has attached a “detailed statement of the factual and legal basis of Accord’s opinion that U.S. Patent Nos. 8541451, 976028, 10550081, 11008289, and 11484531 are invalid, unenforceable, and/or will not be infringed.” Accord Notice Letter at 2. Neither the Accord Notice Letter nor its attached “detailed statement” provide any substantive invalidity allegation with respect to the ‘451 patent, ‘028 patent, ‘081 patent, and ‘289 patent.

225. In the Notice Letter, Accord offered confidential access to portions of its ANDA No. 218100, on terms and conditions set forth in the Accord Notice Letter (“the Accord Offer”). Accord requested that Plaintiffs accept the Accord Offer before receiving access to the Accord ANDA. The Accord Offer contained restrictions that contravene 21 U.S.C. § 355(j)(5)(C)(i)(III).

226. On information and belief, the active ingredient of the Accord ANDA Product is revfenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions, methods of use, and processes described and claimed in one or more claims of the Patents-in-Suit.

227. On information and belief, Accord asserts in ANDA No. 218100 that the Accord ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA,

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

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

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

230. On information and belief, Accord had knowledge of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent when it submitted and filed ANDA No. 218100.

231. On information and belief, Accord intends to and will infringe, actively induce infringement, and/or contribute to infringement of one or more claims of the Patents-in-Suit upon receiving FDA approval of ANDA No. 218100 and prior to the expiration of the Patents-in-Suit.

232. On information and belief, Accord will commercially manufacture, use, offer for sale, and/or sell the Accord ANDA Product throughout the United States, import the Accord 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 Patents-in-Suit.

233. On information and belief, Accord knows that the Accord ANDA Product is especially made or adapted for use in a way that would infringe the Patents-in-Suit, and is not suitable for substantial non-infringing use. On information and belief, Accord 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 Patents-in-Suit.

234. On information and belief, Accord uses processes covered by one or more claims of the Patents-in-Suit to prepare the Accord ANDA Product.

235. On information and belief, the Accord ANDA Product resulting from the processes claimed in one or more Patents-in-Suit is and/or is intended to be made, used, offered for sale, and/or sold without material change to the product resulting from the processes claimed by one or more Patents-in-Suit.

236. The Accord ANDA Product resulting from the processes claimed by one or more Patents-in-Suit is not a nonessential and/or trivial component of another product.

237. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Accord with respect to infringement of the Patents-in-Suit.

238. This action is being commenced within 45 days of receipt of the Accord Notice Letter.

Lupin

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

240. On information and belief, Lupin included in the Lupin ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Lupin Paragraph IV Certification”) that, in its opinion and to the best of its knowledge, the ’451 patent, the ’028 patent, the ’081 patent, the ’289 patent, and the ’531 patent are invalid, unenforceable, and/or will not be infringed by the Lupin ANDA Product.

241. Lupin filed the Lupin Paragraph IV Certification without adequate justification for asserting that the Patents-in-Suit are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Lupin ANDA Product.

242. In the Notice Letter, Lupin offered confidential access to portions of its ANDA No. 218088, on terms and conditions set forth in the Lupin Notice Letter (“the Lupin Offer”). Lupin requested that Plaintiffs accept the Lupin Offer before receiving access to the Lupin ANDA. The Lupin Offer contained restrictions that contravene 21 U.S.C. § 355(j)(5)(C)(i)(III).

243. On information and belief, the active ingredient of the Lupin ANDA Product is revfenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions, methods of use, and processes described and claimed in one or more claims of the Patents-in-Suit.

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

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

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

247. On information and belief, Lupin had knowledge of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent when it submitted and filed ANDA No. 218088.

248. On information and belief, Lupin intends to and will infringe, actively induce infringement, and/or contribute to infringement of one or more claims of the Patents-in-Suit upon receiving FDA approval of ANDA No. 218088 and prior to the expiration of the Patents-in-Suit.

249. On information and belief, Lupin will commercially manufacture, use, offer for sale, and/or sell the Lupin ANDA Product throughout the United States, import the Lupin 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 Patents-in-Suit.

250. On information and belief, Lupin knows that the Lupin ANDA Product is especially made or adapted for use in a way that would infringe the Patents-in-Suit, and is not suitable for substantial non-infringing use. On information and belief, Lupin 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 Patents-in-Suit.

251. On information and belief, Lupin uses processes covered by one or more claims of the Patents-in-Suit to prepare the Lupin ANDA Product.

252. On information and belief, the Lupin ANDA Product resulting from the processes claimed in one or more Patents-in-Suit is and/or is intended to be made, used, offered for sale, and/or sold without material change to the product resulting from the processes claimed by one or more Patents-in-Suit.

253. The Lupin ANDA Product resulting from the processes claimed by one or more Patents-in-Suit is not a nonessential and/or trivial component of another product.

254. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Lupin with respect to infringement of the Patents-in-Suit.

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

Orbicular

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

257. On information and belief, Orbicular included in the Orbicular ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Orbicular Paragraph IV Certification”) that, in its opinion and to the best of its knowledge, the ’451 patent, the ’028 patent, the ’081 patent, and the ’289 patent are invalid, unenforceable, and/or will not be infringed by the Orbicular ANDA Product.

258. Orbicular filed the Orbicular Paragraph IV Certification without adequate justification for asserting that the Patents-in-Suit are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Orbicular ANDA Product.

259. The Orbicular Notice Letter states that Orbicular “has certified to the FDA . . . that [the Patents-in-Suit] are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the drug products described in Orbicular’s ANDA.” Orbicular Notice

Letter at 2. Orbicular also attached a “detailed statement of the factual and legal bases for Orbicular’s assertion of invalidity, unenforceability, and/or noninfringement of [the ’451, ’028, ’081, and ’289 patents] regarding revefenacin inhalation solution, 175 mcg/3 mL.” Neither the Orbicular Notice Letter nor its attached “detailed statement” provide any substantive invalidity allegation with respect to any of the Patents-in-Suit.

260. In the Notice Letter, Orbicular offered confidential access to portions of its ANDA No. 217868, on terms and conditions set forth in the Orbicular Notice Letter (“the Orbicular Offer”). Orbicular requested that Plaintiffs accept the Orbicular Offer before receiving access to the Orbicular ANDA. The Orbicular Offer contained restrictions that contravene 21 U.S.C. § 355(j)(5)(C)(i)(III).

261. On information and belief, the active ingredient of the Orbicular ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions, methods of use, and processes described and claimed in one or more claims of one or more of the Patents-in-Suit.

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

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

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

265. On information and belief, Orbicular had knowledge of one or more of the '451, '028, '081, and '289 patents when it submitted and filed ANDA No. 217868.

266. On information and belief, Orbicular intends to and will infringe, actively induce infringement, and/or contribute to infringement of one or more claims of one or more of the '451, '028, '081, and '289 patents upon receiving FDA approval of ANDA No. 217868 and prior to the expiration of one or more of the '451, '028, '081, and '289 patents.

267. On information and belief, Orbicular will commercially manufacture, use, offer for sale, and/or sell the Orbicular ANDA Product throughout the United States, import the Orbicular 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 one or more of the Patents-in-Suit.

