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

SUMITOMO DAINIPPON PHARMA CO., LTD. and SUNOVION PHARMACEUTICALS INC., Plaintiffs, v. AUROBINDO PHARMA LTD., DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC., LUPIN LTD., TEVA PHARMACEUTICALS USA, INC., MSN LABORATORIES PRIVATE LTD., SUN PHARMA GLOBAL FZE, ACCORD HEALTHCARE INC., AMNEAL PHARMACEUTICALS, LLC, FIRST TIME US GENERICS, LLC, INVAGEN PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC., TORRENT PHARMACEUTICALS LTD., WATSON LABORATORIES INC., ZYDUS PHARMACEUTICALS (USA) INC., JUBILANT GENERICS, LTD. Defendants.	Civil Action No. _____

PLAINTIFFS SUMITOMO DAINIPPON PHARMA CO., LTD. AND SUNOVION PHARMACEUTICALS INC.'S
COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo") and Sunovion Pharmaceuticals Inc. ("Sunovion") (collectively, "Plaintiffs"), for their complaint against Defendants Aurobindo Pharma Ltd. ("Aurobindo"); Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") and Dr. Reddy's Laboratories, Inc. ("DRL Inc.") (collectively, "DRL"); Lupin Ltd. ("Lupin"); Teva Pharmaceuticals USA, Inc. ("Teva"); MSN Laboratories Private Ltd. ("MSN"); Sun Pharma Global FZE ("Sun"); Accord Healthcare, Inc. ("Accord"); Amneal Pharmaceuticals,

LLC ("Amneal"); First Time US Generics, LLC ("FTUG"); InvaGen Pharmaceuticals, Inc. ("InvaGen"); Par Pharmaceutical, Inc. ("Par"); Torrent Pharmaceuticals Ltd. ("Torrent"); Watson Laboratories, Inc. ("Watson"); Zydus Pharmaceuticals (USA) Inc. ("Zydus"); and Jubilant Generics, Ltd. ("Jubilant") (collectively, "Defendants") allege as follows:

NATURE OF ACTION

1. This is an action for infringement of United States Patent No. 9,815,827 (the "'827 patent") under 35 U.S.C. § 271(e)(2) and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §§ 271(b) and (c) relating to Plaintiffs' commercially successful product, Latuda®. A true and accurate copy of the '827 patent is attached hereto as Exhibit A.

THE PARTIES

Plaintiffs

2. Plaintiff Sumitomo is a company organized and existing under the laws of Japan, with a principal place of business at 6-8, Doshomachi 2-chome, Chuo-ku, Osaka, Osaka 541-0045, Japan.

3. Plaintiff Sunovion is a corporation organized and existing under the laws of Delaware, with a principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

Defendant Aurobindo

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

5. On information and belief, Aurobindo is in the business of developing, manufacturing, distributing and selling generic drugs throughout the United States, including in the District of New Jersey. On further information and belief, Aurobindo is working to achieve final approval by the U.S. Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 208045.

The DRL Defendants

6. On information and belief, Defendant DRL Ltd. is a company organized and existing under the laws of India, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad Telangana 500 034, India.

7. On information and belief, Defendant DRL Inc. is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at 107 College Road East, Princeton, New Jersey, 08540.

8. On information and belief, DRL Inc. is a wholly-owned subsidiary of DRL Ltd.

9. On information and belief, DRL is in the business of developing, manufacturing, distributing and selling generic drugs throughout the United States, including in the District of New Jersey. On further information and belief, DRL is working to achieve final approval by the FDA of ANDA No. 208047.

Defendant Lupin

10. On information and belief, Defendant Lupin is a company organized and existing under the laws of India, with a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India.

11. On information and belief, Lupin is in the business of developing, manufacturing, distributing, and selling generic drugs throughout the United States, including in the District of

New Jersey. On further information and belief, Lupin is working to achieve final approval by the FDA of ANDA No. 208031.

Defendant Teva

12. On information and belief, Defendant Teva is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

13. On information and belief, Teva is in the business of developing, manufacturing, distributing, and selling generic drugs throughout the United States, including in the District of New Jersey. On further information and belief, Teva is working to achieve final approval by the FDA of ANDA No. 208060.

Defendant MSN

14. On information and belief, Defendant MSN is a company organized and existing under the laws of India with a principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad – 18, Telangana, India.

15. On information and belief, MSN is in the business of developing, manufacturing, distributing and selling generic drugs throughout the United States, including in the District of New Jersey. On further information and belief, MSN is working to achieve final approval by the FDA of ANDA No. 208037.

Defendant Sun

16. On information and belief, Defendant Sun is a company organized and existing under the laws of the United Arab Emirates, having a principal place of business at Office #43, Block Y, SAIF Zone, P.O. Box 122304, Sharjah, United Arab Emirates.

17. On information and belief, Sun is in the business of developing, manufacturing, distributing, and selling generic drugs throughout the United States, including in the District of New Jersey. On further information and belief, Sun is working to achieve final approval by the FDA of ANDA No. 208066.

Defendant Accord

18. On information and belief, Defendant Accord is a corporation organized and existing under the laws of the State of North Carolina with a principal place of business at 1009 Slater Rd., Suite 210-B, Durham, North Carolina 27703.

19. On information and belief, Accord is in the business of developing, manufacturing, distributing, and selling generic drugs throughout the United States, including in the District of New Jersey. On further information and belief, Accord is working to achieve final approval by the FDA of ANDA No. 208049.

Defendant Amneal

20. On information and belief, Defendant Amneal is a limited liability company organized under the laws of Delaware, having a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

21. On information and belief, Amneal is in the business of manufacturing, distributing, and selling generic drugs throughout the United States, including in the District of New Jersey. On further information and belief, Amneal is working to achieve final approval by the FDA of ANDA No. 208002.

Defendant FTUG

22. On information and belief, Defendant FTUG is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 505 Park Way, Suite 6, Broomall, Pennsylvania 19008.

23. On information and belief, FTUG is in the business of developing, manufacturing, distributing, and selling generic drugs throughout the United States, including in the District of New Jersey. On further information and belief, FTUG is working to achieve final approval by the FDA of ANDA No. 207995.

Defendant InvaGen

24. On information and belief, Defendant InvaGen is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 7 Oser Avenue, Hauppauge, New York 11788.

25. On information and belief, InvaGen is in the business of developing, manufacturing, distributing, and selling generic drugs throughout the United States, including in the District of New Jersey. On information and belief, InvaGen is working to achieve final approval by the FDA of ANDA No. 208028.

Defendant Par

26. On information and belief, Defendant Par is a corporation organized and existing under the laws of the State of New York with a principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977.

27. On information and belief, Par is in the business of developing, manufacturing, distributing, and selling generic drugs throughout the United States, including in the District of New Jersey. On further information and belief, Par is working to achieve final approval by the FDA of ANDA No. 207948.

Defendant Torrent

28. On information and belief, Defendant Torrent is a company organized and existing under the laws of India with a principal place of business at Torrent Tower, Fourth Floor, Off. Ashram Road, Ahmedabad 380 009, Gujarat, India.

29. On information and belief, Torrent is in the business of developing, manufacturing, distributing, and selling generic drugs throughout the United States, including in the District of New Jersey. On further information and belief, Torrent is working to achieve final approval by the FDA of ANDA No. 208055.

Defendant Watson

30. On information and belief, Defendant Watson is a corporation organized and existing under the laws of the State of Nevada, with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

31. On information and belief, Watson is in the business of developing, manufacturing, distributing, and selling generic drugs throughout the United States, including in the District of New Jersey. On further information and belief, Watson is working to achieve final approval by the FDA of ANDA No. 208016.

Defendant Zydus

32. On information and belief, Defendant Zydus is a corporation organized and existing under the laws of the State of New Jersey with a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

33. On information and belief, Zydus is in the business of developing, manufacturing, distributing, and selling generic drugs throughout the United States, including in the District of

New Jersey. On further information and belief, Zydus is working to achieve final approval by the FDA of ANDA No. 208052.

Defendant Jubilant

34. On information and belief, Jubilant is a company organized and existing under the laws of India, with a principal place of business at 1A, Sector 16A, Noida 201 301, Uttar Pradesh, India.

35. On information and belief, Jubilant is in the business of developing, manufacturing, distributing and selling generic drugs throughout the United States, including in the District of New Jersey. On further information and belief, Jubilant is working to achieve final approval by the FDA of ANDA No. 210388.

JURISDICTION AND VENUE

36. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.*, including §§ 271(e)(2), 271(b), 271(c), and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

* * * * *

Jurisdiction and Venue for Defendant Aurobindo

37. This Court has personal jurisdiction over Aurobindo by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Aurobindo regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Aurobindo derives substantial revenue from the sale of pharmaceutical products in New Jersey and has availed itself of the privilege of

conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of Aurobindo's filing of its ANDA and the causes of action Plaintiffs raise here, as alleged herein.

38. Further, this Court has personal jurisdiction over Aurobindo because Aurobindo has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, Aurobindo intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, Aurobindo, either directly or through its subsidiaries, agents, and/or affiliates manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, Aurobindo developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, Aurobindo filed ANDA No. 208045, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

39. On information and belief, Aurobindo intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

40. On information and belief, Aurobindo's conduct has or will cause foreseeable harm and injury to Plaintiffs.

41. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were Aurobindo to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

42. Further, this Court has personal jurisdiction over Aurobindo because Aurobindo has previously been sued in this district and has not challenged personal jurisdiction, and Aurobindo has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Janssen Prod., L.P. v. Aurobindo Pharma Ltd.*, Civ. No. 17-6872 (D.N.J.); *Takeda Pharm. Co. Ltd. v. Aurobindo Pharma Ltd.*, Civ. No. 15-7635 (D.N.J.); *The Medicines Co. v. Aurobindo Pharma Ltd.*, Civ. No. 14-2367 (D.N.J.); *Otsuka Pharm. Co., Ltd. v. Aurobindo Pharma Ltd.*, Civ. No. 14-6890 (D.N.J.).

43. Alternatively, to the extent the above facts do not establish personal jurisdiction over Aurobindo, this Court may exercise jurisdiction over Aurobindo pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Aurobindo would be a foreign defendant not subject to personal jurisdiction in the courts of any State; (c) Aurobindo has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling pharmaceutical products that are distributed throughout the United States; and (d) Aurobindo filed an ANDA with the FDA and sent notice of its Paragraph IV certification to an entity in New Jersey, such that this Court's exercise of jurisdiction over Aurobindo satisfies due process.

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

45. Venue is proper in this district under 28 U.S.C. § 1400(b) because Aurobindo "committed an act of infringement" in this district. On information and belief, Aurobindo submitted ANDA No. 208045 pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetics Act ("FFDCA") (codified at 21 U.S.C. § 355(j)), and, upon receiving final approval of such ANDA, will manufacture, sell, offer to sell, and/or import Aurobindo's proposed generic

lurasidone hydrochloride tablets in the United States, including in the District of New Jersey. Thus, Aurobindo has committed an act of infringement in this district.

Jurisdiction and Venue for the DRL Defendants

46. This Court has personal jurisdiction over DRL Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, DRL Ltd. regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, such subsidiaries and/or affiliates include DRL, Inc. On information and belief, DRL Ltd. derives substantial revenue from the sale of pharmaceutical products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of DRL Ltd.'s filing of its ANDA (submitted, on information and belief, in concert with DRL Inc.) and the causes of action Plaintiffs raise here, as alleged herein.

