IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB, INC. and UCB BIOPHARMA SRL, Plaintiffs, v. ANNORA PHARMA PRIVATE LIMITED, APOTEX INC., APOTEX CORP., AUROBINDO PHARMA USA INC., AUROBINDO PHARMA LTD., LUPIN LTD., MICRO LABS LTD., MICRO LABS USA, INC., MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LTD. and ZYDUS PHARMACEUTICALS (USA) INC., Defendants.	)	C.A. No. 20-987 (CFC)

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs UCB, Inc. and UCB Biopharma SRL (collectively, "UCB"), by their undersigned attorneys, bring this action against Defendants Annora Pharma Private Ltd. ("Annora"), Apotex Inc. and Apotex Corp. (collectively, "Apotex"), Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. (collectively, "Aurobindo"), Lupin Limited ("Lupin"), Micro Labs USA, Inc. and Micro Labs Ltd. (collectively, "Micro Labs"), MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (collectively, "MSN"), and Zydus Pharmaceuticals (USA) Inc. ("Zydus," and together with Annora, Apotex, Aurobindo, Lupin, Micro Labs, and MSN, the "Defendants") and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, arises from (a) Annora's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No.

214831 ("Annora's ANDA"); (b) Apotex's submission to the FDA of ANDA No. 214875 ("Apotex's ANDA"); (c) Aurobindo's submission to the FDA of ANDA No. 214848 ("Aurobindo's ANDA"); (d) Lupin's submission to the FDA of ANDA No. 214918 ("Lupin's ANDA"); (e) Micro Labs's submission to the FDA of ANDA No. 214880 ("Micro Labs's ANDA"); (f) MSN's submission to the FDA of ANDA Nos. 214922, 214924, and 214921 (collectively, "MSN's ANDAs"); and (g) Zydus's submission to the FDA of ANDA No. 214501 ("Zydus's ANDA," and together with Annora's ANDA, Apotex's ANDA, Aurobindo's ANDA, Lupin's ANDA, Micro Labs's ANDA, and MSN's ANDAs, "Defendants' ANDAs"); by which Defendants seek approval to market generic versions of UCB's pharmaceutical product Briviact® (brivaracetam) prior to the expiration of U.S. Patent Nos. 6,784,197 ("the '197 Patent"), 6,911,461 ("the '461 Patent"), and 8,492,416 ("the '416 Patent") (collectively, the "Patents-in-Suit").

THE PARTIES

UCB

2. Plaintiff UCB, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 1950 Lake Park Drive, Smyrna, Georgia 30080.

3. Plaintiff UCB Biopharma SRL is a corporation organized and existing under the laws of Belgium, having an office and place of business at Allée de la Recherche 60, B-1070 Brussels, Belgium.

Annora

4. On information and belief, Defendant Annora Pharma Private Ltd is a corporation organized and existing under the laws of India, having its principal place of business at Sy. No. 261, Plot No. 5,7,8,9,13 and 14, Annaram Village, Jinnaram Mandal, Medak Hyderabad TG 502313, India.

Apotex

5. On information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

6. On information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 N. Commerce Parkway, Suite 400, Weston, Florida 33326.

7. On information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc.

Aurobindo

8. On information and belief, Defendant Aurobindo Pharma USA Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520.

9. On information and belief, Defendant Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad 500038, Telangana, India.

10. On information and belief, Defendant Aurobindo Pharma USA Inc. is a wholly-owned subsidiary of Aurobindo Pharma, Ltd.

Lupin

11. On information and belief, Defendant Lupin Limited is a corporation organized and existing under the laws of the Republic of India, having its principal place of business at Kalpataru Inspire, 3rd Floor, Off Western Express Highway, Santacruz (East), Mumbai, Mumbai City MH 400 055, India.

Micro Labs

12. On information and belief, Micro Labs USA, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 106 Allen Road, Suite 102, Basking Ridge, New Jersey 07920.

13. On information and belief, Micro Labs Ltd. is a corporation organized and existing under the laws of the Republic of India, having its principal place of business at 31, Race Course Road, Bangalore 560 001, India.

14. On information and belief, Micro Labs USA, Inc. is a wholly-owned subsidiary of Micro Labs Ltd.

MSN

15. On information and belief, Defendant MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

16. On information and belief, Defendant MSN Laboratories Private Limited is a corporation organized and existing under the laws of the Republic of India, having its principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad 500 018, Telangana, India.

17. On information and belief, MSN Pharmaceuticals Inc. is a wholly-owned subsidiary of MSN Laboratories Private Limited.

Zydus

18. On information and belief, Defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

19. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271.

20. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

Annora

21. This Court has personal jurisdiction over Annora because, on information and belief, Annora, *inter alia*, has continuous and systematic contacts with the State of Delaware; regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos; has purposefully availed itself of the privilege of doing business in the State of Delaware; and intends to sell Annora's generic version of Briviact® in the State of Delaware upon approval of Annora's ANDA.

22. On information and belief, Annora is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Annora manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

23. On information and belief, Annora sells generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

24. On information and belief, Annora plans to sell its generic version of Briviact® in the State of Delaware, list its generic version of Briviact® on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of its generic version of Briviact® in

the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

25. On information and belief, Annora knows and intends that its proposed generic version of Briviact® will be distributed and sold in Delaware and will thereby displace sales of Briviact®, causing injury to UCB. Annora intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed generic version of Briviact®.

26. Annora has engaged in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction or venue in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Boehringer Ingelheim Pharms. Inc. v. Annora Pharma Private Ltd.*, C.A. No. 20-277-CFC, D.I. 8 (D. Del. Apr. 27, 2020); *Amgen Inc. v. Annora Pharma Private Ltd.*, C.A. No. 20-122-CFC, D.I. 9 (D. Del. Mar. 26, 2020); *Vifor Fresenius Med. Care Renal Pharma Ltd. v. Annora Pharma Private Ltd.*, C.A. No. 18-1996-MN, D.I. 12 (D. Del. Mar. 1, 2019); *Boehringer Ingelheim Pharms. Inc. v. Annora Pharma Private Ltd.*, C.A. No. 18-1786-CFC-SRF, D.I. 19 (D. Del. Jan. 18, 2019).

27. In the alternative, this Court has personal jurisdiction over Annora pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) as (a) UCB's claims arise under federal law; (b) Annora is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Annora has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Annora's ANDA to the FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Annora satisfies due process.

28. Venue is proper in this district for Annora pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Annora is a corporation organized and existing under the laws of the Republic of India and may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c)(3).