268. On information and belief, Orbicular knows that the Orbicular ANDA Product is especially made or adapted for use in a way that would infringe one or more of the '451, '028, '081, and '289 patents, and is not suitable for substantial non-infringing use. On information and belief, Orbicular knowingly has taken and intends to take active steps to, and will, induce and/or contribute to infringement of one or more claims of one or more of the '451, '028, '081, and '289 patents.

269. On information and belief, Orbicular uses processes covered by one or more claims of one or more of the '451, '028, '081, and '289 patents to prepare the Orbicular ANDA Product.

270. On information and belief, the Orbicular ANDA Product resulting from the processes claimed in one or more of the '451, '028, '081, and '289 patents is and/or is intended to be made, used, offered for sale, and/or sold without material change to the product resulting from the processes claimed by one or more of the '451, '028, '081, and '289 patents.

271. The Orbicular ANDA Product resulting from the processes claimed by one or more of the '451, '028, '081, and '289 patents is not a nonessential and/or trivial component of another product.

272. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Orbicular with respect to infringement of one or more of the '451, '028, '081, and '289 patents.

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

Cipla

274. 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 refefenacin 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.

275. On information and belief, Cipla included in the Cipla ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Cipla Paragraph IV Certification”) that, in its opinion and to the best of its knowledge, the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent are invalid, unenforceable, and/or will not be infringed by the Cipla ANDA Product.

276. Cipla filed the Cipla Paragraph IV Certification without adequate justification for asserting that the Patents-in-Suit are invalid, unenforceable, and/or not infringed by the

commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Cipla ANDA Product.

277. In the Cipla Notice Letter, Cipla offered confidential access to portions of its ANDA No. 217958, on terms and conditions set forth in the Cipla Notice Letter (“the Cipla Offer”). Cipla requested that Plaintiffs accept the Cipla Offer before receiving access to the Cipla ANDA. The Cipla Offer contained restrictions that contravene 21 U.S.C. § 355(j)(5)(C)(i)(III).

278. 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, methods of use, and processes described and claimed in one or more claims of the Patents-in-Suit.

279. 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®.

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

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

282. On information and belief, Cipla had knowledge of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent when it submitted and filed ANDA No. 217958.

283. 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 Patents-in-Suit upon receiving FDA approval of ANDA No. 217958 and prior to the expiration of the Patents-in-Suit.

284. On information and belief, Cipla will commercially manufacture, use, offer for sale, and/or sell the Cipla ANDA Product throughout the United States, 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 Patents-in-Suit.

285. 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 Patents-in-Suit, 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 Patents-in-Suit.

286. On information and belief, Cipla uses processes covered by one or more claims of the Patents-in-Suit to prepare the Cipla ANDA Product.

287. On information and belief, the Cipla ANDA Product resulting from the processes claimed in one or more Patents-in-Suit is and/or is intended to be made, used, offered for sale, and/or sold without material change to the product resulting from the processes claimed by one or more Patents-in-Suit.

288. The Cipla ANDA product resulting from the processes claimed by one or more Patents-in-Suit is not a nonessential and/or trivial component of another product.

289. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Cipla with respect to infringement of the Patents-in-Suit.

290. This action is being commenced within 45 days of receipt of the Cipla Notice Letter.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 8,541,451 BY EUGIA

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

292. 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 '451 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '451 patent under 35 U.S.C. § 271(e)(2)(A).

293. Eugia's commercial manufacture, sale, offer for sale, or use of the Eugia ANDA Product within the United States, or importation of the Eugia ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

294. Eugia's commercial manufacture, sale, offer for sale, or use of the Eugia ANDA Product within the United States, or importation of the Eugia ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(g).

295. On information and belief, Eugia intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Eugia ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218128 and any amendments thereto, *i.e.*, prior to the expiration of the '451 patent.

296. On information and belief, Eugia had knowledge of the '451 patent when it submitted ANDA No. 218128. Eugia's infringement has been, and continues to be, deliberate.

297. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '451 patent is not enjoined.

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

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 9,765,028 BY EUGIA

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

300. 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 '028 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '028 patent under 35 U.S.C. § 271(e)(2)(A).

301. Eugia's commercial manufacture, sale, offer for sale, or use of the Eugia ANDA Product within the United States, or importation of the Eugia ANDA Product into the United States, during the term of the '028 patent would infringe one or more claims of the '028 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

302. On information and belief, Eugia intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Eugia ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218128 and any amendments thereto, *i.e.*, prior to the expiration of the '028 patent.

303. On information and belief, Eugia had knowledge of the '028 patent when it submitted ANDA No. 218128. Eugia's infringement has been, and continues to be, deliberate.

304. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '028 patent is not enjoined.

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

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 10,550,081 BY EUGIA

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

307. 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 '081 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '081 patent under 35 U.S.C. § 271(e)(2)(A).

308. Eugia's commercial manufacture, sale, offer for sale, or use of the Eugia ANDA Product within the United States, or importation of the Eugia ANDA Product into the United States, during the term of the '081 patent would infringe one or more claims of the '081 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

309. On information and belief, Eugia intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Eugia ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218128 and any amendments thereto, *i.e.*, prior to the expiration of the '081 patent.

310. On information and belief, Eugia had knowledge of the '081 patent when it submitted ANDA No. 218128. Eugia's infringement has been, and continues to be, deliberate.

311. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '081 patent is not enjoined.

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

COUNT IV
INFRINGEMENT OF U.S. PATENT NO. 11,008,289 BY EUGIA

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

314. 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 '289 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

315. Eugia's commercial manufacture, sale, offer for sale, or use of the Eugia ANDA Product within the United States, or importation of the Eugia ANDA Product into the United States, during the term of the '289 patent would induce infringement and/or infringe one or more claims of the '289 patent under 35 U.S.C. §§ 271(b) and/or (g).

316. On information and belief, Eugia intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Eugia ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218128 and any amendments thereto, *i.e.*, prior to the expiration of the '289 patent.

317. On information and belief, Eugia had knowledge of the '289 patent when it submitted ANDA No. 218128. Eugia's infringement has been, and continues to be, deliberate.

318. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '289 patent is not enjoined.

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

COUNT V
INFRINGEMENT OF U.S. PATENT NO. 11,484,531 BY EUGIA

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

321. 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 '531 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '531 patent under 35 U.S.C. § 271(e)(2)(A).

322. Unless enjoined, upon FDA approval of Eugia's ANDA No. 218128, Eugia will infringe one or more claims of the '531 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

323. 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.

324. 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 '531 patent by marketing Eugia's ANDA Product with the FDA-approved package insert.

325. The '531 patent has one independent claim, claim 1, which states:

1. A method for treating chronic obstructive pulmonary disease in a patient, the method comprising:

(a) selecting a patient having chronic obstructive pulmonary disease for treatment based on the patient having a peak inspiratory flow

rate less than about 60 L/min and a percent predicted forced expiratory volume in one second less than about 50 percent; and

(b) administering a pharmaceutical composition comprising about 175 µg of refefenacin, or a pharmaceutically acceptable salt thereof, in 3 mL of an aqueous solution to the selected patient once daily using a nebulizer.