47. On information and belief, DRL Ltd. wholly owns DRL Inc.

48. Further, this Court has personal jurisdiction over DRL Ltd. because DRL Ltd. has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, DRL Ltd. intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, DRL Ltd., either directly or through its subsidiaries, agents, and/or affiliates, manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, DRL Ltd. developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, DRL Ltd., in concert with DRL Inc., filed ANDA No. 208047, seeking approval from

the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

49. On information and belief, DRL Ltd. intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

50. On information and belief, DRL Ltd.'s conduct has or will cause foreseeable harm and injury to Plaintiffs.

51. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were DRL Ltd. to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

52. Further, this Court has personal jurisdiction over DRL Ltd. because DRL Ltd. has previously been sued in this district and has not challenged personal jurisdiction, and DRL Ltd. has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Teva Pharms. USA, Inc. v. Dr. Reddy's Labs. Ltd.*, Civ. No. 17-517 (D.N.J.); *Dexcel Pharma Techs. Ltd. v. Dr. Reddy's Labs. Ltd.*, Civ. No. 15-8042 (D.N.J.); *Alcon Labs. Inc. v. Dr. Reddy's Labs. Ltd.*, Civ. No. 16-6775 (D.N.J.).

53. Alternatively, to the extent the above facts do not establish personal jurisdiction over DRL Ltd., this Court may exercise jurisdiction over DRL Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) DRL Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; (c) DRL Ltd. has

sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling pharmaceutical products that are distributed throughout the United States; and (d) DRL Ltd. filed an ANDA with the FDA and sent notice of its Paragraph IV certification to an entity in New Jersey, such that this Court's exercise of jurisdiction over DRL Ltd. satisfies due process.

54. This Court has personal jurisdiction over DRL Inc. by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, DRL Inc. regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, DRL Inc. derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of DRL Inc.'s filing of its ANDA (submitted, on information and belief, in concert with DRL Ltd.) and the causes of action Plaintiffs raise here, as alleged herein.

55. On information and belief, DRL Inc. is incorporated under the laws of the State of New Jersey. On information and belief, DRL Inc. has its principal place of business at 107 College Road East, Princeton, New Jersey 08540. On information and belief, DRL Inc. conducts business in New Jersey as a pharmaceutical manufacturer and wholesaler (New Jersey Business Entity ID No. 0100518911). On information and belief, DRL Inc. is currently licensed to do business with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals in the State of New Jersey (License No. 5002312).

56. Further, this Court has personal jurisdiction over DRL Inc. because DRL Inc. committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and on information and belief, DRL Inc. intends a future course of conduct that includes acts of patent infringement in

New Jersey. On information and belief, DRL Inc., either directly or through its subsidiaries, agents, and/or affiliates, manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, DRL Inc. developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, DRL Inc., in concert with DRL Ltd., filed ANDA No. 208047, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

57. On information and belief, DRL Inc. intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

58. On information and belief, DRL Inc.'s conduct has or will cause foreseeable harm and injury to Plaintiffs.

59. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were DRL, Inc. to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

60. Further, this Court has personal jurisdiction over DRL Inc. because DRL Inc. has previously been sued in this district and has not challenged personal jurisdiction, and DRL Inc. has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Teva Pharms. USA, Inc. v. Dr. Reddy's Labs., Ltd.*, Civ. No. 17-517 (D.N.J.);

Celgene Corp. v. Dr. Reddy's Labs. Inc., Civ. No. 16-7704 (D.N.J.); *Alcon Pharms. Ltd. v. Dr. Reddy's Labs. Inc.*, Civ. No. 15-5756 (D.N.J.).

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

62. Venue is proper in this district under 28 U.S.C. § 1400(b) because DRL Ltd. "committed an act of infringement" in this district. On information and belief, DRL Ltd., in concert with DRL Inc., submitted ANDA No. 208047 pursuant to Section 505(j) of the FFDCA, and, upon receiving final approval of its ANDA, will manufacture, sell, offer to sell, and/or import DRL's proposed generic lurasidone hydrochloride tablets in the United States, including in the District of New Jersey. Thus, DRL Ltd. has committed an act of infringement in this district.

63. Venue is also proper in this district under 28 U.S.C. § 1400(b) because DRL Ltd.'s subsidiary, DRL Inc., resides in New Jersey. Further, venue is proper in this district because DRL Ltd. has a "regular and established place of business" in this district. DRL Ltd.'s subsidiary, DRL Inc., has a principal place of business at 107 College Road East, Princeton, New Jersey 08540. Further, venue is proper in this district because DRL Ltd.'s subsidiary, DRL Inc., is currently licensed to do business with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals in the State of New Jersey (License No. 5002312).

64. Venue is proper in this district under 28 U.S.C. § 1400(b) because DRL Inc. "committed an act of infringement" in this district. On information and belief, DRL Inc., in concert with DRL Ltd., submitted ANDA No. 208047 pursuant to Section 505(j) of the FFDCA, and, upon receiving final approval of its ANDA, will manufacture, sell, offer to sell, and/or

import DRL's proposed generic lurasidone hydrochloride tablets in the United States, including in the District of New Jersey. Thus, DRL Inc. has committed an act of infringement in this district.

65. Venue is also proper in this district under 28 U.S.C. § 1400(b) because New Jersey is the judicial district in which DRL Inc. resides.

66. Further, venue is proper in this district under 28 U.S.C. § 1400(b) because DRL Inc. has a "regular and established place of business" in this district. On information and belief, DRL Inc. has a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

Jurisdiction and Venue for Defendant Lupin

67. This Court has personal jurisdiction over Lupin by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Lupin regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Lupin derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of Lupin's filing of its ANDA and the causes of action Plaintiffs raise here, as alleged herein.

68. Further, this Court has personal jurisdiction over Lupin because Lupin has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, Lupin intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Lupin manufactures, sells, offers for sale, markets, distributes, and/or imports versions

of pharmaceutical products in the United States, including New Jersey. On information and belief, Lupin developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, Lupin filed ANDA No. 208031, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

69. On information and belief, Lupin intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

70. On information and belief, Lupin's conduct has or will cause foreseeable harm and injury to Plaintiffs.

71. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were Lupin to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

72. Further, this Court has personal jurisdiction over Lupin because Lupin has previously been sued in this district and has not challenged personal jurisdiction, and Lupin has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Horizon Therapeutics LLC v. Lupin Ltd.*, Civ. No. 17-5900 (D.N.J.); *AstraZeneca AB v. Lupin Ltd.*, Civ. No. 15-6092 (D.N.J.); *Senju Pharm Co. v. Lupin Ltd.*, Civ. No, 16-1097 (D.N.J.).

73. Alternatively, to the extent the above facts do not establish personal jurisdiction over Lupin, this Court may exercise jurisdiction over Lupin pursuant to Fed. R. Civ. P. 4(k)(2)

because: (a) Plaintiffs' claims arise under federal law; (b) Lupin would be a foreign defendant not subject to personal jurisdiction in the courts of any State; (c) Lupin has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling pharmaceutical products that are distributed throughout the United States; and (d) Lupin filed an ANDA with the FDA and sent notice of its Paragraph IV certification to an entity in New Jersey, such that this Court's exercise of jurisdiction over Lupin satisfies due process.

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

75. Venue is proper in this district under 28 U.S.C. § 1400(b) because Lupin "committed an act of infringement" in this district. On information and belief, Lupin submitted ANDA No. 208031 pursuant to Section 505(j) of the FFDCA, and, upon receiving approval of such ANDA, will manufacture, sell, offer to sell, and/or import Lupin's proposed generic lurasidone hydrochloride tablets in the United States, including in the District of New Jersey. Thus, Lupin has committed an act of infringement in this district.

Jurisdiction and Venue for Defendant Teva

76. This Court has personal jurisdiction over Teva by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Teva regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Teva derives substantial revenue from the sale of those products in New Jersey, and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of Teva's filing of ANDA No. 208060 and the causes of action Plaintiffs raise here, as alleged herein.

77. On information and belief, Teva is registered to do business in New Jersey (Business Entity ID No. 0100250184). On information and belief, Teva has at least three places of business in New Jersey: (1) 8 Gloria Lane, Fairfield, New Jersey 07004; (2) 208 Passaic Avenue, Fairfield, New Jersey 07004; (3) 2 University Plaza Drive No. 220, Hackensack, New Jersey 07601.

78. Further, this Court has personal jurisdiction over Teva because Teva has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, Teva intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, Teva directly or through its subsidiaries, agents, and/or affiliates, manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, Teva developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, Teva filed ANDA No. 208060, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

79. On information and belief, Teva intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

80. On information and belief, Teva's conduct has or will cause foreseeable harm and injury to Plaintiffs.

81. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were

Teva to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

82. Further, this Court has personal jurisdiction over Teva because Teva has previously been sued in this district and has not challenged personal jurisdiction, and Teva has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, Civ. No. 17-864 (D.N.J.); *Merck Sharp & Dohme Corp. v. Teva Pharms. USA, Inc.*, Civ. No. 17-6921 (D.N.J.); *BTG Int'l Ltd. v. Teva Pharms. USA, Inc.*, Civ. No. 17-6435 (D.N.J.); *Sucampo AG v. Teva Pharm. Industries, Ltd.*, Civ. No. 17-7451 (D.N.J.); *Boehringer Ingelheim Pharms., Inc. v. Teva Pharms. USA, Inc. et al.*, Civ. No. 17-11510 (D.N.J.); *Sebela Int'l Ltd. v. Actavis Labs. FL, Inc. et al.*, Civ. No. 17-4789 (D.N.J.).

83. Further, Teva has previously consented to personal jurisdiction in this district regarding ANDA No. 208060. *See Sumitomo Dainippon Pharma Co., Ltd. v. Teva Pharms. USA, Inc.*, Civ. No. 15-6401 (D.N.J).

84. In addition, Teva has previously elected to avail itself of the benefits of litigating its patent disputes in the District of New Jersey. *See, e.g.*, *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, Civ. No. 17-275 (D.N.J.); *Teva Pharms. USA, Inc. v. Dr. Reddy's Labs., Ltd.*, Civ. No. 17-517 (D.N.J.).

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

86. Venue is proper in this district under 28 U.S.C. § 1400(b) because Teva has at least three places of business in New Jersey: (1) 8 Gloria Lane, Fairfield, New Jersey 07004; (2) 208 Passaic Avenue, Fairfield, New Jersey 07004; (3) 2 University Plaza Drive No. 220,

Hackensack, New Jersey 07601. Further, venue is also proper in this district because Teva is currently licensed to do business with the New Jersey Department of Health as a "Wholesale[r]" (Registration No. 5003436) and a "Manufacturer and Wholesale[r]" of pharmaceuticals in New Jersey (Registration No. 5000583).

87. Venue is proper in this district under 28 U.S.C. § 1400(b) because Teva "committed an act of infringement" in this district. On information and belief, Teva submitted ANDA No. 208060 pursuant to Section 505(j) of the FFDCA, and, upon receiving final approval of such ANDA, will manufacture, sell, offer to sell, and/or import Teva's proposed generic lurasidone hydrochloride tablets in the United States, including in the District of New Jersey. Thus, Teva has committed an act of infringement in this district.

Jurisdiction and Venue for Defendant MSN

88. This Court has personal jurisdiction over MSN by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, MSN regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, MSN derives substantial revenue from the sale of pharmaceutical products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of MSN's filing of its ANDA and the causes of action Plaintiffs raise here, as alleged herein.

89. Further, this Court has personal jurisdiction over MSN because MSN has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, MSN intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, either directly or through its subsidiaries, agents, and/or

affiliates, MSN manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, MSN developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, MSN filed ANDA No. 208037, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

90. On information and belief, MSN intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

91. On information and belief, MSN's conduct has or will cause foreseeable harm and injury to Plaintiffs.

92. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were MSN to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

93. Further, this Court has personal jurisdiction over MSN because MSN has previously been sued in this district and has not challenged personal jurisdiction, and MSN has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Mitsubishi Tanabe Pharma Corp. v. MSN Labs. Private Ltd.*, Civ. No. 17-5302 (D.N.J.); *Forest Labs., LLC v. MSN Labs. Private Ltd.*, Civ. No. 17-10140 (D.N.J.).