Apotex

29. This Court has personal jurisdiction over Apotex because, on information and belief, Apotex, *inter alia*, has continuous and systematic contacts with the State of Delaware; regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos; has purposefully availed itself of the privilege of doing business in the State of Delaware; and intends to sell Apotex's generic version of Briviact® in the State of Delaware upon approval of Apotex's ANDA.

30. Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware.

31. On information and belief, Apotex is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Apotex manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

32. On information and belief, Apotex sells generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

33. On information and belief, Apotex plans to sell its generic version of Briviact® in the State of Delaware, list its generic version of Briviact® on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of its generic version of Briviact® in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

34. On information and belief, Apotex knows and intends that its proposed generic version of Briviact® will be distributed and sold in Delaware and will thereby displace sales of Briviact®, causing injury to UCB. Apotex intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed generic version of Briviact®.

35. Apotex Inc. and Apotex Corp. have engaged in patent litigation concerning FDA-approved drug products in this judicial district, have not contested personal jurisdiction or venue in such litigation in this judicial district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Anacor Pharms., Inc. v. Apotex Inc. et al.*, C.A. No. 18-1673-RGA, D.I. 30 (D. Del. Oct 25, 2018); *Bayer Healthcare LLC et al. v. Apotex Inc. et al.*, C.A. No. 18-1465-LPS, D.I. 7 (D. Del. Sept 21, 2018); *Onyx Therapeutics, Inc. v. Apotex Inc. et al.*, C.A. No. 18-132, D.I. 10 (D. Del. Jan 24, 2018).

36. In the alternative, this Court has personal jurisdiction over Apotex Inc. pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) as (a) UCB's claims arise under federal law; (b) Apotex Inc. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Apotex Inc. has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Apotex's ANDA to the FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Apotex Inc. satisfies due process.

37. Venue is proper in this district for Apotex Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Apotex Inc. is a corporation organized and existing under the laws of Canada and may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c)(3).

38. Venue is proper in this district for Apotex Corp. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware.

Aurobindo

39. This Court has personal jurisdiction over Aurobindo because, on information and belief, Aurobindo, *inter alia*, has continuous and systematic contacts with the State of Delaware; regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos; has purposefully availed itself of the privilege of doing business in the State of Delaware; and intends to sell Aurobindo's generic version of Briviact® in the State of Delaware upon approval of Aurobindo's ANDA.

40. Aurobindo Pharma USA Inc. is a corporation organized and existing under the laws of the State of Delaware.

41. On information and belief, Aurobindo is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Aurobindo manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

42. On information and belief, Aurobindo sells generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

43. On information and belief, Aurobindo plans to sell its generic version of Briviact® in the State of Delaware, list its generic version of Briviact® on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of its generic version of Briviact® in

the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

44. On information and belief, Aurobindo knows and intends that its proposed generic version of Briviact® will be distributed and sold in Delaware and will thereby displace sales of Briviact®, causing injury to UCB. Aurobindo intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed generic version of Briviact®.

45. Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. have engaged in patent litigation concerning FDA-approved drug products in this judicial district, have not contested personal jurisdiction or venue in such litigation in this judicial district, and have purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Arena Pharms., Inc. et al. v. Aurobindo Pharma USA Inc. et al.*, C.A. No. 19-811-RGA, D.I. 10 (D. Del. May 1, 2019); *Millennium Pharms., Inc. v. Aurobindo Pharma USA Inc. et al.*, C.A. No. 19-471-CFC-SRF, D.I. 9 (D. Del. Mar 6, 2019); *Anacor Pharms., Inc. v. Aurobindo Pharma USA Inc. et al.*, C.A. No. 18-1673-RGA, D.I. 35 (D. Del. Oct 25, 2018).

46. In the alternative, this Court has personal jurisdiction over Aurobindo Pharma Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) as (a) UCB's claims arise under federal law; (b) Aurobindo Pharma Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Aurobindo Pharma Ltd. has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Aurobindo's ANDA to the FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Aurobindo Pharma Ltd. satisfies due process.

47. Venue is proper in this district for Aurobindo Pharma Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India and may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c)(3).

48. Venue is proper in this district for Aurobindo Pharma USA, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware.

Lupin

49. This Court has personal jurisdiction over Lupin because, on information and belief, Lupin, *inter alia*, has continuous and systematic contacts with the State of Delaware; regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos; has purposefully availed itself of the privilege of doing business in the State of Delaware; and intends to sell Lupin's generic version of Briviact® in the State of Delaware upon approval of Lupin's ANDA.

50. On information and belief, Lupin controls and dominates Lupin Pharmaceuticals, Inc., a wholly-owned subsidiary of Lupin, and therefore, the activities of Lupin Pharmaceuticals, Inc. in this jurisdiction are attributed to Lupin. Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware.

51. On information and belief, Lupin is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Lupin manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

52. On information and belief, Lupin sells generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

53. On information and belief, Lupin plans to sell its generic version of Briviact® in the State of Delaware, list its generic version of Briviact® on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of its generic version of Briviact® in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

54. On information and belief, Lupin knows and intends that its proposed generic version of Briviact® will be distributed and sold in Delaware and will thereby displace sales of Briviact®, causing injury to UCB. Lupin intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed generic version of Briviact®.

55. Lupin has engaged in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction or venue in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Anacor Pharms., Inc. v. Lupin Ltd. et al.*, C.A. No. 18-1606-RGA, D.I. 16 (D. Del. Oct 17, 2018); *Amgen Inc. v. Lupin Ltd. et al.*, C.A. No. 17-816-GMS, D.I. 8 (D. Del. June 23, 2017); *Omeros Corp. v. Lupin Ltd. et al.*, C.A. No. 17-803-RGA, D.I. 9 (D. Del. June 22, 2017).

56. In the alternative, this Court has personal jurisdiction over Lupin pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) as (a) UCB's claims arise under federal law; (b) Lupin is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Lupin has sufficient contacts in the United States as a whole, including, but not limited to,

participating in the preparation and submission of Lupin's ANDA to the FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Lupin satisfies due process.

57. Venue is proper in this district for Lupin pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, (1) Lupin is a corporation organized and existing under the laws of the Republic of India and may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c)(3) and (2) Lupin Pharmaceuticals, Inc., a wholly-owned subsidiary of Lupin, is a corporation organized and existing under the laws of the State of Delaware.

Micro Labs

58. This Court has personal jurisdiction over Micro Labs because, on information and belief, Micro Labs, *inter alia*, has continuous and systematic contacts with the State of Delaware; regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos; has purposefully availed itself of the privilege of doing business in the State of Delaware; and intends to sell Micro Labs's generic version of Briviact® in the State of Delaware upon approval of Micro Labs's ANDA.