326. A healthcare provider will directly infringe one of more of the claims of the '531 patent. Specifically, a healthcare provider administering Eugia's ANDA Product in accordance with Eugia's package insert will perform all of the steps of one or more claims of the '531 patent.

327. 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).

328. 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®.

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

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

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

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

333. 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.” (Ex. F at § 2).

334. The “Dosage Form 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.” (Ex. F at § 3).

335. A healthcare provider will select a patient having COPD for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50%.

336. The YUPELRI® package insert describes the treatment of moderate to very severe patients in Clinical Studies. (Ex. F at § 14.2).

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

338. The GOLD guidelines, Table 2.6, categorize severe COPD based on FEV₁ of equal to or greater than 30% and less than 50%.

339. 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.

340. The YUPELRI® package insert, in Section 2, Dosing and Administration, instructs treating patients by administering YUPELRI® by nebulizer.

341. The GOLD guidelines, such as at pages 69-70, advise healthcare providers to check the patient’s ability to use an inhaler.

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

343. A healthcare provider will select a nebulizer for patients with a PIFR of less than about 60 L/min. *See, e.g.*, Mahler 2017; Mahler 2014.

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

345. On information and belief, Eugia knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and FEV₁ of less than 50%.

346. 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 PIFR of less than about 60 L/min and FEV₁ of less than 50%.

347. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '531 patent is not enjoined.

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

COUNT VI
INFRINGEMENT OF U.S. PATENT NO. 8,541,451 BY MANKIND

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

350. 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 '451 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '451 patent under 35 U.S.C. § 271(e)(2)(A).

351. Mankind's commercial manufacture, sale, offer for sale, or use of the Mankind ANDA Product within the United States, or importation of the Mankind ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

352. Mankind's commercial manufacture, sale, offer for sale, or use of the Mankind ANDA Product within the United States, or importation of the Mankind ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(g).

353. On information and belief, Mankind intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mankind ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218089 and any amendments thereto, *i.e.*, prior to the expiration of the '451 patent.

354. On information and belief, Mankind had knowledge of the '451 patent when it submitted ANDA No. 218089. Mankind's infringement has been, and continues to be, deliberate.

355. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '451 patent is not enjoined.

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

COUNT VII
INFRINGEMENT OF U.S. PATENT NO. 9,765,028 BY MANKIND

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

358. 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 '028 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '028 patent under 35 U.S.C. § 271(e)(2)(A).

359. Mankind's commercial manufacture, sale, offer for sale, or use of the Mankind ANDA Product within the United States, or importation of the Mankind ANDA Product into the United States, during the term of the '028 patent would infringe one or more claims of the '028 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

360. On information and belief, Mankind intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mankind ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218089 and any amendments thereto, *i.e.*, prior to the expiration of the '028 patent.

361. On information and belief, Mankind had knowledge of the '028 patent when it submitted ANDA No. 218089. Mankind's infringement has been, and continues to be, deliberate.

362. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '028 patent is not enjoined.

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

COUNT VIII
INFRINGEMENT OF U.S. PATENT NO. 10,550,081 BY MANKIND

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

365. 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 '081 patent constitutes infringement, either literally or under

the doctrine of equivalents, of one or more claims of the '081 patent under 35 U.S.C. § 271(e)(2)(A).

366. Mankind's commercial manufacture, sale, offer for sale, or use of the Mankind ANDA Product within the United States, or importation of the Mankind ANDA Product into the United States, during the term of the '081 patent would infringe one or more claims of the '081 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

367. On information and belief, Mankind intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mankind ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218089 and any amendments thereto, *i.e.*, prior to the expiration of the '081 patent.

368. On information and belief, Mankind had knowledge of the '081 patent when it submitted ANDA No. 218089. Mankind's infringement has been, and continues to be, deliberate.

369. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '081 patent is not enjoined.

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

COUNT IX
INFRINGEMENT OF U.S. PATENT NO. 11,008,289 BY MANKIND

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

372. 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 '289 patent constitutes infringement, either literally or under

the doctrine of equivalents, of one or more claims of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

373. Mankind's commercial manufacture, sale, offer for sale, or use of the Mankind ANDA Product within the United States, or importation of the Mankind ANDA Product into the United States, during the term of the '289 patent would induce infringement and/or infringe one or more claims of the '289 patent under 35 U.S.C. §§ 271(b) and/or (g).

374. On information and belief, Mankind intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mankind ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218089 and any amendments thereto, *i.e.*, prior to the expiration of the '289 patent.

375. On information and belief, Mankind had knowledge of the '289 patent when it submitted ANDA No. 218089. Mankind's infringement has been, and continues to be, deliberate.

376. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '289 patent is not enjoined.

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

COUNT X
INFRINGEMENT OF U.S. PATENT NO. 11,484,531 BY MANKIND

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

379. 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 '531 patent constitutes infringement, either literally or under

the doctrine of equivalents, of one or more claims of the '531 patent under 35 U.S.C. § 271(e)(2)(A).

380. Unless enjoined, upon FDA approval of Mankind's ANDA No. 218089, Mankind will infringe one or more claims of the '531 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

381. 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.

382. 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 '531 patent by marketing Mankind's ANDA Product with the FDA-approved package insert.

383. The '531 patent has one independent claim, claim 1, which states:

1. A method for treating chronic obstructive pulmonary disease in a patient, the method comprising:

(a) selecting a patient having chronic obstructive pulmonary disease for treatment based on the patient having a peak inspiratory flow rate less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50 percent; and

(b) administering a pharmaceutical composition comprising about 175 µg of refefenacin, or a pharmaceutically acceptable salt thereof, in 3 mL of an aqueous solution to the selected patient once daily using a nebulizer.

384. A healthcare provider will directly infringe one of more of the claims of the '531 patent. Specifically, a healthcare provider administering Mankind's ANDA Product in accordance

with Mankind's package insert will perform all of the steps of one or more claims of the '531 patent.

385. 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).

386. 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®.

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

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

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

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

391. The "Dosage and Administration" section of the YUPELRI® package insert 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." (Ex. F at § 2).

392. The “Dosage Form and Strengths” section of the YUPELRI® package insert states that YUPELRI® is an “Inhalation solution: 175 mcg of refefenacin in 3 mL of sterile, clear, colorless, aqueous solution in unit dose vials.” (Ex. F at § 3).

393. A healthcare provider will select a patient having COPD for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50%.

394. The YUPELRI® package insert describes the treatment of moderate to very severe patients in Clinical Studies. (Ex. F at § 14.2).

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

396. The GOLD guidelines, Table 2.6, categorize severe COPD based on FEV₁ of equal to or greater than 30% and less than 50%.

397. 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.

398. The YUPELRI® package insert, in Section 2, Dosing and Administration, instructs treating patients by administering YUPELRI® by nebulizer.

399. The GOLD guidelines, such as at pages 69-70, advise healthcare providers to check the patient’s ability to use an inhaler.

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

401. A healthcare provider will select a nebulizer for patients with a PIFR of less than about 60 L/min. *See, e.g.,* Mahler 2017; Mahler 2014.

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

403. On information and belief, Mankind knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and FEV₁ of less than 50%.

404. 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 PIFR of less than about 60 L/min and FEV₁ of less than 50%.

405. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '531 patent is not enjoined.