94. Alternatively, to the extent the above facts do not establish personal jurisdiction over MSN, this Court may exercise jurisdiction over MSN pursuant to Fed. R. Civ. P. 4(k)(2)

because: (a) Plaintiffs' claims arise under federal law; (b) MSN would be a foreign defendant not subject to personal jurisdiction in the courts of any State; (c) MSN has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling pharmaceutical products that are distributed throughout the United States; and (d) MSN filed an ANDA with the FDA and sent notice of its Paragraph IV certification to an entity in New Jersey, such that this Court's exercise of jurisdiction over MSN satisfies due process.

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

96. Venue is proper in this district under 28 U.S.C. § 1400(b) because MSN "committed an act of infringement" in this district. On information and belief, MSN submitted ANDA No. 208037 pursuant to Section 505(j) of the FFDCA, and, upon receiving final approval of its ANDA, will manufacture, sell, offer to sell, and/or import MSN's proposed generic lurasidone hydrochloride tablets in the United States, including in the District of New Jersey. Thus, MSN has committed an act of infringement in this district.

Jurisdiction and Venue for Defendant Sun

97. This Court has personal jurisdiction over Sun by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Sun regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Sun derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of Sun's filing of its ANDA and the causes of action Plaintiffs raise here, as alleged herein.

98. Further, this Court has personal jurisdiction over Sun because Sun has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, Sun intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, Sun, directly or through its subsidiaries, agents, and/or affiliates, manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, Sun developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, Sun filed ANDA No. 208066, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

99. On information and belief, Sun intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

100. On information and belief, Sun's conduct has or will cause foreseeable harm and injury to Plaintiffs.

101. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were Sun to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

102. Further, this Court has personal jurisdiction over Sun because Sun has previously been sued in this district and has not challenged personal jurisdiction, and Sun has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*,

Dexcel Pharma Techs. Ltd. v. Sun Pharma Global FZE, Civ. No. 15-8017 (D.N.J.); *Takeda Pharm. Co. Ltd. v. Sun Pharma Global FZE*, Civ. No. 14-4616 (D.N.J.); *Depomed Inc. v. Sun Pharma Global FZE*, Civ. No. 11-3553 (D.N.J.).

103. In addition, Sun has previously elected to avail itself of the benefits of litigating its patent disputes in the District of New Jersey. *See, e.g.*, *Sun Pharma Global FZE v. Lupin Limited*, Civ. No. 18-02213 (D.N.J.).

104. Alternatively, to the extent the above facts do not establish personal jurisdiction over Sun, this Court may exercise jurisdiction over Sun pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Sun would be a foreign defendant not subject to personal jurisdiction in the courts of any State; (c) Sun has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling pharmaceutical products that are distributed throughout the United States; and (d) Sun filed an ANDA with the FDA and sent notice of its Paragraph IV certification to an entity in New Jersey, such that this Court's exercise of jurisdiction over Sun satisfies due process.

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

106. Venue is proper in this district under 28 U.S.C. § 1400(b) because Sun "committed an act of infringement" in this district. On information and belief, Sun submitted ANDA No. 208066 pursuant to Section 505(j) of the FFDCA, and, upon receiving final approval of its ANDA, will manufacture, sell, offer to sell, and/or import Sun's proposed generic lurasidone hydrochloride tablets in the United States, including in the District of New Jersey. Thus, Sun has committed an act of infringement in this district.

Jurisdiction and Venue for Defendant Accord

107. This Court has personal jurisdiction over Accord by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Accord regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Accord derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of Accord's filing of its ANDA and the causes of action Plaintiffs raise here, as alleged herein.

108. On information and belief, Accord is licensed with the State of New Jersey Department of Health as a "Manufacturer" of pharmaceuticals (Registration No. 5003815).

109. Further, this Court has personal jurisdiction over Accord because Accord committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and on information and belief, Accord intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Accord manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, Accord developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, Accord filed ANDA No. 208049, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

110. On information and belief, Accord intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

111. On information and belief, Accord's conduct has or will cause foreseeable harm and injury to Plaintiffs.

112. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were Accord to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

113. Further, this Court has personal jurisdiction over Accord because Accord has previously been sued in this district and has not challenged personal jurisdiction, and Accord has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Sanofi-Aventis US LLC v. Accord Healthcare, Inc.*, Civ. No. 14-8079 (D.N.J.); *Otsuka Pharm. Co. v. Intas Pharm. Ltd., Accord Healthcare, Inc.*, Civ. No. 14-3996 (D.N.J.).

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

115. Venue is proper in this district under 28 U.S.C. § 1400(b) because Accord "committed an act of infringement" in this district. On information and belief, Accord submitted ANDA No. 208049 pursuant to Section 505(j) of the FFDCA, and, upon receiving final approval of its ANDA, will manufacture, sell, offer to sell, and/or import Accord's proposed generic lurasidone hydrochloride tablets in the United States, including in the District of New Jersey. Thus, Accord has committed an act of infringement in this district.

Jurisdiction and Venue for Defendant Amneal

116. This Court has personal jurisdiction over Amneal by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Amneal regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Amneal derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of Amneal's filing of its ANDA and the causes of action Plaintiffs raise here, as alleged herein.

117. On information and belief, Amneal has a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. On information and belief, Amneal is licensed in New Jersey as a "Manufacturer and Wholesale[r]" (Reg. No. 5002991).

118. Further, this Court has personal jurisdiction over Amneal because Amneal has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, Amneal intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, Amneal manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, Amneal developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, Amneal prepared and filed ANDA No. 208002, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including in New Jersey.

119. On information and belief, Amneal intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such product by the FDA.

120. On information and belief, Amneal's conduct has or will cause foreseeable harm and injury to Plaintiffs.

121. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were Amneal to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

122. Further, this Court has personal jurisdiction over Amneal because Amneal has previously been sued in this district and has not challenged personal jurisdiction, and Amneal has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *AstraZeneca Pharms. LP v. Amneal Pharms. LLC*, Civ. No. 17-1968 (D.N.J.); *Sucampo AG v. Amneal Pharms. LLC*, Civ. No. 17-2577 (D.N.J.); *Jazz Pharms., Inc. v. Amneal Pharms. LLC*, Civ. No. 17-1440 (D.N.J.).

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

124. Venue is proper in this district under 28 U.S.C. § 1400(b) because Amneal "committed an act of infringement" in this district. Amneal submitted its ANDA No. 208002 pursuant to Section 505(j) of the FFDCA, and, upon receiving final approval of its ANDA, will manufacture, sell, offer to sell, and/or import Amneal's proposed generic lurasidone hydrochloride tablets in the United States, including in the District of New Jersey. Thus, Amneal has committed an act of infringement in this district.

125. Venue is proper in this district under 28 U.S.C. § 1400(b) because Amneal has a regular and established place of business in this district at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

Jurisdiction and Venue for Defendant FTUG

126. This Court has personal jurisdiction over FTUG by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, FTUG regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, FTUG derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of FTUG's filing of its ANDA and the causes of action Plaintiffs raise here, as alleged herein.

127. Further, this Court has personal jurisdiction over FTUG because FTUG has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, FTUG intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, FTUG manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, FTUG developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, FTUG filed ANDA No. 207995, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

128. On information and belief, FTUG intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

129. On information and belief, FTUG's conduct has or will cause foreseeable harm and injury to Plaintiffs.

130. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were FTUG to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

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

132. Venue is proper in this district under 28 U.S.C. § 1400(b) because FTUG "committed an act of infringement" in this district. On information and belief, FTUG submitted its ANDA No. 207995 pursuant to Section 505(j) of the FFDCA and, upon receiving final approval of its ANDA, will manufacture, sell, offer to sell, and/or import FTUG's proposed generic lurasidone hydrochloride tablets in the United States, including in the District of New Jersey. Thus, FTUG has committed an act of infringement in this district.

Jurisdiction and Venue for Defendant InvaGen

133. This Court has personal jurisdiction over InvaGen by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, InvaGen regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, InvaGen derives substantial revenue from the sale of

those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of InvaGen's filing of its ANDA and the causes of action Plaintiffs raise here, as alleged herein.

134. Further, this Court has personal jurisdiction over InvaGen because InvaGen has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, InvaGen intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, InvaGen manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, InvaGen developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, InvaGen filed ANDA No. 208028, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

135. On information and belief, InvaGen intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

136. On information and belief, InvaGen's conduct has or will cause foreseeable harm and injury to Plaintiffs.

137. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were InvaGen Inc. to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

138. Further, this Court has personal jurisdiction over InvaGen because InvaGen has previously been sued in this district and has not challenged personal jurisdiction, and InvaGen has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Mitsubishi Tanabe Pharma Corp. v. InvaGen Pharms. Inc.*, Civ. No. 17-6375 (D.N.J.); *Shire Dev. LLC. v. InvaGen Pharms. Inc.*, Civ. No. 15-367 (D.N.J.).

139. Further, InvaGen has previously consented to personal jurisdiction in this district regarding ANDA No. 208028. *See Sumitomo Dainippon Pharma Co., Ltd. v. InvaGen Pharms. Inc.*, Civ. No. 15-281 (D.N.J).

140. Further, InvaGen has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having previously transferred a case into this judicial district by stating that "personal jurisdiction exists in New Jersey over . . . InvaGen . . . ." *Roxane Labs., Inc. v. Camber Pharms., Inc.*, Civ. No. 14-4042 (D.N.J. Apr. 4, 2014) (ECF No. 28 at 18).

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

142. Venue is proper in this district under 28 U.S.C. § 1400(b) because InvaGen "committed an act of infringement" in this district. InvaGen submitted its ANDA No. 208028 pursuant to Section 505(j) of the FFDCA, and, upon receiving final approval of its ANDA, will manufacture, sell, offer to sell, and/or import InvaGen's proposed generic lurasidone hydrochloride tablets in the United States, including in the District of New Jersey. Thus, InvaGen has committed an act of infringement in this district.

Jurisdiction and Venue for Defendant Par

143. This Court has personal jurisdiction over Par by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief,

either directly or through its subsidiaries, agents, and/or affiliates, Par regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Par derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of Par's filing of its ANDA and the causes of action Plaintiffs raise here, as alleged herein.

144. On information and belief, Par is licensed with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals in the State of New Jersey (Registration No. 5004032).

145. Further, this Court has personal jurisdiction over Par because Par has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and on information and belief, Par intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Par manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, Par developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, Par filed ANDA No. 207948, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

146. On information and belief, Par intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

147. On information and belief, Par's conduct has or will cause foreseeable harm and injury to Plaintiffs.

148. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were Par Inc. to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

149. Further, this Court has personal jurisdiction over Par because Par has previously been sued in this district and has not challenged personal jurisdiction, and Par has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Horizon Therapeutics, LLC v. Par Pharm. Inc.*, Civ. No. 17-5901 (D.N.J.); *West-Ward Pharms. Corp. v. Par Pharm. Inc.*, Civ. No. 16-05456 (D.N.J.); *Merck Sharp & Dohme Corp. v. Par Sterile Products, LLC,* Civ. No. 16-00948 (D.N.J.).

150. In addition, Par has previously elected to avail itself of the benefits of litigating its patent disputes in the District of New Jersey. *See, e.g.*, *Par Pharm., Inc. v. Luitpold Pharms., Inc.*, Civ. No. 16-01190 (D.N.J.); *Par Pharm., Inc. v. Breckenridge Pharm., Inc.*, Civ. No. 13-04000 (D.N.J.).

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

152. Venue is proper in this district under 28 U.S.C. § 1400(b) because Par "committed an act of infringement" in this district. On information and belief, Par submitted ANDA No. 207948 pursuant to Section 505(j) of the FFDCA, and, upon receiving final approval of its ANDA, will manufacture, sell, offer to sell, and/or import Par's proposed generic lurasidone

hydrochloride tablets in the United States, including in the District of New Jersey. Thus, Par has committed an act of infringement in this district.

153. Further, venue is proper in this district because Par is currently licensed with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals in the State of New Jersey (Registration No. 5004032).