59. On information and belief, Micro Labs is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Micro Labs manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

60. On information and belief, Micro Labs sells generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

61. On information and belief, Micro Labs USA, Inc. plans to sell its generic version of Briviact® in the State of Delaware, list its generic version of Briviact® on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of its generic version of Briviact® in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

62. On information and belief, Micro Labs knows and intends that its proposed generic version of Briviact® will be distributed and sold in Delaware and will thereby displace sales of Briviact®, causing injury to UCB. Micro Labs intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed generic version of Briviact®.

63. Micro Labs USA, Inc. and Micro Labs Ltd. have engaged in patent litigation concerning FDA-approved drug products in this judicial district, have not contested personal jurisdiction or venue in such litigation in this judicial district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Hikma Pharms. USA Inc. et al. v. Micro Labs Ltd. et al.*, C.A. No. 19-883-CFC-CJB, D.I. 19 (D. Del. May 10, 2019); *Genentech, Inc. et al. v. Micro Labs Ltd. et al.*, C.A. No. 19-111-RGA, D.I. 9 (D. Del. Jan 18, 2019); *Bayer Intellectual Prop. GmbH et al. v. Micro Labs Ltd. et al.*, C.A. No. 17-560-TBD, D.I. 9 (D. Del. May 12, 2017).

64. In the alternative, this Court has personal jurisdiction over Micro Labs Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) as (a) UCB's claims arise under federal law; (b) Micro Labs Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Micro Labs Ltd. has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Micro Labs's ANDA to the FDA, and/or manufacturing and/or selling pharmaceutical products distributed

throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Micro Labs Ltd. satisfies due process.

65. Venue is proper in this district for Micro Labs Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Micro Labs Ltd. is a corporation organized and existing under the laws of the Republic of India and may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c)(3).

66. Venue is proper in this district for Micro Labs USA, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b).

MSN

67. This Court has personal jurisdiction over MSN because, on information and belief, MSN, *inter alia*, has continuous and systematic contacts with the State of Delaware; regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos; has purposefully availed itself of the privilege of doing business in the State of Delaware; and intends to sell MSN's generic versions of Briviact® in the State of Delaware upon approval of MSN's ANDAs.

68. MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, and on information and belief is a wholly owned subsidiary of MSN Laboratories Private Ltd.

69. On information and belief, MSN is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which MSN manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

70. On information and belief, MSN sells generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

71. On information and belief, MSN plans to sell its generic versions of Briviact® in the State of Delaware, list its generic versions of Briviact® on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of its generic versions of Briviact® in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

72. On information and belief, MSN knows and intends that its proposed generic versions of Briviact® will be distributed and sold in Delaware and will thereby displace sales of Briviact®, causing injury to UCB. MSN intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed generic versions of Briviact®.

73. MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. have engaged in patent litigation concerning FDA-approved drug products in this judicial district, have not contested personal jurisdiction or venue in such litigation in this judicial district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Genentech, Inc. v. MSN Labs. Private Ltd. et al.*, C.A. No. 19-205-RGA, D.I. 9 (D. Del. Jan 31, 2019); *Onyx Therapeutics, Inc. v. MSN Pharms., Inc. et al.*, C.A. No. 17-1833-LPS, D.I. 8 (D. Del. Dec 20, 2017); *Biogen MA Inc. v. MSN Labs. Private Ltd. et al.*, C.A. No. 17-845-LPS, D.I. 12 (D. Del. June 28, 2017).

74. In the alternative, this Court has personal jurisdiction over MSN Laboratories Private Limited pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) as (a) UCB's claims arise under federal law; (b) MSN Laboratories Private Limited is a foreign defendant not subject to

general personal jurisdiction in the courts of any state; and (c) MSN Laboratories Private Limited has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of MSN's ANDAs to the FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over MSN Laboratories Private Limited satisfies due process.

75. Venue is proper in this district for MSN Pharmaceuticals Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware.

76. Venue is proper in this district for MSN Laboratories Private Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, MSN Laboratories Private Ltd. is a corporation organized and existing under the laws of the Republic of India and may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c)(3).

Zydus

77. This Court has personal jurisdiction over Zydus because, on information and belief, Zydus, *inter alia*, has continuous and systematic contacts with the State of Delaware; regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos; has purposefully availed itself of the privilege of doing business in the State of Delaware; and intends to sell Zydus's generic version of Briviact® in the State of Delaware upon approval of Zydus's ANDA.

78. On information and belief, Zydus is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Zydus manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

79. On information and belief, Zydus sells generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

80. On information and belief, Zydus plans to sell its generic version of Briviact® in the State of Delaware, list its generic version of Briviact® on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of its generic version of Briviact® in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

81. On information and belief, Zydus knows and intends that its proposed generic version of Briviact® will be distributed and sold in Delaware and will thereby displace sales of Briviact®, causing injury to UCB. Zydus intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed generic version of Briviact®.

82. Zydus has engaged in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction or venue in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Amgen Inc. et al. v. Zydus Pharms. (USA) Inc. et al.*, C.A. No. 20-075-CFC-CJB, D.I. 10 (D. Del. Apr 20, 2020); *H. Lundbeck A/S et al. v. Zydus Pharms. (USA) Inc. et al.*, C.A. No. 18-150-LPS, D.I. 13 (D. Del. Jan 25, 2018); *Millennium Pharms., Inc. et al. v. Zydus Pharms. (USA) Inc. et al.*, C.A. No. 17-423-CFC, D.I. 9 (D. Del. Apr 13, 2017).

83. Venue is proper in this district for Zydus pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

84. The '197 Patent, entitled "2-oxo-l-pyrrolidine Derivatives, Processes for Preparing Them and Their Uses," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") on August 31, 2004. UCB Biopharma SRL is the owner of all right, title, and interest in the '197 Patent. A true and correct copy of the '197 Patent is attached hereto as Exhibit A.

85. The '461 Patent, entitled "2-oxo-l-pyrrolidine Derivatives, Processes for Preparing Them and Their Uses," was duly and lawfully issued by the USPTO on June 28, 2005. UCB Biopharma SRL is the owner of all right, title, and interest in the '461 Patent. A true and correct copy of the '461 Patent is attached hereto as Exhibit B.

86. The '416 Patent, entitled "2-oxo-l-pyrrolidine Derivatives, Processes for Preparing Them and Their Uses," was duly and lawfully issued by the USPTO on July 23, 2013. UCB Biopharma SRL is the owner of all right, title, and interest in the '416 Patent. A true and correct copy of the '416 Patent is attached hereto as Exhibit C.