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

COUNT XI
INFRINGEMENT OF U.S. PATENT NO. 8,541,451 BY TEVA

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

408. Teva's submission of ANDA No. 217015 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 Teva ANDA Product in/into the United States prior to the expiration of the '451 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '451 patent under 35 U.S.C. § 271(e)(2)(A).

409. Teva's commercial manufacture, sale, offer for sale, or use of the Teva ANDA Product within the United States, or importation of the Teva ANDA Product into the United States,

during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

410. Teva's commercial manufacture, sale, offer for sale, or use of the Teva ANDA Product within the United States, or importation of the Teva ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(g).

411. On information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Teva ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217015 and any amendments thereto, *i.e.*, prior to the expiration of the '451 patent.

412. On information and belief, Teva had knowledge of the '451 patent when it submitted ANDA No. 217015. Teva's infringement has been, and continues to be, deliberate.

413. Plaintiffs will be substantially and irreparably harmed if Teva's infringement of the '451 patent is not enjoined.

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

COUNT XII
INFRINGEMENT OF U.S. PATENT NO. 9,765,028 BY TEVA

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

416. Teva's submission of ANDA No. 217015 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 Teva ANDA Product in/into the United States prior to the expiration of the '028 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '028 patent under 35 U.S.C. § 271(e)(2)(A).

417. Teva's commercial manufacture, sale, offer for sale, or use of the Teva ANDA Product within the United States, or importation of the Teva ANDA Product into the United States, during the term of the '028 patent would infringe one or more claims of the '028 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

418. On information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Teva ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217015 and any amendments thereto, *i.e.*, prior to the expiration of the '028 patent.

419. On information and belief, Teva had knowledge of the '028 patent when it submitted ANDA No. 217015. Teva's infringement has been, and continues to be, deliberate.

420. Plaintiffs will be substantially and irreparably harmed if Teva's infringement of the '028 patent is not enjoined.

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

COUNT XIII
INFRINGEMENT OF U.S. PATENT NO. 10,550,081 BY TEVA

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

423. Teva's submission of ANDA No. 217015 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 Teva ANDA Product in/into the United States prior to the expiration of the '081 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '081 patent under 35 U.S.C. § 271(e)(2)(A).

424. Teva's commercial manufacture, sale, offer for sale, or use of the Teva ANDA Product within the United States, or importation of the Teva ANDA Product into the United

States, during the term of the '081 patent would infringe one or more claims of the '081 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

425. On information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Teva ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217015 and any amendments thereto, *i.e.*, prior to the expiration of the '081 patent.

426. On information and belief, Teva had knowledge of the '081 patent when it submitted ANDA No. 217015. Teva's infringement has been, and continues to be, deliberate.

427. Plaintiffs will be substantially and irreparably harmed if Teva's infringement of the '081 patent is not enjoined.

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

COUNT XIV
INFRINGEMENT OF U.S. PATENT NO. 11,008,289 BY TEVA

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

430. Teva's submission of ANDA No. 217015 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 Teva ANDA Product in/into the United States prior to the expiration of the '289 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

431. Teva's commercial manufacture, sale, offer for sale, or use of the Teva ANDA Product within the United States, or importation of the Teva ANDA Product into the United States, during the term of the '289 patent would induce infringement and/or infringe one or more claims of the '289 patent under 35 U.S.C. §§ 271(b) and/or (g).

432. On information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Teva ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217015 and any amendments thereto, *i.e.*, prior to the expiration of the '289 patent.

433. On information and belief, Teva had knowledge of the '289 patent when it submitted ANDA No. 217015. Teva's infringement has been, and continues to be, deliberate.

434. Plaintiffs will be substantially and irreparably harmed if Teva's infringement of the '289 patent is not enjoined.

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

COUNT XV
INFRINGEMENT OF U.S. PATENT NO. 11,484,531 BY TEVA

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

437. Teva's submission of ANDA No. 217015 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 Teva ANDA Product in/into the United States prior to the expiration of the '531 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '531 patent under 35 U.S.C. § 271(e)(2)(A).

438. Unless enjoined, upon FDA approval of Teva's ANDA No. 217015, Teva will infringe one or more claims of the '531 patent by actively inducing infringement by others under 35 U.S.C. § 271(b)

439. On information and belief, upon FDA approval of Teva's ANDA No. 217015, Teva intends to manufacture, market, sell, and offer to sell Teva's ANDA Product with an FDA-

approved package insert that will direct healthcare providers and patients in the use of Teva's ANDA Product.

440. On information and belief, Teva will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Teva knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '531 patent by marketing Teva's ANDA Product with the FDA-approved package insert.

441. The '531 patent has one independent claim, claim 1, which states:

1. A method for treating chronic obstructive pulmonary disease in a patient, the method comprising:

(a) selecting a patient having chronic obstructive pulmonary disease for treatment based on the patient having a peak inspiratory flow rate less than about 60 L/min and a percent predicted forced expiratory volume in one second less than about 50 percent; and

(b) administering a pharmaceutical composition comprising about 175 µg of rевеfенасin, or a pharmaceutically acceptable salt thereof, in 3 mL of an aqueous solution to the selected patient once daily using a nebulizer.

442. A healthcare provider will directly infringe one or more of the claims of the '531 patent. Specifically, a healthcare provider administering Teva's ANDA Product in accordance with Teva's package insert will perform all of the steps of one or more claims of the '531 patent.

443. 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).

444. 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®.

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

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

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

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

449. 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." (Ex. F at § 2).

450. The "Dosage Form 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." (Ex. F at § 3).

451. A healthcare provider will select a patient having COPD for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50%.

452. The YUPELRI® package insert describes the treatment of moderate to very severe patients in Clinical Studies. (Ex. F at § 14.2).

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

454. The GOLD guidelines, Table 2.6, categorize severe COPD based on FEV₁ of equal to or greater than 30% and less than 50%.

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

456. The YUPELRI® package insert, in Section 2, Dosing and Administration, instructs treating patients by administering YUPELRI® by nebulizer.

457. The GOLD guidelines, such as at pages 69-70, advise healthcare providers to check the patient's ability to use an inhaler.

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

459. A healthcare provider will select a nebulizer for patients with a PIFR of less than about 60 L/min. *See, e.g., Mahler 2017; Mahler 2014.*

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

461. On information and belief, Teva knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and FEV₁ of less than 50%.

462. On information and belief, Teva 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 PIFR of less than about 60 L/min and FEV₁ of less than 50%.

463. Plaintiffs will be substantially and irreparably harmed if Teva's infringement of the '531 patent is not enjoined.

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

COUNT XVI
INFRINGEMENT OF U.S. PATENT NO. 8,541,451 BY ACCORD

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

466. Accord's submission of ANDA No. 218100 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 Accord ANDA Product in/into the United States prior to the expiration of the '451 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '451 patent under 35 U.S.C. § 271(e)(2)(A).

467. Accord's commercial manufacture, sale, offer for sale, or use of the Accord ANDA Product within the United States, or importation of the Accord ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

468. Accord's commercial manufacture, sale, offer for sale, or use of the Accord ANDA Product within the United States, or importation of the Accord ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(g).

469. On information and belief, Accord intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218100 and any amendments thereto, *i.e.*, prior to the expiration of the '451 patent.