Jurisdiction and Venue for Defendant Torrent

154. This Court has personal jurisdiction over Torrent by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Torrent regularly and continuously transacts business within New Jersey including by selling pharmaceutical products in New Jersey. On information and belief, Torrent derives substantial revenue from the sale of its pharmaceutical products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of Torrent's filing of its ANDA and the causes of action Plaintiffs raise here, as alleged herein.

155. Further, this Court has personal jurisdiction over Torrent because Torrent has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, Torrent intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, Torrent, directly or through its subsidiaries, agents, and/or affiliates manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, Torrent developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, Torrent filed ANDA No. 208055, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

156. On information and belief, Torrent intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

157. On information and belief, Torrent's conduct has or will cause foreseeable harm and injury to Plaintiffs.

158. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were Torrent to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

159. Further, this Court has personal jurisdiction over Torrent because Torrent has previously been sued in this district and has not challenged personal jurisdiction, and Torrent has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Forest Labs. LLC v. Torrent Pharms. Ltd.*, Civ. No. 17-10273 (D.N.J.); *Takeda Pharm. Co. Ltd. v. Torrent Pharms. Ltd.*, Civ. No. 17-3186 (D.N.J.); *Otsuka Pharm. Co. Ltd. v. Torrent Pharms. Ltd.*, Civ. No. 14-4671 (D.N.J.).

160. Alternatively, to the extent the above facts do not establish personal jurisdiction over Torrent, this Court may exercise jurisdiction over Torrent pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Torrent would be a foreign defendant not subject to personal jurisdiction in the courts of any State; (c) Torrent has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling pharmaceutical products that are distributed throughout the United States; and (d) Torrent

filed an ANDA with the FDA and sent notice of its Paragraph IV certification to an entity in New Jersey, such that this Court's exercise of jurisdiction over Torrent satisfies due process.

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

162. Venue is proper in this district under 28 U.S.C. § 1400(b) because Torrent "committed an act of infringement" in this district. On information and belief, Torrent submitted its ANDA No. 208055 pursuant to Section 505(j) of the FFDCA, and, upon receiving final approval of its ANDA, will manufacture, sell, offer to sell, and/or import Torrent's proposed generic lurasidone hydrochloride tablets in the United States, including in the District of New Jersey. Thus, Torrent has committed an act of infringement in this district.

Jurisdiction and Venue for Defendant Watson

163. This Court has personal jurisdiction over Watson by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Watson regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Watson derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of Watson's filing of its ANDA and the causes of action Plaintiffs raise here, as alleged herein.

164. On information and belief, Watson has a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

165. Further, this Court has personal jurisdiction over Watson because Watson has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and

belief, Watson intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Watson manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, Watson developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, Watson filed ANDA No. 208016, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

166. On information and belief, Watson intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

167. On information and belief, Watson's conduct has or will cause foreseeable harm and injury to Plaintiffs.

168. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were Watson to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

169. Further, this Court has personal jurisdiction over Watson because Watson has previously been sued in this district and has not challenged personal jurisdiction, and Watson has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Senju Pharm. Co. v. Watson Labs., Inc.*, Civ. No. 16-1522 (D.N.J.); *Jazz Pharms. Inc.*

v. Watson Labs., Inc., Civ. No. 16-1505 (D.N.J.); *Alcon Pharms., Ltd. v. Watson Labs., Inc.*, Civ. No. 16-101 (D.N.J.).

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

171. Venue is proper in this district under 28 U.S.C. § 1400(b) because Watson has a "regular and established place of business" in this district. Watson has a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

172. Venue is proper in this district under 28 U.S.C. § 1400(b) because Watson "committed an act of infringement" in this district. Watson submitted its ANDA No. 208016 pursuant to Section 505(j) of the FFDCA, and, upon receiving final approval of its ANDA, will manufacture, sell, offer to sell, and/or import Watson's proposed generic lurasidone hydrochloride tablets in the United States, including in the District of New Jersey. Thus, Watson has committed an act of infringement in this district.

Jurisdiction and Venue for Defendant Zydus

173. This Court has personal jurisdiction over Zydus by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, Zydus, either directly or through its subsidiaries, agents, and/or affiliates, regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Zydus derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of Zydus's filing of its ANDA and the causes of action Plaintiffs raise here, as alleged herein.

174. On information and belief, Zydus is incorporated under the laws of the State of New Jersey. On information and belief, Zydus has a principal place of business at 73 Route 31 North, Suite 103, Pennington, New Jersey 08534. On information and belief, Zydus is currently licensed to do business with the New Jersey Department of Health as a "Wholesale[r]" of pharmaceuticals in the State of New Jersey (License No. 5003171).

175. Further, this Court has personal jurisdiction over Zydus because Zydus has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, Zydus intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Zydus manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, Zydus developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, Zydus filed ANDA No. 208052, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

176. On information and belief, Zydus intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

177. On information and belief, Zydus's conduct has or will cause foreseeable harm and injury to Plaintiffs.

178. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were

Zydus to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

179. Further, this Court has personal jurisdiction over Zydus because Zydus has previously been sued in this district and has not challenged personal jurisdiction, and Zydus has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Valeant Pharms. Luxembourg S.A.R.L. v. Zydus Pharms. (USA), Inc.*, Civ. No. 17-449 (D.N.J.); *Celgene Corp. v. Zydus Pharms. (USA), Inc.*, Civ. No. 17-2528, (D.N.J.); *Helsinn Healthcare S.A. v. Zydus Pharms. (USA) Inc.*, Civ. No. 16-4239 (D.N.J.).

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

181. Venue is proper in this district under 28 U.S.C. § 1400(b) because Zydus "committed an act of infringement" in this district. On information and belief, Zydus submitted ANDA No. 208052 pursuant to Section 505(j) of the FFDCA, and, upon receiving final approval of such ANDA, will manufacture, sell, offer to sell, and/or import Zydus's proposed generic lurasidone hydrochloride tablets in the United States, including in the District of New Jersey. Thus, Zydus has committed an act of infringement in this district.

182. Venue is also proper in this district under 28 U.S.C. §1400(b) because New Jersey is the judicial district in which Zydus resides.

183. Venue is also proper in this district under 28 U.S.C. § 1400(b) because Zydus has a "regular and established place of business" in this district. Zydus has a principal place of business of 73 Route 31 North, Pennington, New Jersey 08534. Venue is also proper in this district because Zydus is currently licensed to do business with the New Jersey Department of

Health as a "Wholesale[r]" of pharmaceuticals in the State of New Jersey (License No. 5003171).

Jurisdiction and Venue for Defendant Jubilant

184. This Court has personal jurisdiction over Jubilant by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, Jubilant regularly and continuously transacts business within New Jersey including by selling pharmaceutical products in New Jersey. On information and belief, Jubilant derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of Jubilant Generics' ANDA filing and the causes of action Plaintiffs raise here, as alleged herein.

185. Further, this Court has personal jurisdiction over Jubilant because Jubilant Generics committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and on information and belief, Jubilant intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, Jubilant, either directly or through its subsidiaries, agents, and/or affiliates manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, Jubilant developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, Jubilant filed ANDA No. 210388, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

186. On information and belief, Jubilant intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

187. On information and belief, Jubilant's conduct has or will cause foreseeable harm and injury to Plaintiffs.

188. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were Jubilant to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

189. Alternatively, to the extent the above facts do not establish personal jurisdiction over Jubilant Generics, this Court may exercise jurisdiction over Jubilant pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Jubilant would be a foreign defendant not subject to personal jurisdiction in the courts of any State; (c) Jubilant has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling pharmaceutical products that are distributed throughout the United States; and (d) Jubilant filed an ANDA with the FDA and sent notice of its Paragraph IV certification to an entity in New Jersey, such that this Court's exercise of jurisdiction over Jubilant Generics satisfies due process.

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

191. Venue is proper in this district under 28 U.S.C. § 1400(b) because Jubilant "committed an act of infringement" in this district. On information and belief, Jubilant submitted ANDA No. 210388 pursuant to Section 505(j) of the FFDCA, and, upon receiving final approval of its ANDA, will manufacture, sell, offer to sell, and/or import Jubilant's

proposed generic lurasidone hydrochloride tablets in the United States, including in the District of New Jersey. Thus, Jubilant has committed an act of infringement in this district.

* * * * *

192. The Court has jurisdiction to adjudicate this action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and justiciable controversy exists between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the parties' adverse legal interests with respect to the '827 patent.

FACTUAL BACKGROUND

Background of the Invention

193. Antipsychotic drug products are used in the management of psychotic symptoms associated with disorders including schizophrenia and bipolar disorder. *See, e.g.*, '827 patent col. 1 ll.47-49.

194. Conventional drug product treatments for psychotic symptoms were known to cause unwanted serious side effects. *See, e.g.*, '827 patent col. 1 ll.57-63.

195. Weight gain is a well-known side effect of conventional antipsychotic drug products. *See, e.g.*, File History of U.S. Application No. 14/471,919, Notice of Allowance dated 2017-07-17 ("Notice of Allowance") at 2 ("[C]onventional antipsychotic drug[s] cause[] serious side effects such as undesired metabolic changes . . . which were considered as closely linked with a weight gain."); *see also* Latuda® Prescribing Information (2/2017) at Section 5.6 ("Atypical antipsychotic drugs have been associated with metabolic changes . . . includ[ing] . . . weight gain." . . . . "Weight gain has been observed with atypical antipsychotic uses.").

196. On information and belief, the physiological relationship between antipsychotic drug product use and patient weight is complex and poorly understood.

197. On information and belief, antipsychotic drug products exert different physiological effects relating to weight.

198. There is a need for drugs that are effective antipsychotics but that do not cause undesirable side effects, such as weight gain.

U.S. Patent No. 9,815,827

199. The '827 patent, entitled "Agent for Treatment of Schizophrenia," issued on November 14, 2017 and names Mitsutaka Nakamura, Masaaki Ogasa, and Shunsuke Sami as inventors.

200. By assignment, plaintiff Sumitomo owns all right, title, and interest in and to the '827 patent.

201. Plaintiff Sunovion is the exclusive licensee to the '827 patent in the United States.

202. Plaintiff Sunovion is the holder of approved New Drug Application ("NDA") No. 200603 for lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg), which are sold in the United States under the registered trademark Latuda®.

203. In conjunction with NDA No. 200603, Sunovion has listed with the FDA nine patents for Latuda®. The listed patents are U.S. Patent Nos. 5,532,372, 8,729,085, 8,883,794, 9,174,975, 9,259,423, 9,555,027, 9,815,827, 9,827,242, and RE45573. The FDA has published these nine patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book." The Orange Book identifies drug products approved on the basis of safety and effectiveness by the FDA under the FFDCA.

204. Latuda®, or approved methods of using Latuda®, are covered by at least one claim of the '827 patent listed in the Orange Book.

205. The '827 patent is directed to methods of treating patients, including those with schizophrenia or manic depressive psychosis, with an antipsychotic without a clinically significant weight gain. The methods of treatment disclosed in the '827 patent accomplish this through the oral administration of a particular dose, 20 mg to 120 mg, of lurasidone or a pharmaceutically acceptable salt of lurasidone (e.g., lurasidone hydrochloride) such that the patient does not experience clinically significant weight gain for specific periods of time, including after six weeks of administration. Administration of such specific doses, and for such specific periods of treatment, result in a patient not experiencing clinically significant weight gain, which was not well understood, routine, or a conventional technique in the art.

Claims 40 and 43 of the '827 patent are illustrative and recite:

> 40. A method of treating a patient with an antipsychotic without a clinically significant weight gain, comprising:
>
> orally administering once daily to the patient a pharmaceutical composition comprising 20 to 120 mg of (1R, 2S, 3R, 4S)-N-[(1R, 2R)-2-[4-(1,2-benzoisothiazol-3-ly)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide or a pharmaceutically acceptable salt thereof as the sole active ingredient such that the patient does not experience a clinically significant weight gain.
>
> 43. The method of claim 41, wherein the administering is conducted such that the patient does not experience a clinically significant weight gain after six weeks of administration.