BRIVIACT®

87. Briviact® is indicated for the treatment of partial-onset seizures in patients 4 years of age and older. Briviact® is indicated for treatment by tablet or oral solution in patients 4 years of age and older and for treatment by injection in patients 16 years and older. Briviact® may reduce the number of partial-onset seizures and may provide additional seizure control.

88. UCB, Inc. holds approved New Drug Application ("NDA") No. 205836 for Briviact® tablets (10 mg, 25 mg, 50 mg, 75 mg, and 100 mg dosage strengths).

89. UCB, Inc. holds approved NDA No. 205837 for Briviact® intravenous solution (50 mg/5 mL dosage strength).

90. UCB, Inc. holds approved NDA No. 205838 for Briviact® oral solution (10 mg/mL dosage strength).

91. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the Patents-in-Suit are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") in connection with NDA Nos. 205836, 205837, and 205838.

PARAGRAPH IV NOTICES

Annora

92. On information and belief, Annora sent UCB a Notice Letter dated July 17, 2020 ("Annora's Notice Letter"), stating that ANDA No. 214831 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(B)(vii)(IV) (a "Paragraph IV certification") alleging that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

93. Annora's Notice Letter further states that Annora submitted ANDA No. 214831 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of brivaracetam tablets (10 mg, 25 mg, 50 mg, 75 mg, and 100 mg dosage strengths) as a purported generic version of Briviact® tablets before the expiration of the Patents-in-Suit.

94. On information and belief, if the FDA approves Annora's ANDA, Annora will manufacture, offer for sale, or sell the generic product listed in Annora's ANDA ("Annora's ANDA Product"), within the United States, including within the State of Delaware, or will import Annora's ANDA Product into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Annora's ANDA Product will directly infringe the Patents-in-Suit and Annora will actively induce and/or contribute to their infringement.

Apotex

95. On information and belief, Apotex sent UCB a Notice Letter dated June 30, 2020 ("Apotex's Notice Letter"), stating that ANDA No. 214875 contains a Paragraph IV certification alleging that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

96. Apotex's Notice Letter further states that Apotex submitted ANDA No. 214875 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of brivaracetam tablets (10 mg, 25 mg, 50 mg, 75 mg, and 100 mg dosage strengths) as a purported generic version of Briviact® tablets before the expiration of the Patents-in-Suit.

97. On information and belief, if the FDA approves Apotex's ANDA, Apotex will manufacture, offer for sale, or sell the generic product listed in Apotex's ANDA ("Apotex's ANDA Product"), within the United States, including within the State of Delaware, or will import Apotex's ANDA Product into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Product will directly infringe the Patents-in-Suit and Apotex will actively induce and/or contribute to their infringement.

Aurobindo

98. On information and belief, Aurobindo Pharma USA Inc. sent UCB a Notice Letter dated July 8, 2020 ("Aurobindo's Notice Letter"), stating that ANDA No. 214848 contains a Paragraph IV certification alleging that the '197 and '461 Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

99. Aurobindo's Notice Letter further states that Aurobindo Pharma USA Inc. submitted ANDA No. 214848 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of brivaracetam tablets (50 mg and 100 mg dosage

strengths) as a purported generic version of Briviact® tablets before the expiration of the '197 and '461 Patents.

100. On information and belief, Aurobindo's counsel sent UCB an Addendum to Aurobindo's Notice Letter dated September 1, 2020, stating that Aurobindo's counsel represents Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. in relation to ANDA No. 214848. On information and belief, Aurobindo Pharma Ltd. is the holder of ANDA No. 214848.

101. On information and belief, if the FDA approves Aurobindo's ANDA, Aurobindo will manufacture, offer for sale, or sell the generic product listed in Aurobindo's ANDA ("Aurobindo's ANDA Product"), within the United States, including within the State of Delaware, or will import Aurobindo's ANDA Product into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Aurobindo's ANDA Product will directly infringe the '197 and '461 Patents and Aurobindo will actively induce and/or contribute to their infringement.

Lupin

102. On information and belief, Lupin sent UCB a Notice Letter dated July 1, 2020 ("Lupin's Notice Letter"), stating that ANDA No. 214918 contains a Paragraph IV certification alleging that the '197 and '461 Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

103. Lupin's Notice Letter further states that Lupin submitted ANDA No. 214918 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of brivaracetam tablets (10 mg, 25 mg, 50 mg, 75 mg, and 100 mg dosage strengths) as a purported generic version of Briviact® tablets before the expiration of the '197 and '461 Patents.

104. On information and belief, if the FDA approves Lupin's ANDA, Lupin will manufacture, offer for sale, or sell the generic products listed in Lupin's ANDA ("Lupin's ANDA

Product"), within the United States, including within the State of Delaware, or will import Lupin's ANDA Product into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Lupin's ANDA Product will directly infringe the '197 and '461 Patents and Lupin will actively induce and/or contribute to their infringement.

Micro Labs

105. On information and belief, Micro Labs sent UCB a Notice Letter dated June 12, 2020 ("Micro Labs's Notice Letter"), stating that ANDA No. 214880 contains a Paragraph IV certification alleging that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

106. Micro Labs's Notice Letter further states that Micro Labs submitted ANDA No. 214880 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of brivaracetam intravenous solution as a purported generic version of Briviact® intravenous solution before the expiration of the Patents-in-Suit.

107. On information and belief, if the FDA approves Micro Labs's ANDA, Micro Labs will manufacture, offer for sale, or sell the generic products listed in Micro Labs's ANDA ("Micro Labs's ANDA Product"), within the United States, including within the State of Delaware, or will import Micro Labs's ANDA Product into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Micro Labs's ANDA Product will directly infringe the Patents-in-Suit and Micro Labs will actively induce and/or contribute to their infringement.

MSN

108. On information and belief, MSN sent UCB a Notice Letter dated June 26, 2020 ("MSN's June 26, 2020 Notice Letter"), stating that ANDA Nos. 214922 and 214924 contain a

Paragraph IV certification alleging that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic products proposed in the ANDAs.

109. MSN's June 26, 2020 Notice Letter further states that MSN submitted ANDA Nos. 214922 and 214924 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of brivaracetam oral and intravenous solutions as purported generic versions of Briviact® oral and intravenous solutions before the expiration of the Patents-in-Suit.