470. On information and belief, Accord had knowledge of the '451 patent when it submitted ANDA No. 218100. Accord's infringement has been, and continues to be, deliberate.

471. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '451 patent is not enjoined.

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

COUNT XVII
INFRINGEMENT OF U.S. PATENT NO. 9,765,028 BY ACCORD

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

474. Accord's submission of ANDA No. 218100 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 Accord ANDA Product in/into the United States prior to the expiration of the '028 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '028 patent under 35 U.S.C. § 271(e)(2)(A).

475. Accord's commercial manufacture, sale, offer for sale, or use of the Accord ANDA Product within the United States, or importation of the Accord ANDA Product into the United States, during the term of the '028 patent would infringe one or more claims of the '028 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

476. On information and belief, Accord intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218100 and any amendments thereto, *i.e.*, prior to the expiration of the '028 patent.

477. On information and belief, Accord had knowledge of the '028 patent when it submitted ANDA No. 218100. Accord's infringement has been, and continues to be, deliberate.

478. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '028 patent is not enjoined.

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

COUNT XVIII
INFRINGEMENT OF U.S. PATENT NO. 10,550,081 BY ACCORD

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

481. Accord's submission of ANDA No. 218100 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 Accord ANDA Product in/into the United States prior to the expiration of the '081 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '081 patent under 35 U.S.C. § 271(e)(2)(A).

482. Accord's commercial manufacture, sale, offer for sale, or use of the Accord ANDA Product within the United States, or importation of the Accord ANDA Product into the United States, during the term of the '081 patent would infringe one or more claims of the '081 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

483. On information and belief, Accord intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218100 and any amendments thereto, *i.e.*, prior to the expiration of the '081 patent.

484. On information and belief, Accord had knowledge of the '081 patent when it submitted ANDA No. 218100. Accord's infringement has been, and continues to be, deliberate.

485. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '081 patent is not enjoined.

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

COUNT XIX
INFRINGEMENT OF U.S. PATENT NO. 11,008,289 BY ACCORD

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

488. Accord's submission of ANDA No. 218100 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 Accord ANDA Product in/into the United States prior to the expiration of the '289 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

489. Accord's commercial manufacture, sale, offer for sale, or use of the Accord ANDA Product within the United States, or importation of the Accord ANDA Product into the United States, during the term of the '289 patent would induce infringement and/or infringe one or more claims of the '289 patent under 35 U.S.C. §§ 271(b) and/or (g).

490. On information and belief, Accord intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218100 and any amendments thereto, *i.e.*, prior to the expiration of the '289 patent.

491. On information and belief, Accord had knowledge of the '289 patent when it submitted ANDA No. 218100. Accord's infringement has been, and continues to be, deliberate.

492. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '289 patent is not enjoined.

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

COUNT XX
INFRINGEMENT OF U.S. PATENT NO. 11,484,531 BY ACCORD

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

495. Accord's submission of ANDA No. 218100 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 Accord ANDA Product in/into the United States prior to the expiration of the '531 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '531 patent under 35 U.S.C. § 271(e)(2)(A).

496. Unless enjoined, upon FDA approval of Accord's ANDA No. 218100, Accord will infringe one or more claims of the '531 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

497. On information and belief, upon FDA approval of Accord's ANDA No. 218100, Accord intends to manufacture, market, sell, and offer to sell Accord's ANDA Product with an FDA-approved package insert that will direct healthcare providers and patients in the use of Accord's ANDA Product.

498. On information and belief, Accord will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Accord knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '531 patent by marketing Accord's ANDA Product with the FDA-approved package insert.

499. The '531 patent has one independent claim, claim 1, which states:

1. A method for treating chronic obstructive pulmonary disease in a patient, the method comprising:

(a) selecting a patient having chronic obstructive pulmonary disease for treatment based on the patient having a peak inspiratory flow rate

less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50 percent; and

(b) administering a pharmaceutical composition comprising about 175 µg of refefenacin, or a pharmaceutically acceptable salt thereof, in 3 mL of an aqueous solution to the selected patient once daily using a nebulizer.

500. A healthcare provider will directly infringe one of more of the claims of the '531 patent. Specifically, a healthcare provider administering Accord's ANDA Product in accordance with Accord's package insert will perform all of the steps of one or more claims of the '531 patent.

501. 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).

502. 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®.

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

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

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

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

507. 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.” (Ex. F at § 2).

508. The “Dosage Form 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.” (Ex. F at § 3).

509. A healthcare provider will select a patient having COPD for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50%.

510. The YUPELRI® package insert describes the treatment of moderate to very severe patients in Clinical Studies. (Ex. F at § 14.2).

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

512. The GOLD guidelines, Table 2.6, categorize severe COPD based on FEV₁ of equal to or greater than 30% and less than 50%.

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

514. The YUPELRI® package insert, in Section 2, Dosing and Administration, instructs treating patients by administering YUPELRI® by nebulizer.

515. The GOLD guidelines, such as at pages 69-70, advise healthcare providers to check the patient’s ability to use an inhaler.

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

517. A healthcare provider will select a nebulizer for patients with a PIFR of less than about 60 L/min. *See, e.g.*, Mahler 2017; Mahler 2014.

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

519. On information and belief, Accord knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and FEV₁ of less than 50%.

520. On information and belief, Accord 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 PIFR of less than about 60 L/min and FEV₁ of less than 50%.

521. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '531 patent is not enjoined.

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

COUNT XXI
INFRINGEMENT OF U.S. PATENT NO. 8,541,451 BY LUPIN

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

524. Lupin's submission of ANDA No. 218088 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 Lupin ANDA Product in/into the United States prior to the expiration of the '451 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '451 patent under 35 U.S.C. § 271(e)(2)(A).

525. Lupin's commercial manufacture, sale, offer for sale, or use of the Lupin ANDA Product within the United States, or importation of the Lupin ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

526. Lupin's commercial manufacture, sale, offer for sale, or use of the Lupin ANDA Product within the United States, or importation of the Lupin ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(g).

527. On information and belief, Lupin intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218088 and any amendments thereto, *i.e.*, prior to the expiration of the '451 patent.

528. On information and belief, Lupin had knowledge of the '451 patent when it submitted ANDA No. 218088. Lupin's infringement has been, and continues to be, deliberate.

529. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '451 patent is not enjoined.

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

COUNT XXII
INFRINGEMENT OF U.S. PATENT NO. 9,765,028 BY LUPIN

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

532. Lupin's submission of ANDA No. 218088 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 Lupin ANDA Product in/into the United States prior to the

expiration of the '028 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '028 patent under 35 U.S.C. § 271(e)(2)(A).

533. Lupin's commercial manufacture, sale, offer for sale, or use of the Lupin ANDA Product within the United States, or importation of the Lupin ANDA Product into the United States, during the term of the '028 patent would infringe one or more claims of the '028 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

534. On information and belief, Lupin intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218088 and any amendments thereto, *i.e.*, prior to the expiration of the '028 patent.

535. On information and belief, Lupin had knowledge of the '028 patent when it submitted ANDA No. 218088. Lupin Inc.'s infringement has been, and continues to be, deliberate.

536. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '028 patent is not enjoined.