('827 patent, Cls. 40, 43.)

206. The claimed elements of exemplary claims 40 and 43 are found in the Latuda® Prescribing Information.

207. The Latuda® Prescribing Information describes Latuda® as "an atypical antipsychotic belong to the chemical class of benzisothiazol derivatives." (Latuda® Prescribing Information (2/2017) at Section 11.)

208. The Latuda® Prescribing Information states "LATUDA tablets are intended for oral administration only. Each tablet contains 20 mg, 40 mg, 60 mg, 80 mg, or 120 mg of lurasidone hydrochloride." (Latuda® Prescribing Information (2/2017) at Section 11; *see also id.* at Section 3.)

209. The Latuda® Prescribing Information describes Latuda® is indicated for treatment of adult and adolescent patients age 13 to 17 years with schizophrenia, monotherapy treatment of adult patients with major depressive episodes associated with bipolar I disorder (bipolar depression), and adjunctive treatment with lithium or valproate in adult patients with major depressive episodes associated with bipolar I disorder (bipolar depression). (Latuda® Prescribing Information (2/2017) at Section 1.)

210. It further describes the dosage and administration for Latuda®. With respect to adult patients with schizophrenia, the Latuda® Prescribing Information states "[t]he recommended starting dose of LATUDA is 40 mg once daily. Initial dose titration is not required. LATUDA has been shown to be effective in a dose range of 40 mg per day to 160 mg per day . . . The maximum recommended dose is 160 mg per day." (Latuda® Prescribing Information (2/2017) at Section 2.1.) With respect to adolescent patients with schizophrenia, the Latuda® Prescribing Information states "[t]he recommended starting dose of LATUDA is 40 mg once daily. Initial dose titration is not required. LATUDA has been shown to be effective in a dose range of 40 mg per day to 80 mg per day . . . The maximum recommended dose is 80 mg per day." (*Id.*)

211. For depressive episodes associated with bipolar I disorder, the Latuda® Prescribing Information states "the recommended starting dose of LATUDA in adults is 20 mg given once daily as monotherapy or as adjunctive therapy with lithium or valproate. Initial dose titration is not required. LATUDA has been shown to be effective in a dose range of 20 mg per day to 120 mg per day as monotherapy or as adjunctive therapy with lithium or valproate . . . The maximum recommended dose, as monotherapy or as adjunctive therapy with lithium or valproate, is 120 mg per day." (Latuda® Prescribing Information (2/2017) at Section 2.2.)

212. When 20 mg to 120 mg of Latuda® is orally administered to patients, they do not experience a clinically significant weight gain. For example, the Latuda® Prescribing Information describes the following:

Weight Gain

Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Schizophrenia

Adults

Pooled data from short-term, placebo-controlled schizophrenia studies are presented in Table 9. The mean weight gain was +0.43 kg for LATUDA-treated patients compared to -0.02 kg for placebo-treated patients. Change in weight from baseline for olanzapine was +4.15 kg and for quetiapine extended-release was +2.09 kg in Studies 3 and 5 *[see Clinical Studies (14.1)]*, respectively. The proportion of patients with a ≥7% increase in body weight (at Endpoint) was 4.8% for LATUDA-treated patients versus 3.3% for placebo-treated patients.

Table 9: Mean Change in Weight (kg) from Baseline in Adult Schizophrenia Studies

		LATUDA				
	Placebo (n=696)	20 mg/day (n=71)	40 mg/day (n=484)	80 mg/day (n=526)	120 mg/day (n=291)	160 mg/day (n=114)
All Patients	-0.02	-0.15	+0.22	+0.54	+0.68	+0.60

In the uncontrolled, longer-term schizophrenia studies (primarily open-label extension studies), LATUDA was associated with a mean change in weight of -0.69 kg at week 24 (n=755), -0.59 kg at week 36 (n=443) and -0.73 kg at week 52 (n=377).

Adolescents

Data from the short-term, placebo-controlled adolescent schizophrenia study are presented in Table 10. The mean weight gain was +0.5 kg for LATUDA-treated patients compared to +0.2 kg for placebo-treated patients. The proportion of patients with a ≥7% increase in body weight (at Endpoint) was 3.3% for LATUDA-treated patients versus 4.5% for placebo-treated patients.

Table 10: Mean Change in Weight (kg) from Baseline in the Adolescent Schizophrenia Study

		LATUDA	
	Placebo (n=111)	40 mg/day (n=109)	80 mg/day (n=104)
All Patients	+0.2	+0.3	+0.7

Table 11: Mean Change in Weight (kg) from Baseline in the Adult Monotherapy Bipolar Depression Study

		LATUDA	
	Placebo (n=151)	20 to 60 mg/day (n=143)	80 to 120 mg/day (n=147)
All Patients	-0.04	+0.56	+0.02

Patients were randomized to flexibly dosed LATUDA 20 to 60 mg/day, LATUDA 80 to 120 mg/day, or placebo

In the uncontrolled, open-label, longer-term bipolar depression study, patients who received LATUDA as monotherapy in the short-term and continued in the longer-term study had a mean change in weight of -0.02 kg at week 24 (n=130).

Adjunctive Therapy with Lithium or Valproate

Data from the adult short-term, flexible-dosed, placebo-controlled adjunctive therapy bipolar depression studies are presented in Table 12. The mean weight gain was +0.11 kg for LATUDA-treated patients compared to +0.16 kg for placebo-treated patients. The proportion of patients with a ≥7% increase in body weight (at Endpoint) was 3.1% for LATUDA-treated patients versus 0.3% for placebo-treated patients.

Table 12: Mean Change in Weight (kg) from Baseline in the Adult Adjunctive Therapy Bipolar Depression Studies

	Placebo (n=307)	LATUDA 20 to 120 mg/day (n=327)
All Patients	+0.16	+0.11

Patients were randomized to flexibly dosed LATUDA 20 to 120 mg/day or placebo as adjunctive therapy with lithium or valproate.

In the uncontrolled, open-label, longer-term bipolar depression study, patients who were treated with LATUDA, as adjunctive therapy with either lithium or valproate in the short-term and continued in the longer-term study, had a mean change in weight of +1.28 kg at week 24 (n=86).

Bipolar Depression

Monotherapy

Data from the adult short-term, flexible-dosed, placebo-controlled monotherapy bipolar depression study are presented in Table 11. The mean weight gain was +0.29 kg for LATUDA-treated patients compared to -0.04 kg for placebo-treated patients. The proportion of patients with a ≥7% increase in body weight (at Endpoint) was 2.4% for LATUDA-treated patients versus 0.7% for placebo-treated patients.

(Latuda® Prescribing Information (2/2017) at Section 5.6.) The change in weight results shown in Tables 9 and 11 reflect the change in weight after six weeks of administration of Latuda® as described in the short-term, placebo-controlled schizophrenia and short-term, flexible-dosed, placebo-controlled monotherapy bipolar depression studies, respectively, described in the Latuda® Prescribing Information. (Latuda® Prescribing Information (2/2017) at Section 14.) The label also describes the weight gain seen in patients from longer term, open-label studies. (Latuda® Prescribing Information (2/2017) at Section 10.)

213. The therapeutic use of Latuda® represents an improvement over prior art methods of treating patients with an antipsychotic drug product, including those patients with schizophrenia and bipolar disorder.

ACTS GIVING RISE TO THIS ACTION

Acts of Aurobindo

214. On information and belief, Aurobindo submitted to the FDA ANDA No. 208045 under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) (Aurobindo's "Proposed ANDA Product") prior to the expiration of the '827 patent. On information and belief, ANDA No. 208045 contains data from bioavailability or bioequivalence studies for such tablets.

215. On information and belief, Aurobindo sent a letter to Plaintiffs regarding the '827 patent ("Aurobindo Notice Letter"), purporting to be a notice pursuant to Section 505(j)(2)(B) of the FFDCA. The Aurobindo Notice Letter purports to inform Plaintiffs that Aurobindo's ANDA

contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The Aurobindo Notice Letter bears the date January 25, 2018.

216. Plaintiff Sunovion received the Aurobindo Notice Letter on January 26, 2018.

217. Plaintiff Sumitomo received the Aurobindo Notice Letter on January 29, 2018.

218. Plaintiffs commenced this action within 45 days after receiving the Aurobindo Notice Letter.

219. On information and belief, Aurobindo's proposed label for its Proposed ANDA Product ("Proposed Aurobindo Label") will refer to the product as, *inter alia*, an atypical antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and depressive episodes associated with Bipolar (I) Disorder (bipolar depression) in adults, and will describe the strength of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. On information and belief, the Proposed Aurobindo Label will instruct physicians and healthcare providers to administer Aurobindo's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and depressive episodes associated with bipolar I disorder (bipolar depression).

220. On information and belief, the Proposed Aurobindo Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg). On information and belief, the weight gain data in the Proposed Aurobindo Label demonstrate that patients receiving Latuda® and/or Aurobindo's Proposed ANDA Product do not experience clinically significant weight gain.

221. On information and belief, the Proposed Aurobindo Label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to

treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

222. On information and belief, the Proposed Aurobindo Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

223. On information and belief, such administration will directly infringe the '827 patent's claims.

224. On information and belief, the FDA has tentatively approved ANDA No. 208045.

225. On information and belief, following approval of ANDA No. 208045, Aurobindo will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in New Jersey.

Acts of DRL

226. On information and belief, DRL submitted to the FDA ANDA No. 208047 under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) (DRL's "Proposed ANDA Product") prior to the expiration of the '827 patent. On information and belief, ANDA No. 208047 contains data from bioavailability or bioequivalence studies for such tablets.

227. On information and belief, DRL's proposed label for its Proposed ANDA Product (the "Proposed DRL Label") will refer to the product as, *inter alia*, an atypical antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and depressive episodes

associated with Bipolar (I) Disorder (bipolar depression) in adults, and will describe the strength of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. On information and belief, the Proposed DRL Label will instruct physicians and healthcare providers to administer DRL's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and depressive episodes associated with bipolar I disorder (bipolar depression).

228. On information and belief, the Proposed DRL Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg). On information and belief, the weight gain data in the Proposed DRL Label demonstrate that patients receiving Latuda® and/or DRL's Proposed ANDA Product do not experience clinically significant weight gain.

229. On information and belief, the Proposed DRL Label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

230. On information and belief, the Proposed DRL Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

231. On information and belief, such administration will directly infringe the '827 patent's claims.

232. On information and belief, the FDA has tentatively approved ANDA No. 208047.

233. On information and belief, following approval of ANDA No. 208047, DRL will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in New Jersey.

Acts of Lupin

234. On information and belief, Lupin submitted to the FDA ANDA No. 208031 under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) (Lupin's "Proposed ANDA Product") prior to the expiration of the '827 patent. On information and belief, ANDA No. 208031 contains data from bioavailability or bioequivalence studies for such tablets.

235. On information and belief, Lupin sent a "Notice of Paragraph IV Certification" regarding the '827 patent to Plaintiffs ("Lupin Notice Letter"), purporting to be a notice pursuant to Section 505(j)(2)(B)(iv) of the FFDCA. The Lupin Notice Letter bears the date January 24, 2018.

236. Plaintiff Sunovion received the Lupin Notice Letter on January 25, 2018.

237. Plaintiff Sumitomo received the Lupin Notice Letter on February 5, 2018.

238. Plaintiffs commenced this action within 45 days after receiving the Lupin Notice Letter.

239. On information and belief, Lupin's proposed label for its Proposed ANDA Product ("Proposed Lupin Label") will refer to the product as, *inter alia*, an atypical antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and depressive episodes associated with Bipolar (I) Disorder (bipolar depression) in adults, and will describe the strength of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80

mg, and 120 mg. On information and belief, the Proposed Lupin Label will instruct physicians and healthcare providers to administer Lupin's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and depressive episodes associated with bipolar I disorder (bipolar depression).