110. On information and belief, MSN sent UCB a Notice Letter dated June 30, 2020 ("MSN's June 30, 2020 Notice Letter," and collectively with MSN's June 26, 2020 Notice Letter, "MSN's Notice Letters"), stating that ANDA No. 214921 contains a Paragraph IV certification alleging that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

111. MSN's June 30, 2020 Notice Letter further states that MSN submitted ANDA No. 214921 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of brivaracetam tablets (10 mg, 25 mg, 50 mg, 75 mg, and 100 mg dosage strengths) as a purported generic version of Briviact® tablets before the expiration of the Patents-in-Suit.

112. On information and belief, if the FDA approves MSN's ANDAs, MSN will manufacture, offer for sale, or sell the generic products listed in MSN's ANDAs (collectively, "MSN's ANDA Products"), within the United States, including within the State of Delaware, or will import MSN's ANDA Products into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of MSN's ANDA Products will directly infringe the Patents-in-Suit and MSN will actively induce and/or contribute to their infringement.

Zydus

113. On information and belief, Zydus sent UCB a Notice Letter dated July 16, 2020 ("Zydus's Notice Letter"), stating that ANDA No. 214501 contains a Paragraph IV certification alleging that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

114. Zydus's Notice Letter further states that Zydus submitted ANDA No. 214501 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of brivaracetam tablets (10 mg, 25 mg, 50 mg, 75 mg, and 100 mg dosage strengths) as a purported generic version of Briviact® tablets before the expiration of the Patents-in-Suit.

115. On information and belief, if the FDA approves Zydus's ANDA, Zydus will manufacture, offer for sale, or sell the generic products listed in Zydus's ANDA ("Zydus's ANDA Product," and together with Annora's ANDA Product, Apotex's ANDA Product, Aurobindo's ANDA Product, Lupin's ANDA Product, Micro Labs's ANDA Product, and MSN's ANDA Products, "Defendants' ANDA Products"), within the United States, including within the State of Delaware, or will import Zydus's ANDA Product into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Zydus's ANDA Product will directly infringe the Patents-in-Suit and Zydus will actively induce and/or contribute to their infringement.

* * *

116. UCB commences this action within 45 days of receiving each of the Notice Letters identified in paragraphs 88–115.

COUNT I
INFRINGEMENT OF THE '197 PATENT BY ANNORA

117. UCB restates, realleges, and incorporates by reference paragraphs 1–116 as if fully set forth herein.

118. On information and belief, Annora submitted Annora's ANDA to the FDA, and thereby seeks FDA approval of Annora's ANDA Product.

119. Annora has infringed at least claims 1 and 21 of the '197 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Annora's ANDA with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, and sale of a generic version of Briviact® tablets prior to the expiration of the '197 Patent. At least claims 1 and 21 of the '197 Patent encompass brivaracetam. In Annora's Notice Letter, Annora has not contested infringement of claims 1 and 21 of the '197 Patent.

120. Annora's commercial manufacture, use, offer to sell, or sale of Annora's ANDA Product before the expiration of the '197 Patent would infringe one or more claims of the '197 Patent, including, but not limited to, claims 1 and 21, under 35 U.S.C. § 271.

121. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Annora's ANDA to be a date which is not any earlier than the expiration date of the '197 Patent, including any extensions, adjustments, and exclusivities associated with the '197 Patent.

COUNT II
INFRINGEMENT OF THE '461 PATENT BY ANNORA

122. UCB restates, realleges, and incorporates by reference paragraphs 1–121 as if fully set forth herein.

123. Annora has infringed claims 1–5 of the '461 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Annora's ANDA with a Paragraph IV certification and thereby seeking FDA

approval for the commercial manufacture, use, offer to sell, and sale of a generic version of Briviact® tablets prior to the expiration of the '461 Patent. Claims 1 and 5 of the '461 Patent encompass brivaracetam, claim 2 of the '461 Patent encompasses pharmaceutical compositions comprising brivaracetam, and claims 3 and 4 of the '461 Patent encompass a method of treating epilepsy, among other conditions, comprising administering a therapeutic dose of brivaracetam. In Annora's Notice Letter, Annora has not contested infringement of claims 1–5 of the '461 Patent.

124. Annora's commercial manufacture, use, offer to sell, or sale of Annora's ANDA Product before the expiration of the '461 Patent would infringe claims 1–5 of the '461 Patent under 35 U.S.C. § 271.

125. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Annora's ANDA to be a date which is not any earlier than the expiration date of the '461 Patent, including any extensions, adjustments, and exclusivities associated with the '461 Patent.

COUNT III
INFRINGEMENT OF THE '416 PATENT BY ANNORA

126. UCB restates, realleges, and incorporates by reference paragraphs 1–125 as if fully set forth herein.

127. Annora has infringed claims 1 and 2 of the '416 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Annora's ANDA with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, or sale of a generic version of Briviact® tablets prior to the expiration of the '416 Patent. Claims 1 and 2 of the '416 Patent encompass a method of treating epilepsy comprising administering a therapeutic dose of brivaracetam. In Annora's Notice Letter, Annora has not contested infringement of claims 1 and 2 of the '416 Patent.

128. Annora's commercial manufacture, use, offer to sell, or sale of Annora's ANDA Product before the expiration of the '416 Patent would infringe claims 1 and 2 of the '416 Patent under 35 U.S.C. § 271.

129. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Annora's ANDA to be a date which is not any earlier than the expiration date of the '416 Patent, including any extensions, adjustments, and exclusivities associated with the '416 Patent.

COUNT IV
INFRINGEMENT OF THE '197 PATENT BY APOTEX

130. UCB restates, realleges, and incorporates by reference paragraphs 1–129 as if fully set forth herein.

131. On information and belief, Apotex submitted Apotex's ANDA to the FDA, and thereby seeks FDA approval of Apotex's ANDA Product.

132. Apotex has infringed at least claims 1 and 21 of the '197 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Apotex's ANDA with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, and sale of a generic version of Briviact® tablets prior to the expiration of the '197 Patent. At least claims 1 and 21 of the '197 Patent encompass brivaracetam. In Apotex's Notice Letter, Apotex has not contested infringement of claims 1 and 21 of the '197 Patent.

133. Apotex's commercial manufacture, use, offer to sell, or sale of Apotex's ANDA Product before the expiration of the '197 Patent would infringe one or more claims of the '197 Patent, including, but not limited to, claims 1 and 21, under 35 U.S.C. § 271.

134. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Apotex's ANDA to

be a date which is not any earlier than the expiration date of the '197 Patent, including any extensions, adjustments, and exclusivities associated with the '197 Patent.