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

COUNT XXIII
INFRINGEMENT OF U.S. PATENT NO. 10,550,081 BY LUPIN

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

539. Lupin's submission of ANDA No. 218088 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 Lupin ANDA Product in/into the United States prior to the

expiration of the '081 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '081 patent under 35 U.S.C. § 271(e)(2)(A).

540. Lupin's commercial manufacture, sale, offer for sale, or use of the Lupin ANDA Product within the United States, or importation of the Lupin ANDA Product into the United States, during the term of the '081 patent would infringe one or more claims of the '081 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

541. On information and belief, Lupin intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218088 and any amendments thereto, *i.e.*, prior to the expiration of the '081 patent.

542. On information and belief, Lupin had knowledge of the '081 patent when it submitted ANDA No. 218088. Lupin's infringement has been, and continues to be, deliberate.

543. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '081 patent is not enjoined.

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

COUNT XXIV
INFRINGEMENT OF U.S. PATENT NO. 11,008,289 BY LUPIN

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

546. Lupin's submission of ANDA No. 218088 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 Lupin ANDA Product in/into the United States prior to the expiration of the '289 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

547. Lupin's commercial manufacture, sale, offer for sale, or use of the Lupin ANDA Product within the United States, or importation of the Lupin ANDA Product into the United States, during the term of the '289 patent would induce infringement and/or infringe one or more claims of the '289 patent under 35 U.S.C. §§ 271(b) and/or (g).

548. On information and belief, Lupin intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218088 and any amendments thereto, *i.e.*, prior to the expiration of the '289 patent.

549. On information and belief, Lupin had knowledge of the '289 patent when it submitted ANDA No. 218088. Lupin's infringement has been, and continues to be, deliberate.

550. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '289 patent is not enjoined.

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

COUNT XXV
INFRINGEMENT OF U.S. PATENT NO. 11,484,531 BY LUPIN

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

553. Lupin's submission of ANDA No. 218088 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 Lupin ANDA Product in/into the United States prior to the expiration of the '531 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '531 patent under 35 U.S.C. § 271(e)(2)(A).

554. Unless enjoined, upon FDA approval of Lupin's ANDA No. 218088, Lupin will infringe one or more claims of the '531 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

555. On information and belief, upon FDA approval of Lupin's ANDA No. 218088, Lupin intends to manufacture, market, sell, and offer to sell Lupin's ANDA Product with an FDA-approved package insert that will direct healthcare providers and patients in the use of Lupin's ANDA Product.

556. On information and belief, Lupin will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Lupin knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '531 patent by marketing Lupin's ANDA Product with the FDA-approved package insert.

557. The '531 patent has one independent claim, claim 1, which states:

1. A method for treating chronic obstructive pulmonary disease in a patient, the method comprising:

(a) selecting a patient having chronic obstructive pulmonary disease for treatment based on the patient having a peak inspiratory flow rate less than about 60 L/min and a percent predicted forced expiratory volume in one second less than about 50 percent; and

(b) administering a pharmaceutical composition comprising about 175 µg of rевеfенасин, or a pharmaceutically acceptable salt thereof, in 3 mL of an aqueous solution to the selected patient once daily using a nebulizer.

558. A healthcare provider will directly infringe one or more of the claims of the '531 patent. Specifically, a healthcare provider administering Lupin's ANDA Product in accordance with Lupin's package insert will perform all of the steps of one or more claims of the '531 patent.

559. 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).

560. 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®.

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

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

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

564. The YUPELRI® package insert instructs that YUPELRI® is “indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).” (Ex. F at § 1).

565. 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.” (Ex. F at § 2).

566. The “Dosage Form 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.” (Ex. F at § 3).

567. A healthcare provider will select a patient having COPD for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50%.

568. The YUPELRI® package insert describes the treatment of moderate to very severe patients in Clinical Studies. (Ex. F at § 14.2).

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

570. The GOLD guidelines, Table 2.6, categorize severe COPD based on FEV₁ of equal to or greater than 30% and less than 50%.

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

572. The YUPELRI® package insert, in Section 2, Dosing and Administration, instructs treating patients by administering YUPELRI® by nebulizer.

573. The GOLD guidelines, such as at pages 69-70, advise healthcare providers to check the patient's ability to use an inhaler.

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

575. A healthcare provider will select a nebulizer for patients with a PIFR of less than about 60 L/min. *See, e.g.,* Mahler 2017; Mahler 2014.

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

577. On information and belief, Lupin knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and FEV₁ of less than 50%.

578. On information and belief, Lupin 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 PIFR of less than about 60 L/min and FEV₁ of less than 50%.

579. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '531 patent is not enjoined.

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

COUNT XXVI
INFRINGEMENT OF U.S. PATENT NO. 8,541,451 BY ORBICULAR

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

582. Orbicular's submission of ANDA No. 217868 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 Orbicular ANDA Product in/into the United States prior to the expiration of the '451 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '451 patent under 35 U.S.C. § 271(e)(2)(A).

583. Orbicular's commercial manufacture, sale, offer for sale, or use of the Orbicular ANDA Product within the United States, or importation of the Orbicular ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

584. Orbicular's commercial manufacture, sale, offer for sale, or use of the Orbicular ANDA Product within the United States, or importation of the Orbicular ANDA Product into the

United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(g).

585. On information and belief, Orbicular intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Orbicular ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217868 and any amendments thereto, *i.e.*, prior to the expiration of the '451 patent.

586. On information and belief, Orbicular had knowledge of the '451 patent when it submitted ANDA No. 217868. Orbicular's infringement has been, and continues to be, deliberate.

587. Plaintiffs will be substantially and irreparably harmed if Orbicular's infringement of the '451 patent is not enjoined.

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

COUNT XXVII
INFRINGEMENT OF U.S. PATENT NO. 9,765,028 BY ORBICULAR

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

590. Orbicular's submission of ANDA No. 217868 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 Orbicular ANDA Product in/into the United States prior to the expiration of the '028 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '028 patent under 35 U.S.C. § 271(e)(2)(A).

591. Orbicular's commercial manufacture, sale, offer for sale, or use of the Orbicular ANDA Product within the United States, or importation of the Orbicular ANDA Product into the

United States, during the term of the '028 patent would infringe one or more claims of the '028 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

592. On information and belief, Orbicular intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Orbicular ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217868 and any amendments thereto, *i.e.*, prior to the expiration of the '028 patent.

593. On information and belief, Orbicular had knowledge of the '028 patent when it submitted ANDA No. 217868. Orbicular's infringement has been, and continues to be, deliberate.

594. Plaintiffs will be substantially and irreparably harmed if Orbicular's infringement of the '028 patent is not enjoined.

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

COUNT XXVIII
INFRINGEMENT OF U.S. PATENT NO. 10,550,081 BY ORBICULAR

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

597. Orbicular's submission of ANDA No. 217868 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 Orbicular ANDA Product in/into the United States prior to the expiration of the '081 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '081 patent under 35 U.S.C. § 271(e)(2)(A).

598. Orbicular's commercial manufacture, sale, offer for sale, or use of the Orbicular ANDA Product within the United States, or importation of the Orbicular ANDA Product into the

United States, during the term of the '081 patent would infringe one or more claims of the '081 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

599. On information and belief, Orbicular intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Orbicular ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217868 and any amendments thereto, *i.e.*, prior to the expiration of the '081 patent.