240. On information and belief, the Proposed Lupin Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg). On information and belief, the weight gain data in the Proposed Lupin Label demonstrate that patients receiving Latuda® and/or Lupin's Proposed ANDA Product do not experience clinically significant weight gain.

241. On information and belief, the Proposed Lupin Label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

242. On information and belief, the Proposed Lupin Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

243. On information and belief, such administration will directly infringe the '827 patent's claims.

244. On information and belief, the FDA has tentatively approved ANDA No. 208031.

245. On information and belief, following approval of ANDA No. 208031, Lupin will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in New Jersey.

Acts of Teva

246. On information and belief, Teva submitted to the FDA ANDA No. 208060 under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) (Teva's "Proposed ANDA Product") prior to the expiration of the '827 patent. On information and belief, ANDA No. 208060 contains data from bioavailability or bioequivalence studies for such tablets.

247. On information and belief, Teva's proposed label for its Proposed ANDA Product ("Proposed Teva Label") will refer to the product as, *inter alia*, an atypical antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and depressive episodes associated with Bipolar (I) Disorder (bipolar depression) in adults, and will describe the strength of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. On information and belief, the Proposed Teva Label will instruct physicians and healthcare providers to administer Teva's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and depressive episodes associated with bipolar I disorder (bipolar depression).

248. On information and belief, the Proposed Teva Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg). On information and belief, the weight gain data in the Proposed Teva Label demonstrate that patients receiving Latuda® and/or Teva's Proposed ANDA Product do not experience clinically significant weight gain.

249. On information and belief, the Proposed Teva Label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter*

alia, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

250. On information and belief, the Proposed Teva Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

251. On information and belief, such administration will directly infringe the '827 patent's claims.

252. On information and belief, the FDA has tentatively approved ANDA No. 208060.

253. On information and belief, following approval of ANDA No. 208060, Teva will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in New Jersey.

Acts of MSN

254. On information and belief, MSN submitted to the FDA ANDA No. 208037 under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) (MSN's "Proposed ANDA Product") prior to the expiration of the '827 patent. On information and belief, ANDA No. 208037 contains data from bioavailability or bioequivalence studies for such tablets.

255. On information and belief, MSN's proposed label for its Proposed ANDA Product ("Proposed MSN Label") will refer to the product as, *inter alia*, an atypical antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and depressive episodes associated with Bipolar (I) Disorder (bipolar depression) in adults, and will describe the strength

of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. On information and belief, the Proposed MSN Label will instruct physicians and healthcare providers to administer MSN's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and depressive episodes associated with bipolar I disorder (bipolar depression).

256. On information and belief, the Proposed MSN Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg). On information and belief, the weight gain data in the Proposed MSN Label demonstrate that patients receiving Latuda® and/or MSN's Proposed ANDA Product do not experience clinically significant weight gain.

257. On information and belief, the Proposed MSN Label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

258. On information and belief, the Proposed MSN Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

259. On information and belief, such administration will directly infringe the '827 patent's claims.

260. On information and belief, the FDA has tentatively approved ANDA No. 208037.

261. On information and belief, following approval of ANDA No. 208037, MSN will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in New Jersey.

Acts of Sun

262. On information and belief, Sun submitted to the FDA ANDA No. 208066 under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) (Sun's "Proposed ANDA Product") prior to the expiration of the '827 patent. On information and belief, ANDA No. 208066 contains data from bioavailability or bioequivalence studies for such tablets.

263. On information and belief, Sun's proposed label for its Proposed ANDA Product ("Proposed Sun Label") will refer to the product as, *inter alia*, an atypical antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and depressive episodes associated with Bipolar (I) Disorder (bipolar depression) in adults, and will describe the strength of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. On information and belief, the Proposed Sun Label will instruct physicians and healthcare providers to administer Sun's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and depressive episodes associated with bipolar I disorder (bipolar depression).

264. On information and belief, the Proposed Sun Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg). On information and belief, the weight gain data in the Proposed Sun Label demonstrate that patients receiving Latuda® and/or Sun's Proposed ANDA Product do not experience clinically significant weight gain.

265. On information and belief, the Proposed Sun Label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*,

schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

266. On information and belief, the Proposed Sun Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

267. On information and belief, such administration will directly infringe the '827 patent's claims.

268. On information and belief, the FDA has tentatively approved ANDA No. 208066.

269. On information and belief, following approval of ANDA No. 208066, Sun will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in New Jersey.

Acts of Accord

270. On information and belief, Accord submitted to the FDA ANDA No. 208049 under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) (Accord's "Proposed ANDA Product") prior to the expiration of the '827 patent. On information and belief, ANDA No. 208049 contains data from bioavailability or bioequivalence studies for such tablets.

271. On information and belief, Accord sent a notification regarding the '827 patent to Plaintiffs ("Accord Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The Accord Notice Letter bears the date February 15, 2018.

272. Plaintiff Sunovion received the Accord Notice Letter on February 16, 2018.

273. Plaintiff Sumitomo received the Accord Notice Letter on February 19, 2018.

274. Plaintiffs commenced this action within 45 days after receiving the Accord Notice Letter.

275. On information and belief, Accord's proposed label for its Proposed ANDA Product ("Proposed Accord Label") will refer to the product as, *inter alia*, an atypical antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and depressive episodes associated with Bipolar (I) Disorder (bipolar depression) in adults, and will describe the strength of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. On information and belief, the Proposed Accord Label will instruct physicians and healthcare providers to administer Accord's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and depressive episodes associated with bipolar I disorder (bipolar depression).

276. On information and belief, Accord's Proposed Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg). On information and belief, the weight gain data in the Proposed Accord Label demonstrate that patients receiving Latuda® and/or Accord's Proposed ANDA Product do not experience clinically significant weight gain.

277. On information and belief, the Proposed Accord Label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

278. On information and belief, the Proposed Accord Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers

to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

279. On information and belief, such administration will directly infringe the '827 patent's claims.

280. On information and belief, the FDA has tentatively approved ANDA No. 208049.

281. On information and belief, following approval of ANDA No. 208049, Accord will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in New Jersey.

Acts of Amneal

282. On information and belief, Amneal submitted to the FDA ANDA No. 208002 under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) (Amneal's "Proposed ANDA Product") prior to the expiration of the '827 patent. On information and belief, Amneal's ANDA No. 208002 contains data from bioavailability or bioequivalence studies for such tablets.

283. On information and belief, Amneal sent a "Notice of Paragraph IV Certification of U.S. Patents 9,815,827 and 9,827,242" to Plaintiffs ("Amneal Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B)(ii)(I), (B)(iv)(I). The Amneal Notice Letter bears the date January 8, 2018.

284. Plaintiff Sunovion received the Amneal Notice Letter on January 9, 2018.

285. Plaintiff Sumitomo received the Amneal Notice Letter on January 11, 2018.

286. Plaintiffs commenced this action within 45 days after receiving the Amneal Notice Letter.

287. On information and belief, Amneal's proposed label for its Proposed ANDA Product ("Proposed Amneal Label") will refer to the product as, *inter alia*, an atypical antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and depressive episodes associated with Bipolar (I) Disorder (bipolar depression) in adults, and will describe the strength of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. On information and belief, the Proposed Amneal Label will instruct physicians and healthcare providers to administer Amneal's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and depressive episodes associated with bipolar I disorder (bipolar depression).

288. On information and belief, the Proposed Amneal Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg). On information and belief, the weight gain data in the Proposed Amneal Label demonstrate that patients receiving Latuda® and/or Amneal's Proposed ANDA Product will not experience clinically significant weight gain.

289. On information and belief, the Proposed Amneal Label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

290. On information and belief, the Proposed Amneal Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

291. On information and belief, such administration will directly infringe the '827 patent's claims.

292. On information and belief, the FDA has tentatively approved ANDA No. 208002.

293. On information and belief, following approval of ANDA No. 208002, Amneal will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in New Jersey.

Acts of FTUG

294. On information and belief, FTUG submitted to the FDA ANDA No. 207995 under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) (FTUG's "Proposed ANDA Product") prior to the expiration of the '827 patent. On information and belief, ANDA No. 207995 contains data from bioavailability or bioequivalence studies for such tablets.

295. On information and belief, FTUG's proposed label for its Proposed ANDA Product ("Proposed FTUG Label") will refer to the product as, *inter alia*, an atypical antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and depressive episodes associated with Bipolar (I) Disorder (bipolar depression) in adults, and will describe the strength of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. On information and belief, the Proposed FTUG Label will instruct physicians and healthcare providers to administer FTUG's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and depressive episodes associated with bipolar I disorder (bipolar depression).

296. On information and belief, the Proposed FTUG Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg). On information and belief, the weight gain data in the Proposed FTUG Label demonstrate that patients receiving Latuda® and/or FTUG's Proposed ANDA Product do not experience clinically significant weight gain.

297. On information and belief, the Proposed FTUG Label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

298. On information and belief, the Proposed FTUG Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

299. On information and belief, such administration will directly infringe the '827 patent's claims.

300. On information and belief, the FDA has tentatively approved ANDA No. 207995.

301. On information and belief, following approval of ANDA No. 207995, FTUG will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in New Jersey.

Acts of InvaGen

302. On information and belief, InvaGen submitted to the FDA ANDA No. 208028 under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg,

and 120 mg) (InvaGen's "Proposed ANDA Product") prior to the expiration of the '827 patent. On information and belief, ANDA No. 208028 contains data from bioavailability or bioequivalence studies for such tablets.

303. On information and belief, InvaGen sent a notice of "Certification of Non-Infringement and/or Invalidity" regarding the '827 patent to Plaintiffs ("InvaGen Notice Letter"), purporting to be a notice pursuant to Section 505(j)(2)(B)(i), (ii) of the FFDCA. The InvaGen Notice Letter bears the date February 7, 2018.

304. Plaintiff Sunovion received the InvaGen Notice Letter on February 8, 2018.

305. Plaintiff Sumitomo received the InvaGen Notice Letter on February 13, 2018.

306. Plaintiffs commenced this action within 45 days after receiving the InvaGen Notice Letter.

307. On information and belief, InvaGen's proposed label for its Proposed ANDA Product ("Proposed InvaGen Label") will refer to the product as, *inter alia*, an atypical antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and depressive episodes associated with Bipolar (I) Disorder (bipolar depression) in adults, and will describe the strength of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. On information and belief, the Proposed InvaGen Label will instruct physicians and healthcare providers to administer InvaGen's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and depressive episodes associated with bipolar I disorder (bipolar depression).

308. On information and belief, the Proposed InvaGen Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg). On information and belief, the weight gain data in the

Proposed InvaGen Label demonstrate that patients receiving Latuda® and/or InvaGen's Proposed ANDA Product do not experience clinically significant weight gain.

309. On information and belief, the Proposed InvaGen label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

310. On information and belief, the Proposed InvaGen Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

311. On information and belief, such administration will directly infringe the '827 patent's claims.

312. On information and belief, the FDA has tentatively approved ANDA No. 208028.

313. On information and belief, following approval of ANDA No. 208028, InvaGen will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in New Jersey.

Acts of Par

314. On information and belief, Par submitted to the FDA ANDA No. 207948 under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) (Par's "Proposed ANDA Product") prior to the expiration of the '827 patent. On

information and belief, ANDA No. 207948 contains data from bioavailability or bioequivalence studies for such tablets.

315. On information and belief, Par sent a "Notice of Paragraph IV Certification" regarding the '827 patent to Plaintiffs ("Par Notice Letter"), purporting to be a notice pursuant to Section 505(j)(2)(B)(ii) of the FFDCA. The Par Notice Letter bears the date February 2, 2018.