COUNT V
INFRINGEMENT OF THE '461 PATENT BY APOTEX

135. UCB restates, realleges, and incorporates by reference paragraphs 1–134 as if fully set forth herein.

136. Apotex has infringed claims 1–5 of the '461 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Apotex's ANDA with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, and sale of a generic version of Briviact® tablets prior to the expiration of the '461 Patent. Claims 1 and 5 of the '461 Patent encompass brivaracetam, claim 2 of the '461 Patent encompasses pharmaceutical compositions comprising brivaracetam, and claims 3 and 4 of the '461 Patent encompass a method of treating epilepsy, among other conditions, comprising administering a therapeutic dose of brivaracetam. In Apotex's Notice Letter, Apotex has not contested infringement of claims 1, 2, and 5 of the '461 Patent.

137. Apotex's commercial manufacture, use, offer to sell, or sale of Apotex's ANDA Product before the expiration of the '461 Patent would infringe claims 1–5 of the '461 Patent under 35 U.S.C. § 271.

138. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Apotex's ANDA to be a date which is not any earlier than the expiration date of the '461 Patent, including any extensions, adjustments, and exclusivities associated with the '461 Patent.

COUNT VI
INFRINGEMENT OF THE '416 PATENT BY APOTEX

139. UCB restates, realleges, and incorporates by reference paragraphs 1–138 as if fully set forth herein.

140. Apotex has infringed claims 1 and 2 of the '416 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Apotex's ANDA with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, or sale of a generic version of Briviact® tablets prior to the expiration of the '416 Patent. Claims 1 and 2 of the '416 Patent encompass a method of treating epilepsy comprising administering a therapeutic dose of brivaracetam.

141. Apotex's commercial manufacture, use, offer to sell, or sale of Apotex's ANDA Product before the expiration of the '416 Patent would infringe claims 1 and 2 of the '416 Patent under 35 U.S.C. § 271.

142. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Apotex's ANDA to be a date which is not any earlier than the expiration date of the '416 Patent, including any extensions, adjustments, and exclusivities associated with the '416 Patent.

COUNT VII
INFRINGEMENT OF THE '197 PATENT BY AUROBINDO

143. UCB restates, realleges, and incorporates by reference paragraphs 1–142 as if fully set forth herein.

144. On information and belief, Aurobindo submitted Aurobindo's ANDA to the FDA, and thereby seeks FDA approval of Aurobindo's ANDA Product.

145. Aurobindo has infringed at least claims 1 and 21 of the '197 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Aurobindo's ANDA with a Paragraph IV certification and thereby

seeking FDA approval for the commercial manufacture, use, offer to sell, and sale of a generic version of Briviact® tablets prior to the expiration of the '197 Patent. At least claims 1 and 21 of the '197 Patent encompass brivaracetam. In Aurobindo's Notice Letter, Aurobindo has not contested infringement of claims 1 and 21 of the '197 Patent.

146. Aurobindo's commercial manufacture, use, offer to sell, or sale of Aurobindo's ANDA Product before the expiration of the '197 Patent would infringe one or more claims of the '197 Patent, including, but not limited to, claims 1 and 21, under 35 U.S.C. § 271.

147. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Aurobindo's ANDA to be a date which is not any earlier than the expiration date of the '197 Patent, including any extensions, adjustments, and exclusivities associated with the '197 Patent.

COUNT VIII
INFRINGEMENT OF THE '461 PATENT BY AUROBINDO

148. UCB restates, realleges, and incorporates by reference paragraphs 1–147 as if fully set forth herein.

149. Aurobindo has infringed claims 1–5 of the '461 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Aurobindo's ANDA with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, and sale of a generic version of Briviact® tablets prior to the expiration of the '461 Patent. Claims 1 and 5 of the '461 Patent encompass brivaracetam, claim 2 of the '461 Patent encompasses pharmaceutical compositions comprising brivaracetam, and claims 3 and 4 of the '461 Patent encompass a method of treating epilepsy, among other conditions, comprising administering a therapeutic dose of brivaracetam. In Aurobindo's Notice Letter, Aurobindo has not contested infringement of claims 1–5 of the '461 Patent.

150. Aurobindo's commercial manufacture, use, offer to sell, or sale of Aurobindo's ANDA Product before the expiration of the '461 Patent would infringe claims 1–5 of the '461 Patent under 35 U.S.C. § 271.

151. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, inter alia, an order of this Court that the FDA set the effective date of approval for Aurobindo's ANDA to be a date which is not any earlier than the expiration date of the '461 Patent, including any extensions, adjustments, and exclusivities associated with the '461 Patent.

COUNT IX
INFRINGEMENT OF THE '197 PATENT BY LUPIN

152. UCB restates, realleges, and incorporates by reference paragraphs 1–151 as if fully set forth herein.

153. On information and belief, Lupin submitted Lupin's ANDA to the FDA, and thereby seeks FDA approval of Lupin's ANDA Product.

154. Lupin has infringed at least claims 1 and 21 of the '197 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Lupin's ANDA with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, and sale of a generic version of Briviact® tablets prior to the expiration of the '197 Patent. At least claims 1 and 21 of the '197 Patent encompass brivaracetam. In Lupin's Notice Letter, Lupin has not contested infringement of claims 1 and 21 of the '197 Patent.

155. Lupin's commercial manufacture, use, offer to sell, or sale of Lupin's ANDA Product before the expiration of the '197 Patent would infringe one or more claims of the '197 Patent, including, but not limited to, claims 1 and 21, under 35 U.S.C. § 271.

156. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Lupin's ANDA to

be a date which is not any earlier than the expiration date of the '197 Patent, including any extensions, adjustments, and exclusivities associated with the '197 Patent.

COUNT X
INFRINGEMENT OF THE '461 PATENT BY LUPIN

157. UCB restates, realleges, and incorporates by reference paragraphs 1–156 as if fully set forth herein.

158. Lupin has infringed claims 1–5 of the '461 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Lupin's ANDA with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, and sale of a generic version of Briviact® tablets prior to the expiration of the '461 Patent. Claims 1 and 5 of the '461 Patent encompass brivaracetam, claim 2 of the '461 Patent encompasses pharmaceutical compositions comprising brivaracetam, and claims 3 and 4 of the '461 Patent encompass a method of treating epilepsy, among other conditions, comprising administering a therapeutic dose of brivaracetam. In Lupin's Notice Letter, Lupin has not contested infringement of claims 1–5 of the '461 Patent.

159. Lupin's commercial manufacture, use, offer to sell, or sale of Lupin's ANDA Product before the expiration of the '461 Patent would infringe claims 1–5 of the '461 Patent under 35 U.S.C. § 271.

160. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Lupin's ANDA to be a date which is not any earlier than the expiration date of the '461 Patent, including any extensions, adjustments, and exclusivities associated with the '461 Patent.