600. On information and belief, Orbicular had knowledge of the '081 patent when it submitted ANDA No. 217868. Orbicular's infringement has been, and continues to be, deliberate.

601. Plaintiffs will be substantially and irreparably harmed if Orbicular's infringement of the '081 patent is not enjoined.

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

COUNT XXIX
INFRINGEMENT OF U.S. PATENT NO. 11,008,289 BY ORBICULAR

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

604. Orbicular's submission of ANDA No. 217868 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 Orbicular ANDA Product in/into the United States prior to the expiration of the '289 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

605. Orbicular's commercial manufacture, sale, offer for sale, or use of the Orbicular ANDA Product within the United States, or importation of the Orbicular ANDA Product into the

United States, during the term of the '289 patent would induce infringement and/or infringe one or more claims of the '289 patent under 35 U.S.C. §§ 271(b) and/or (g).

606. On information and belief, Orbicular intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Orbicular ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217868 and any amendments thereto, *i.e.*, prior to the expiration of the '289 patent.

607. On information and belief, Orbicular had knowledge of the '289 patent when it submitted ANDA No. 217868. Orbicular's infringement has been, and continues to be, deliberate.

608. Plaintiffs will be substantially and irreparably harmed if Orbicular's infringement of the '289 patent is not enjoined.

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

COUNT XXX
INFRINGEMENT OF U.S. PATENT NO. 8,541,451 BY CIPLA

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

611. 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 '451 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '451 patent under 35 U.S.C. § 271(e)(2)(A).

612. Cipla's commercial manufacture, sale, offer for sale, or use of the Cipla ANDA Product within the United States, or importation of the Cipla ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

613. Cipla's commercial manufacture, sale, offer for sale, or use of the Cipla ANDA Product within the United States, or importation of the Cipla ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(g).

614. On information and belief, Cipla intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Cipla ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217958 and any amendments thereto, *i.e.*, prior to the expiration of the '451 patent.

615. On information and belief, Cipla had knowledge of the '451 patent when it submitted ANDA No. 217958. Cipla's infringement has been, and continues to be, deliberate.

616. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '451 patent is not enjoined.

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

COUNT XXXI
INFRINGEMENT OF U.S. PATENT NO. 9,765,028 BY CIPLA

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

619. 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 '028 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '028 patent under 35 U.S.C. § 271(e)(2)(A).

620. Cipla's commercial manufacture, sale, offer for sale, or use of the Cipla ANDA Product within the United States, or importation of the Cipla ANDA Product into the United

States, during the term of the '028 patent would infringe one or more claims of the '028 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

621. On information and belief, Cipla intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Cipla ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217958 and any amendments thereto, *i.e.*, prior to the expiration of the '028 patent.

622. On information and belief, Cipla had knowledge of the '028 patent when it submitted ANDA No. 217958. Cipla's infringement has been, and continues to be, deliberate.

623. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '028 patent is not enjoined.

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

COUNT XXXII
INFRINGEMENT OF U.S. PATENT NO. 10,550,081 BY CIPLA

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

626. 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 '081 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '081 patent under 35 U.S.C. § 271(e)(2)(A).

627. Cipla's commercial manufacture, sale, offer for sale, or use of the Cipla ANDA Product within the United States, or importation of the Cipla ANDA Product into the United States, during the term of the '081 patent would infringe one or more claims of the '081 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

628. On information and belief, Cipla intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Cipla ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217958 and any amendments thereto, *i.e.*, prior to the expiration of the '081 patent.

629. On information and belief, Cipla had knowledge of the '081 patent when it submitted ANDA No. 217958. Cipla's infringement has been, and continues to be, deliberate.

630. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '081 patent is not enjoined.

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

COUNT XXXIII
INFRINGEMENT OF U.S. PATENT NO. 11,008,289 BY CIPLA

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

633. 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 '289 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

634. Cipla's commercial manufacture, sale, offer for sale, or use of the Cipla ANDA Product within the United States, or importation of the Cipla ANDA Product into the United States, during the term of the '289 patent would induce infringement and/or infringe one or more claims of the '289 patent under 35 U.S.C. §§ 271(b) and/or (g).

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

proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217958 and any amendments thereto, *i.e.*, prior to the expiration of the '289 patent.

636. On information and belief, Cipla had knowledge of the '289 patent when it submitted ANDA No. 217958. Cipla's infringement has been, and continues to be, deliberate.

637. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '289 patent is not enjoined.

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

COUNT XXXIV
INFRINGEMENT OF U.S. PATENT NO. 11,484,531 BY CIPLA

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

640. 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 '531 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '531 patent under 35 U.S.C. § 271(e)(2)(A).

641. Unless enjoined, upon FDA approval of Cipla's ANDA No. 217958, Cipla will infringe one or more claims of the '531 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

642. 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.

643. 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 '531 patent by marketing Cipla's ANDA Product with the FDA-approved package insert.

644. The '531 patent has one independent claim, claim 1, which states:

1. A method for treating chronic obstructive pulmonary disease in a patient, the method comprising:

(a) selecting a patient having chronic obstructive pulmonary disease for treatment based on the patient having a peak inspiratory flow rate less than about 60 L/min and a percent predicted forced expiratory volume in one second less than about 50 percent; and

(b) administering a pharmaceutical composition comprising about 175 µg of rевеfенасin, or a pharmaceutically acceptable salt thereof, in 3 mL of an aqueous solution to the selected patient once daily using a nebulizer.

645. A healthcare provider will directly infringe one of more of the claims of the '531 patent. Specifically, a healthcare provider administering Cipla's ANDA Product in accordance with Cipla's package insert will perform all of the steps of one or more claims of the '531 patent.

646. 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).

647. 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®.

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

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

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

651. The YUPELRI® package insert instructs that YUPELRI® is “indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).” (Ex. F at § 1).

652. 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.” (Ex. F at § 2).

653. The “Dosage Form 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.” (Ex. F at § 3).

654. A healthcare provider will select a patient having COPD for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and a percent predicted force expiratory volume in one second less than about 50%.

655. The YUPELRI® package insert describes the treatment of moderate to very severe patients in Clinical Studies. (Ex. F at § 14.2).

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

657. The GOLD guidelines, Table 2.6, categorize severe COPD based on FEV₁ of equal to or greater than 30% and less than 50%.

658. 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.

659. The YUPELRI® package insert, in Section 2, Dosing and Administration, instructs treating patients by administering YUPELRI® by nebulizer.

660. The GOLD guidelines, such as at pages 69-70, advise healthcare providers to check the patient's ability to use an inhaler.

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

662. A healthcare provider will select a nebulizer for patients with a PIFR of less than about 60 L/min. *See, e.g.,* Mahler 2017; Mahler 2014.

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

664. On information and belief, Cipla knows that some healthcare providers will select patients for treatment with YUPELRI® based on the patient having a PIFR of less than about 60 L/min and FEV₁ of less than 50%.

665. 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 PIFR of less than about 60 L/min and FEV₁ of less than 50%.

666. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '531 patent is not enjoined.