316. Plaintiff Sunovion received the Par Notice Letter on February 5, 2018.

317. Plaintiff Sumitomo received the Par Notice Letter on February 5, 2018.

318. Plaintiffs commenced this action within 45 days after receiving the Par Notice Letter.

319. On information and belief, Par's proposed label for its Proposed ANDA Product ("Proposed Par Label") will refer to the product as, *inter alia*, an atypical antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and depressive episodes associated with Bipolar (I) Disorder (bipolar depression) in adults, and will describe the strength of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. On information and belief, the Proposed Par Label will instruct physicians and healthcare providers to administer Par's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and depressive episodes associated with bipolar I disorder (bipolar depression).

320. On information and belief, the Proposed Par Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg). On information and belief, the weight gain data in the Proposed Par Label demonstrate that patients receiving Latuda® and/or Par's Proposed ANDA Product do not experience clinically significant weight gain.

321. On information and belief, the Proposed Par Label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

322. On information and belief, the Proposed Par Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

323. On information and belief, such administration will directly infringe the '827 patent's claims.

324. On information and belief, the FDA has tentatively approved ANDA No. 207948.

325. On information and belief, following approval of ANDA No. 207948, Par will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in New Jersey.

Acts of Torrent

326. On information and belief, Torrent submitted to the FDA ANDA No. 208055 under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) (Torrent's "Proposed ANDA Product") prior to the expiration of the '827 patent. On information and belief, ANDA No. 208055 contains data from bioavailability or bioequivalence studies for such tablets.

327. On information and belief, Torrent's proposed label for its Proposed ANDA Product ("Proposed Torrent Label") will refer to the product as, *inter alia*, an atypical

antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and depressive episodes associated with Bipolar (I) Disorder (bipolar depression) in adults, and will describe the strength of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. On information and belief, the Proposed Torrent Label will instruct physicians and healthcare providers to administer Torrent's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and depressive episodes associated with bipolar I disorder (bipolar depression).

328. On information and belief, the Proposed Torrent Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg). On information and belief, the weight gain data in the Proposed Torrent Label demonstrate that patients receiving Latuda® and/or Torrent's Proposed ANDA Product do not experience clinically significant weight gain.

329. On information and belief, the Proposed Torrent Label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

330. On information and belief, the Proposed Torrent Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

331. On information and belief, such administration will directly infringe the '827 patent's claims.

332. On information and belief, the FDA has tentatively approved ANDA No. 208055.

333. On information and belief, following approval of ANDA No. 208055, Torrent will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in New Jersey.

Acts of Watson

334. On information and belief, Watson submitted to the FDA ANDA No. 208016 under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) (Watson's "Proposed ANDA Product") prior to the expiration of the '827 patent. On information and belief, ANDA No. 208016 contains data from bioavailability or bioequivalence studies for such tablets.

335. On information and belief, Watson's proposed label for its Proposed ANDA Product ("Proposed Watson Label") will refer to the product as, *inter alia*, an atypical antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and depressive episodes associated with Bipolar (I) Disorder (bipolar depression) in adults, and will describe the strength of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. On information and belief, the Proposed Watson Label will instruct physicians and healthcare providers to administer Watson's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and depressive episodes associated with bipolar I disorder (bipolar depression).

336. On information and belief, the Proposed Watson Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg). On information and belief, the weight gain data in the

Proposed Watson Label demonstrate that patients receiving Latuda® and/or Watson's Proposed ANDA Product do not experience clinically significant weight gain.

337. On information and belief, the Proposed Watson Label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

338. On information and belief, the Proposed Watson Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

339. On information and belief, such administration will directly infringe the '827 patent's claims.

340. On information and belief, the FDA has tentatively approved ANDA No. 208016.

341. On information and belief, following approval of ANDA No. 208016, Watson will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in New Jersey.

Acts of Zydus

342. On information and belief, Zydus submitted to the FDA ANDA No. 208052 under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) (Zydus's "Proposed ANDA Product") prior to the expiration of the '827 patent. On information and belief, Zydus's ANDA No. 208052 contains data from bioavailability or bioequivalence studies for such tablets.

343. On information and belief, Zydus's proposed label for its Proposed ANDA Product ("Proposed Zydus Label") will refer to the product as, *inter alia*, an atypical antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and depressive episodes associated with Bipolar (I) Disorder (bipolar depression) in adults, and will describe the strength of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. On information and belief, the Proposed Zydus Label will instruct physicians and healthcare providers to administer Zydus's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and depressive episodes associated with bipolar I disorder (bipolar depression).

344. On information and belief, Zydus's Proposed Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg, 60mg, 80 mg, and 120 mg). On information and belief, the weight gain data in the Proposed Zydus Label demonstrate that patients receiving Latuda® and/or Zydus's Proposed ANDA Product do not experience clinically significant weight gain.

345. On information and belief, the Proposed Zydus Label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

346. On information and belief, the Proposed Zydus Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

347. On information and belief, such administration will directly infringe the '827 patent's claims.

348. On information and belief, the FDA has tentatively approved ANDA No. 208052.

349. On information and belief, following approval of ANDA No. 208052, Zydus will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in New Jersey.

Acts of Jubilant

350. On information and belief, Jubilant submitted to the FDA ANDA No. 210388 under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) (Jubilant's "Proposed ANDA Product") prior to the expiration of the '827 patent. On information and belief, Jubilant's ANDA No. 210388 contains data from bioavailability or bioequivalence studies for such tablets.

351. On information and belief, Jubilant's proposed label for its Proposed ANDA Product ("Proposed Jubilant Label") will refer to the product as, *inter alia*, an atypical antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and depressive episodes associated with Bipolar (I) Disorder (bipolar depression) in adults, and will describe the strength of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. On information and belief, the Proposed Jubilant Label will instruct physicians and healthcare providers to administer Jubilant's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and depressive episodes associated with bipolar I disorder (bipolar depression).

352. On information and belief, the Proposed Jubilant Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg). On information and belief, the weight gain data in the Proposed Jubilant Label demonstrate that patients receiving Latuda® and/or the Proposed Jubilant ANDA Product do not experience clinically significant weight gain.

353. On information and belief, the Proposed Jubilant Label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

354. On information and belief, the Proposed Jubilant Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

355. On information and belief, such administration will directly infringe the '827 patent's claims.

356. On information and belief, the FDA has tentatively approved ANDA No. 210388.

357. On information and belief, following approval of ANDA No. 210388, Jubilant will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in this district.

COUNT I

Infringement of the '827 Patent Under 35 U.S.C. § 271(e)(2) by Aurobindo's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

358. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

359. Aurobindo submitted its ANDA No. 208045 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting such application, Aurobindo has committed an act of infringement of the '827 patent under 35 U.S.C. § 271(e)(2)(A).

360. The commercial manufacture, importation, use, sale, or offer for sale of Aurobindo's Proposed ANDA Product will constitute an act of infringement of the '827 patent.

361. On information and belief, Aurobindo became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

362. On information and belief, Aurobindo will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Aurobindo will engage in such activities upon the FDA's approval of Aurobindo's ANDA.

363. On information and belief, Aurobindo knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

364. The commercial manufacture, importation, use, sale, or offer for sale of Aurobindo's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

365. Unless and until Aurobindo is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

366. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Aurobindo's ANDA be a date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT II

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271(b) and/or (c) by Aurobindo's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

367. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

368. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

369. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

370. On information and belief, Aurobindo's Proposed ANDA Product is covered by the claims of the '827 patent.

371. Aurobindo has actual knowledge of the '827 patent.

372. On information and belief, Aurobindo became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

373. On information and belief, Aurobindo has acted with full knowledge of the '827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '827 patent.

374. On information and belief, Aurobindo will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Aurobindo will engage in such activities upon the FDA's approval of Aurobindo's ANDA.

375. The commercial manufacture, use, sale, offer for sale, and/or importation of Aurobindo's Proposed ANDA Product will induce the actual infringement of the '827 patent.

376. On information and belief, Aurobindo knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product will actively induce the actual infringement of the '827 patent.

377. On information and belief, Aurobindo will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the '827 patent.

378. On information and belief, Aurobindo will encourage another's infringement of the '827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the '827 patent.

379. Aurobindo's act of infringement will be done with the knowledge of the '827 patent and with the intent to encourage infringement.

380. The foregoing actions by Aurobindo will constitute active inducement of the infringement of the '827 patent.

381. On information and belief, Aurobindo knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the

'827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

382. On information and belief, Aurobindo knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

383. The commercial manufacture, use, sale, offer for sale, and/or importation of Aurobindo's Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

384. On information and belief, Aurobindo knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

385. The foregoing actions by Aurobindo will constitute contributory infringement of the '827 patent.

386. On information and belief, Aurobindo intends to, and will, actively induce and contribute to the infringement of the '827 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

387. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and /or importation of Aurobindo's Proposed ANDA Product by Aurobindo will induce and/or contribute to infringement of the '827 patent.

388. The commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's Proposed ANDA Product, which will actively induce and/or contribute to the infringement of the '827 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

389. Unless Aurobindo is enjoined from actively inducing and contributing to the infringement of the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

390. On information and belief, despite having actual notice of the '827 patent, Aurobindo continues to prepare to actively induce and/or contribute to infringement of the '827 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT III

Infringement of the '827 Patent Under 35 U.S.C. § 271(e)(2) by DRL's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

391. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

392. DRL submitted its ANDA No. 208047 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting such application, DRL has committed an act of infringement of the '827 patent under 35 U.S.C. § 271(e)(2)(A).

393. The commercial manufacture, importation, use, sale, or offer for sale of DRL's Proposed ANDA Product will constitute an act of infringement of the '827 patent.

394. On information and belief, DRL became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

395. On information and belief, DRL will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, DRL will engage in such activities upon the FDA's approval of DRL's ANDA.

396. On information and belief, DRL knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

397. The commercial manufacture, importation, use, sale, or offer for sale of DRL's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

398. Unless and until DRL is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

399. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for DRL's ANDA be a date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT IV

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271(b) and/or (c) by DRL's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

400. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

401. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

402. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

403. On information and belief, DRL's Proposed ANDA Product is covered by the claims of the '827 patent.

404. DRL has actual knowledge of the '827 patent.

405. On information and belief, DRL became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

406. On information and belief, DRL has acted with full knowledge of the '827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '827 patent.

407. On information and belief, DRL will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, DRL will engage in such activities upon the FDA's approval of DRL's ANDA.

408. The commercial manufacture, use, sale, offer for sale, and/or importation of DRL's Proposed ANDA Product will induce the actual infringement of the '827 patent.

409. On information and belief, DRL knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product will actively induce the actual infringement of the '827 patent.

410. On information and belief, DRL will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the '827 patent.

411. On information and belief, DRL will encourage another's infringement of the '827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the '827 patent.

412. DRL's act of infringement will be done with the knowledge of the '827 patent and with the intent to encourage infringement.

413. The foregoing actions by DRL will constitute active inducement of the infringement of the '827 patent.

414. On information and belief, DRL knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the '827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

415. On information and belief, DRL knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

416. The commercial manufacture, use, sale, offer for sale, and/or importation of DRL's Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

417. On information and belief, DRL knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

418. The foregoing actions by DRL will constitute contributory infringement of the '827 patent.

419. On information and belief, DRL intends to, and will, actively induce and contribute to the infringement of the '827 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

420. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and /or importation of DRL's Proposed ANDA Product by DRL will induce and/or contribute to infringement of the '827 patent.

421. The commercial manufacture, use, offer for sale, sale, and/or importation of DRL's Proposed ANDA Product, which will actively induce and/or contribute to the infringement of the '827 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

422. Unless DRL is enjoined from actively inducing and contributing to the infringement of the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

423. On information and belief, despite having actual notice of the '827 patent, DRL continues to prepare to actively induce and/or contribute to infringement of the '827 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT V

Infringement of the '827 Patent Under 35 U.S.C. § 271(e)(2) by Lupin's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

424. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

425. Lupin submitted its ANDA No. 208031 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting such application, Lupin has committed an act of infringement of the '827 patent under 35 U.S.C. § 271(e)(2)(A).

426. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's Proposed ANDA Product will constitute an act of infringement of the '827 patent.