COUNT XI
INFRINGEMENT OF THE '197 PATENT BY MICRO LABS

161. UCB restates, realleges, and incorporates by reference paragraphs 1–160 as if fully set forth herein.

162. On information and belief, Micro Labs submitted Micro Labs's ANDA to the FDA, and thereby seeks FDA approval of Micro Labs's ANDA Product.

163. Micro Labs has infringed at least claims 1 and 21 of the '197 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Micro Labs's ANDA with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, and sale of a generic version of Briviact® intravenous solution prior to the expiration of the '197 Patent. At least claims 1 and 21 of the '197 Patent encompass brivaracetam. In Micro Labs's Notice Letter, Micro Labs has not contested infringement of claims 1 and 21 of the '197 Patent.

164. Micro Labs's commercial manufacture, use, offer to sell, or sale of Micro Labs's ANDA Product before the expiration of the '197 Patent would infringe one or more claims of the '197 Patent, including, but not limited to, claims 1 and 21, under 35 U.S.C. § 271.

165. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Micro Labs's ANDA to be a date which is not any earlier than the expiration date of the '197 Patent, including any extensions, adjustments, and exclusivities associated with the '197 Patent.

COUNT XII
INFRINGEMENT OF THE '461 PATENT BY MICRO LABS

166. UCB restates, realleges, and incorporates by reference paragraphs 1–165 as if fully set forth herein.

167. Micro Labs has infringed claims 1–5 of the '461 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Micro Labs's ANDA with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, and sale of a generic version of Briviact® intravenous solution prior to the expiration of the '461 Patent. Claims 1 and 5 of the '461 Patent encompass brivaracetam, claim 2 of the '461 Patent encompasses

pharmaceutical compositions comprising brivaracetam, and claims 3 and 4 of the '461 Patent encompass a method of treating epilepsy, among other conditions, comprising administering a therapeutic dose of brivaracetam. In Micro Labs's Notice Letter, Micro Labs has not contested infringement of claims 1–5 of the '461 Patent.

168. Micro Labs's commercial manufacture, use, offer to sell, or sale of Micro Labs's ANDA Product before the expiration of the '461 Patent would infringe claims 1–5 of the '461 Patent under 35 U.S.C. § 271.

169. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Micro Labs's ANDA to be a date which is not any earlier than the expiration date of the '461 Patent, including any extensions, adjustments, and exclusivities associated with the '461 Patent.

COUNT XIII
INFRINGEMENT OF THE '416 PATENT BY MICRO LABS

170. UCB restates, realleges, and incorporates by reference paragraphs 1–169 as if fully set forth herein.

171. Micro Labs has infringed claims 1 and 2 of the '416 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Micro Labs's ANDA with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, or sale of a generic version of Briviact® intravenous solution prior to the expiration of the '416 Patent. Claims 1 and 2 of the '416 Patent encompass a method of treating epilepsy comprising administering a therapeutic dose of brivaracetam. In Micro Labs's Notice Letter, Micro Labs has not contested infringement of claims 1 and 2 of the '416 Patent.

172. Micro Labs's commercial manufacture, use, offer to sell, or sale of Micro Labs's ANDA Product before the expiration of the '416 Patent would infringe claims 1 and 2 of the '416 Patent under 35 U.S.C. § 271.

173. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Micro Labs's ANDA to be a date which is not any earlier than the expiration date of the '416 Patent, including any extensions, adjustments, and exclusivities associated with the '416 Patent.

COUNT XIV
INFRINGEMENT OF THE '197 PATENT BY MSN

174. UCB restates, realleges, and incorporates by reference paragraphs 1–173 as if fully set forth herein.

175. On information and belief, MSN submitted MSN's ANDAs to the FDA, and thereby seeks FDA approval of MSN's ANDA Products.

176. MSN has infringed at least claims 1 and 21 of the '197 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting MSN's ANDAs with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, and sale of generic versions of Briviact® tablets, oral solution, and intravenous solution, prior to the expiration of the '197 Patent. At least claims 1 and 21 of the '197 Patent encompass brivaracetam. In MSN's Notice Letters, MSN has not contested infringement of claims 1 and 21 of the '197 Patent.

177. MSN's commercial manufacture, use, offer to sell, or sale of MSN's ANDA Products before the expiration of the '197 Patent would infringe one or more claims of the '197 Patent, including, but not limited to, claims 1 and 21, under 35 U.S.C. § 271.

178. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for MSN's ANDAs to

be a date which is not any earlier than the expiration date of the '197 Patent, including any extensions, adjustments, and exclusivities associated with the '197 Patent.

COUNT XV
INFRINGEMENT OF THE '461 PATENT BY MSN

179. UCB restates, realleges, and incorporates by reference paragraphs 1–178 as if fully set forth herein.

180. MSN has infringed claims 1–5 of the '461 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting MSN's ANDAs with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, and sale of generic versions of Briviact® tablets, oral solution, and intravenous solution, prior to the expiration of the '461 Patent. Claims 1 and 5 of the '461 Patent encompass brivaracetam, claim 2 of the '461 Patent encompasses pharmaceutical compositions comprising brivaracetam, and claims 3 and 4 of the '461 Patent encompass a method of treating epilepsy, among other conditions, comprising administering a therapeutic dose of brivaracetam. In MSN's Notice Letters, MSN has not contested infringement of claims 1, 2, and 5 of the '461 Patent.

181. MSN's commercial manufacture, use, offer to sell, or sale of MSN's ANDA Products before the expiration of the '461 Patent would infringe claims 1–5 of the '461 Patent under 35 U.S.C. § 271.

182. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for MSN's ANDAs to be a date which is not any earlier than the expiration date of the '461 Patent, including any extensions, adjustments, and exclusivities associated with the '461 Patent.

COUNT XVI
INFRINGEMENT OF THE '416 PATENT BY MSN

183. UCB restates, realleges, and incorporates by reference paragraphs 1–182 as if fully set forth herein.

184. MSN has infringed claims 1 and 2 of the '416 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting MSN's ANDAs with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, or sale of generic versions of Briviact® tablets, oral solution, and intravenous solution, prior to the expiration of the '416 Patent. Claims 1 and 2 of the '416 Patent encompass a method of treating epilepsy comprising administering a therapeutic dose of brivaracetam.

185. MSN's commercial manufacture, use, offer to sell, or sale of MSN's ANDA Products before the expiration of the '416 Patent would infringe claims 1 and 2 of the '416 Patent under 35 U.S.C. § 271.

186. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for MSN's ANDAs to be a date which is not any earlier than the expiration date of the '416 Patent, including any extensions, adjustments, and exclusivities associated with the '416 Patent

COUNT XVII
INFRINGEMENT OF THE '197 PATENT BY ZYDUS

187. UCB restates, realleges, and incorporates by reference paragraphs 1–186 as if fully set forth herein.

188. On information and belief, Zydus submitted Zydus's ANDA to the FDA, and thereby seeks FDA approval of Zydus's ANDA Product.

189. Zydus has infringed at least claims 1 and 21 of the '197 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Zydus's ANDA with a Paragraph IV certification and thereby

seeking FDA approval for the commercial manufacture, use, offer to sell, and sale of a generic version of Briviact® tablets prior to the expiration of the '197 Patent. At least claims 1 and 21 of the '197 Patent encompass brivaracetam. In Zydus's Notice Letter, Zydus has not contested infringement of claims 1 and 21 of the '197 Patent.

190. Zydus's commercial manufacture, use, offer to sell, or sale of Zydus's ANDA Product before the expiration of the '197 Patent would infringe one or more claims of the '197 Patent, including, but not limited to, claims 1 and 21, under 35 U.S.C. § 271.

191. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Zydus's ANDA to be a date which is not any earlier than the expiration date of the '197 Patent, including any extensions, adjustments, and exclusivities associated with the '197 Patent.

COUNT XVIII
INFRINGEMENT OF THE '461 PATENT BY ZYDUS

192. UCB restates, realleges, and incorporates by reference paragraphs 1–191 as if fully set forth herein.

193. Zydus has infringed claims 1–5 of the '461 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Zydus's ANDA with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, and sale of a generic version of Briviact® tablets, prior to the expiration of the '461 Patent. Claims 1 and 5 of the '461 Patent encompass brivaracetam, claim 2 of the '461 Patent encompasses pharmaceutical compositions comprising brivaracetam, and claims 3 and 4 of the '461 Patent encompass a method of treating epilepsy, among other conditions, comprising administering a therapeutic dose of brivaracetam. In Zydus's Notice Letter, Zydus has not contested infringement of claim 5 of the '461 Patent.

194. Zydus's commercial manufacture, use, offer to sell, or sale of Zydus's ANDA Product before the expiration of the '461 Patent would infringe claims 1–5 of the '461 Patent under 35 U.S.C. § 271.

195. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Zydus's ANDA to be a date which is not any earlier than the expiration date of the '461 Patent, including any extensions, adjustments, and exclusivities associated with the '461 Patent.

COUNT XIX
INFRINGEMENT OF THE '416 PATENT BY ZYDUS

196. UCB restates, realleges, and incorporates by reference paragraphs 1–195 as if fully set forth herein.

197. Zydus has infringed claims 1 and 2 of the '416 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Zydus's ANDA with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, or sale of a generic version of Briviact® tablets prior to the expiration of the '416 Patent. Claims 1 and 2 of the '416 Patent encompass a method of treating epilepsy comprising administering a therapeutic dose of brivaracetam. In Zydus's Notice Letter, Zydus has not contested infringement of claims 1 and 2 of the '416 Patent.

198. Zydus's commercial manufacture, use, offer to sell, or sale of Zydus's ANDA Product before the expiration of the '416 Patent would infringe claims 1 and 2 of the '416 Patent under 35 U.S.C. § 271.

199. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Zydus's ANDA to

be a date which is not any earlier than the expiration date of the '416 Patent, including any extensions, adjustments, and exclusivities associated with the '416 Patent.

REQUEST FOR RELIEF

WHEREFORE, UCB prays for a judgment in its favor and against Defendants and respectfully requests the following relief:

(A) A judgment that Annora has infringed one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 214831;

(B) A judgment that the commercial manufacture, use, offer to sell, or sale, or importation into the United States, of Annora's ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the Patents-in-Suit pursuant to 35 U.S.C. § 271;

(C) A judgment that Apotex has infringed one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 214875;

(D) A judgment that the commercial manufacture, use, offer to sell, or sale, or importation into the United States, of Apotex's ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the Patents-in-Suit pursuant to 35 U.S.C. § 271;

(E) A judgment that Aurobindo has infringed one or more claims of each of the '197 and '461 Patents under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 214848;

(F) A judgment that the commercial manufacture, use, offer to sell, or sale, or importation into the United States, of Aurobindo's ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the '197 and '461 Patents pursuant to 35 U.S.C. § 271;

(G) A judgment that Lupin has infringed one or more claims of each of the '197 and '461 Patents under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 214918;

(H) A judgment that the commercial manufacture, use, offer to sell, or sale, or importation into the United States, of Lupin's ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the '197 and '461 Patents pursuant to 35 U.S.C. § 271;

(I) A judgment that Micro Labs has infringed one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 214880;

(J) A judgment that the commercial manufacture, use, offer to sell, or sale, or importation into the United States, of Micro Labs's ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the Patents-in-Suit pursuant to 35 U.S.C. § 271;

(K) A judgment that MSN has infringed one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271(e)(2) by submitting ANDA Nos. 214922, 214924, and 214921;

(L) A judgment that the commercial manufacture, use, offer to sell, or sale, or importation into the United States, of MSN's ANDA Products, or inducing or contributing to such conduct, would constitute infringement of the Patents-in-Suit pursuant to 35 U.S.C. § 271;

(M) A judgment that Zydus has infringed one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 214501;

(N) A judgment that the commercial manufacture, use, offer to sell, or sale, or importation into the United States, of Zydus's ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the Patents-in-Suit pursuant to 35 U.S.C. § 271;

(O) Entry of preliminary and permanent injunctions enjoining Defendants, their officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in active concert or participation with any of them or on their behalf, from commercially manufacturing, using, offering for sale, or selling Defendants' ANDA Products within the United States, or importing Defendants' ANDA Products into the United States, until the expiration of the

Patents-in-Suit, including any extensions, adjustments, and exclusivities applicable to the Patents-in-Suit, and from otherwise infringing the claims of the Patents-in-Suit;

(P) An order that the effective date of any approval of any of Defendants' ANDAs be a date that is not earlier than the expiration of the Patents-in-Suit, including any extensions, adjustments, and exclusivities associated with the Patents-in-Suit;

(Q) An award of damages or other monetary relief, together with interest, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Products, or any product that infringes the Patents-in-Suit, or induces or contributes to such conduct, prior to the expiration of the Patents-in-Suit including any extensions, adjustments, and exclusivities applicable to the Patents-in-Suit;

(R) A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to UCB its reasonable attorneys' fees;

(S) Awarding UCB its costs and expenses in this action; and

(T) Granting any and all other relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

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