667. 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 each of the Patents-in-Suit by the filing of 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 each of the Patents-in-Suit under 35 U.S.C. § 271(a), (b), and/or (g);
- (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(a), (b), and/or (g);
- (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 '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 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 Patents-in-Suit, inclusive of any extension(s) to patent term;

(f) A permanent injunction restraining and enjoining Eugia, whether alone or in concert 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 Patents-in-Suit in/into the United States, or practicing any processes or methods as claimed in the Patents-in-Suit, or from actively inducing or contributing to the infringement of any claim of the Patents-in-Suit, before the expiration of the Patents-in-Suit, 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 latest expiration date of the Patents-in-Suit, 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

(l) A judgment under 35 U.S.C. § 271(e)(2)(A) that Mankind has infringed one or more claims of each of the Patents-in-Suit by the filing of ANDA No. 218089;

(m) 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 each of the Patents-in-Suit under 35 U.S.C. § 271(a), (b), and/or (g);

(n) 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(a), (b), and/or (g);

(o) 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 '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(p) 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 Patents-in-Suit, inclusive of any extension(s) to patent term;

(q) 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 Patents-in-Suit in/into the United States, or practicing any processes or methods as claimed in the Patents-in-Suit, or from actively inducing or contributing to the infringement of any claim of the Patents-in-Suit, before the expiration of the Patents-in-Suit, inclusive of any extension(s) to patent term in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(r) 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 latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

- (s) 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;
- (t) An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4);
- (u) Costs and expenses in this action; and
- (v) Such further and other relief as this Court may deem just and proper.

Teva

- (w) A judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed one or more claims of each of the Patents-in-Suit by the filing of ANDA No. 217015;
- (x) A judgment that Teva's manufacturing, using, selling, offering for sale, and/or importing the Teva ANDA Product in/into the United States will infringe one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271(a), (b), and/or (g);
- (y) A declaration under 28 U.S.C. §§ 2201-02 that if Teva, 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 Teva ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), and/or (g);
- (z) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 217015 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 '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(aa) A judgment under 35 U.S.C. §§ 271(e)(4)(B) and 283 providing injunctive relief against Teva, 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 Teva ANDA Product before the expiration of the Patents-in-Suit, inclusive of any extension(s) to patent term;

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

(cc) 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 Teva engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Teva ANDA Product prior to the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

(dd) 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;

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

(ff) Costs and expenses in this action; and

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

Accord

(hh) A judgment under 35 U.S.C. § 271(e)(2)(A) that Accord has infringed one or more claims of each of the Patents-in-Suit by the filing of ANDA No. 218100;

(ii) A judgment that Accord's manufacturing, using, selling, offering for sale, and/or importing the Accord ANDA Product in/into the United States will infringe one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271(a), (b), and/or (g);

(jj) A declaration under 28 U.S.C. §§ 2201-02 that if Accord, 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 Accord ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), and/or (g);

(kk) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 218100 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 '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(ll) A judgment under 35 U.S.C. §§ 271(e)(4)(B) and 283 providing injunctive relief against Accord, 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 Accord ANDA Product before the expiration of the Patents-in-Suit, inclusive of any extension(s) to patent term;

(mm) A permanent injunction restraining and enjoining Accord, whether alone or in concert with a subsidiary company, from making, using, selling, offering for sale, and/or importing the Accord ANDA Product or any pharmaceutical composition as claimed in the Patents-in-Suit

in/into the United States, or practicing any processes or methods as claimed in the Patents-in-Suit, or from actively inducing or contributing to the infringement of any claim of the Patents-in-Suit, before the expiration of the Patents-in-Suit, inclusive of any extension(s) to patent term in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(nn) 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 Accord engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Accord ANDA Product prior to the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

(oo) 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;

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

(qq) Costs and expenses in this action; and

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

Lupin

(ss) A judgment that Lupin under 35 U.S.C. § 271(e)(2)(A) has infringed one or more claims of each of the Patents-in-Suit by the filing of ANDA No. 218088;

(tt) A judgment that Lupin's manufacturing, using, selling, offering for sale, and/or importing the Lupin ANDA Product in/into the United States will infringe one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271(a), (b), and/or (g);

(uu) A declaration under 28 U.S.C. §§ 2201-02 that if Lupin, 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 Lupin ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), and/or (g);

(vv) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 218088 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 '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(ww) A judgment under 35 U.S.C. §§ 271(e)(4)(B) and 283 providing injunctive relief against Lupin, 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 Lupin ANDA Product before the expiration of the Patents-in-Suit, inclusive of any extension(s) to patent term;

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

(yy) 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 Lupin engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Lupin ANDA Product prior to the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

(zz) 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;

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

(bbb) Costs and expenses in this action; and

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

Orbicular

(ddd) A judgment under 35 U.S.C. § 271(e)(2)(A) that Orbicular has infringed one or more claims of each of one or more of the '451 patent, the '028 patent, the '081 patent and the '289 patent by the filing of ANDA No. 217868;

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

(fff) A declaration under 28 U.S.C. §§ 2201-02 that if Orbicular, 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 Orbicular ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), and/or (g);

(ggg) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 217868 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 '451 patent, the '028 patent, the '081 patent, the '289 patent and the '531 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(hhh) A judgment under 35 U.S.C. §§ 271(e)(4)(B) and 283 providing injunctive relief against Orbicular, 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 Orbicular ANDA Product before the expiration of the '451 patent, the '028 patent, the '081 patent, the '289 patent and the '531 patent, inclusive of any extension(s) to patent term;

(iii) A permanent injunction restraining and enjoining Orbicular, whether alone or in concert with a subsidiary company, from making, using, selling, offering for sale, and/or importing the Orbicular ANDA Product or any pharmaceutical composition as claimed in the Patents-in-Suit in/intro the United States, or practicing any processes or methods as claimed in the Patents-in-Suit, or from actively inducing or contributing to the infringement of any claim of the Patents-in-Suit, before the expiration of the '451 patent, the '028 patent, the '081 patent, the '289 patent and the '531 patent, respectively, inclusive of any extension(s) to patent term in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(jjj) 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 Orbicular engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Orbicular ANDA Product prior to the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

(kkk) 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;

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

(mmm) Costs and expenses in this action; and

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

Cipla

(ooo) A judgment under 35 U.S.C. § 271(e)(2)(A) that Cipla has infringed one or more claims of each of the Patents-in-Suit by the filing of ANDA No. 217958;

(ppp) 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 each of the Patents-in-Suit under 35 U.S.C. § 271(a), (b), and/or (g);

(qqq) 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(a), (b), and/or (g);

(rrr) 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 '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(sss) 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 Patents-in-Suit, inclusive of any extension(s) to patent term;

(ttt) 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 Patents-in-Suit in/into

the United States, or practicing any processes or methods as claimed in the Patents-in-Suit, or from actively inducing or contributing to the infringement of any claim of the Patents-in-Suit, before the expiration of the Patents-in-Suit, inclusive of any extension(s) to patent term in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(uuu) 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 latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

(vvv) 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;

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

(xxx) Costs and expenses in this action; and

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

Dated: February 16, 2023

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 not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding.

Dated: February 16, 2023

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: February 16, 2023

Respectfully submitted,

/s/ Arnold B. Calmann

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