427. On information and belief, Lupin became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

428. On information and belief, Lupin will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Lupin will engage in such activities upon the FDA's approval of Lupin's ANDA.

429. On information and belief, Lupin knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

430. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

431. Unless and until Lupin is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

432. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Lupin's ANDA be a date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT VI

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271(b) and/or (c) by Lupin's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

433. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

434. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

435. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

436. On information and belief, Lupin's Proposed ANDA Product is covered by the claims of the '827 patent.

437. Lupin has actual knowledge of the '827 patent.

438. On information and belief, Lupin became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

439. On information and belief, Lupin has acted with full knowledge of the '827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '827 patent.

440. On information and belief, Lupin will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Lupin will engage in such activities upon the FDA's approval of Lupin's ANDA.

441. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's Proposed ANDA Product will induce the actual infringement of the '827 patent.

442. On information and belief, Lupin knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product will actively induce the actual infringement of the '827 patent.

443. On information and belief, Lupin will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the '827 patent.

444. On information and belief, Lupin will encourage another's infringement of the '827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the '827 patent.

445. Lupin's act of infringement will be done with the knowledge of the '827 patent and with the intent to encourage infringement.

446. The foregoing actions by Lupin will constitute active inducement of the infringement of the '827 patent.

447. On information and belief, Lupin knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the '827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

448. On information and belief, Lupin knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

449. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

450. On information and belief, Lupin knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

451. The foregoing actions by Lupin will constitute contributory infringement of the '827 patent.

452. On information and belief, Lupin intends to, and will, actively induce and contribute to the infringement of the '827 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

453. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and /or importation of Lupin's Proposed ANDA Product by Lupin will induce and/or contribute to infringement of the '827 patent.

454. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's Proposed ANDA Product, which will actively induce and/or contribute to the infringement of the '827 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

455. Unless Lupin is enjoined from actively inducing and contributing to the infringement of the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

456. On information and belief, despite having actual notice of the '827 patent, Lupin continues to prepare to actively induce and/or contribute to infringement of the '827 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT VII

Infringement of the '827 Patent Under 35 U.S.C. § 271(e)(2) by Teva's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

457. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

458. Teva submitted its ANDA No. 208060 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting such application, Teva has committed an act of infringement of the '827 patent under 35 U.S.C. § 271(e)(2)(A).

459. The commercial manufacture, importation, use, sale, or offer for sale of Teva's Proposed ANDA Product will constitute an act of infringement of the '827 patent.

460. On information and belief, Teva became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

461. On information and belief, Teva will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Teva will engage in such activities upon the FDA's approval of Teva's ANDA.

462. On information and belief, Teva knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

463. The commercial manufacture, importation, use, sale, or offer for sale of Teva's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

464. Unless and until Teva is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

465. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Teva's ANDA be a

date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT VIII

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271(b) and/or (c) by Teva's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

466. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

467. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

468. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

469. On information and belief, Teva's Proposed ANDA Product is covered by the claims of the '827 patent.

470. Teva has actual knowledge of the '827 patent.

471. On information and belief, Teva became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

472. On information and belief, Teva has acted with full knowledge of the '827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '827 patent.

473. On information and belief, Teva will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Teva will engage in such activities upon the FDA's approval of Teva's ANDA.

474. The commercial manufacture, use, sale, offer for sale, and/or importation of Teva's Proposed ANDA Product will induce the actual infringement of the '827 patent.

475. On information and belief, Teva knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product will actively induce the actual infringement of the '827 patent.

476. On information and belief, Teva will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the '827 patent.

477. On information and belief, Teva will encourage another's infringement of the '827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the '827 patent.

478. Teva's act of infringement will be done with the knowledge of the '827 patent and with the intent to encourage infringement.

479. The foregoing actions by Teva will constitute active inducement of the infringement of the '827 patent.

480. On information and belief, Teva knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the '827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

481. On information and belief, Teva knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

482. The commercial manufacture, use, sale, offer for sale, and/or importation of Teva's Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

483. On information and belief, Teva knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

484. The foregoing actions by Teva will constitute contributory infringement of the '827 patent.

485. On information and belief, Teva intends to, and will, actively induce and contribute to the infringement of the '827 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

486. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and /or importation of Teva's Proposed ANDA Product by Teva will induce and/or contribute to infringement of the '827 patent.

487. The commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Proposed ANDA Product, which will actively induce and/or contribute to the infringement of the '827 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

488. Unless Teva is enjoined from actively inducing and contributing to the infringement of the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

489. On information and belief, despite having actual notice of the '827 patent, Teva continues to prepare to actively induce and/or contribute to infringement of the '827 patent in

disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT IX

Infringement of the '827 Patent Under 35 U.S.C. § 271(e)(2) by MSN's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

490. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

491. MSN submitted its ANDA No. 208037 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting such application, MSN has committed an act of infringement of the '827 patent under 35 U.S.C. § 271(e)(2)(A).

492. The commercial manufacture, importation, use, sale, or offer for sale of MSN's Proposed ANDA Product will constitute an act of infringement of the '827 patent.

493. On information and belief, MSN became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

494. On information and belief, MSN will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, MSN will engage in such activities upon the FDA's approval of MSN's ANDA.

495. On information and belief, MSN knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

496. The commercial manufacture, importation, use, sale, or offer for sale of MSN's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

497. Unless and until MSN is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

498. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for MSN's ANDA be a date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT X

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271(b) and/or (c) by MSN's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

499. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

500. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

501. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

502. On information and belief, MSN's Proposed ANDA Product is covered by the claims of the '827 patent.

503. MSN has actual knowledge of the '827 patent.

504. On information and belief, MSN became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

505. On information and belief, MSN has acted with full knowledge of the '827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '827 patent.

506. On information and belief, MSN will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, MSN will engage in such activities upon the FDA's approval of MSN's ANDA.

507. The commercial manufacture, use, sale, offer for sale, and/or importation of MSN's Proposed ANDA Product will induce the actual infringement of the '827 patent.

508. On information and belief, MSN knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product will actively induce the actual infringement of the '827 patent.

509. On information and belief, MSN will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the '827 patent.

510. On information and belief, MSN will encourage another's infringement of the '827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the '827 patent.

511. MSN's act of infringement will be done with the knowledge of the '827 patent and with the intent to encourage infringement.

512. The foregoing actions by MSN will constitute active inducement of the infringement of the ’827 patent.

513. On information and belief, MSN knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the ’827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

514. On information and belief, MSN knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

515. The commercial manufacture, use, sale, offer for sale, and/or importation of MSN’s Proposed ANDA Product will contribute to the actual infringement of the ’827 patent.

516. On information and belief, MSN knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the ’827 patent.

517. The foregoing actions by MSN will constitute contributory infringement of the ’827 patent.

518. On information and belief, MSN intends to, and will, actively induce and contribute to the infringement of the ’827 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

519. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and /or importation of MSN’s Proposed ANDA Product by MSN will induce and/or contribute to infringement of the ’827 patent.

520. The commercial manufacture, use, offer for sale, sale, and/or importation of MSN’s Proposed ANDA Product, which will actively induce and/or contribute to the

infringement of the ’827 patent, in violation of Plaintiffs’ patent rights, will cause harm to Plaintiffs for which damages are inadequate.

521. Unless MSN is enjoined from actively inducing and contributing to the infringement of the ’827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

522. On information and belief, despite having actual notice of the ’827 patent, MSN continues to prepare to actively induce and/or contribute to infringement of the ’827 patent in disregard of Plaintiffs’ rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

COUNT XI

Infringement of the ’827 Patent Under 35 U.S.C. § 271(e)(2) by Sun’s Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

523. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

524. Sun submitted its ANDA No. 208066 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting such application, Sun has committed an act of infringement of the ’827 patent under 35 U.S.C. § 271(e)(2)(A).

525. The commercial manufacture, importation, use, sale, or offer for sale of Sun’s Proposed ANDA Product will constitute an act of infringement of the ’827 patent.

526. On information and belief, Sun became aware of the ’827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

527. On information and belief, Sun will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Sun will engage in such activities upon the FDA's approval of Sun's ANDA.

528. On information and belief, Sun knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

529. The commercial manufacture, importation, use, sale, or offer for sale of Sun's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

530. Unless and until Sun is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

531. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Sun's ANDA be a date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT XII

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271(b) and/or (c) by Sun's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

532. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

533. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

534. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

535. On information and belief, Sun's Proposed ANDA Product is covered by the claims of the '827 patent.

536. Sun has actual knowledge of the '827 patent.

537. On information and belief, Sun became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

538. On information and belief, Sun has acted with full knowledge of the '827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '827 patent.

539. On information and belief, Sun will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Sun will engage in such activities upon the FDA's approval of Sun's ANDA.

540. The commercial manufacture, use, sale, offer for sale, and/or importation of Sun's Proposed ANDA Product will induce the actual infringement of the '827 patent.

541. On information and belief, Sun knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product will actively induce the actual infringement of the '827 patent.

542. On information and belief, Sun will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA approval, a

label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the '827 patent.

543. On information and belief, Sun will encourage another's infringement of the '827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the '827 patent.

544. Sun's act of infringement will be done with the knowledge of the '827 patent and with the intent to encourage infringement.

545. The foregoing actions by Sun will constitute active inducement of the infringement of the '827 patent.

546. On information and belief, Sun knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the '827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

547. On information and belief, Sun knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

548. The commercial manufacture, use, sale, offer for sale, and/or importation of Sun's Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

549. On information and belief, Sun knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

550. The foregoing actions by Sun will constitute contributory infringement of the '827 patent.

551. On information and belief, Sun intends to, and will, actively induce and contribute to the infringement of the '827 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

552. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and /or importation of Sun's Proposed ANDA Product by Sun will induce and/or contribute to infringement of the '827 patent.

553. The commercial manufacture, use, offer for sale, sale, and/or importation of Sun's Proposed ANDA Product, which will actively induce and/or contribute to the infringement of the '827 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

554. Unless Sun is enjoined from actively inducing and contributing to the infringement of the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

555. On information and belief, despite having actual notice of the '827 patent, Sun continues to prepare to actively induce and/or contribute to infringement of the '827 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT XIII

Infringement of the '827 Patent Under 35 U.S.C. § 271(e)(2) by Accord's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

556. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

557. Accord submitted its ANDA No. 208049 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting such

application, Accord has committed an act of infringement of the '827 patent under 35 U.S.C. § 271(e)(2)(A).

558. The commercial manufacture, importation, use, sale, or offer for sale of Accord's Proposed ANDA Product will constitute an act of infringement of the '827 patent.

559. On information and belief, Accord became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

560. On information and belief, Accord will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Accord will engage in such activities upon the FDA's approval of Accord's ANDA.

561. On information and belief, Accord knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

562. The commercial manufacture, importation, use, sale, or offer for sale of Accord's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

563. Unless and until Accord is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

564. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Accord's ANDA be a date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT XIV

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271(b) and/or (c) by Accord's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

565. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

566. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

567. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

568. On information and belief, Accord's Proposed ANDA Product is covered by the claims of the '827 patent.

569. Accord has actual knowledge of the '827 patent.

570. On information and belief, Accord became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

571. On information and belief, Accord has acted with full knowledge of the '827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '827 patent.

572. On information and belief, Accord will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Accord will engage in such activities upon the FDA's approval of Accord's ANDA.

573. The commercial manufacture, use, sale, offer for sale, and/or importation of Accord's Proposed ANDA Product will induce the actual infringement of the '827 patent.

574. On information and belief, Accord knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product will actively induce the actual infringement of the ’827 patent.

575. On information and belief, Accord will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the ’827 patent.

576. On information and belief, Accord will encourage another’s infringement of the ’827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the ’827 patent.

577. Accord’s act of infringement will be done with the knowledge of the ’827 patent and with the intent to encourage infringement.

578. The foregoing actions by Accord will constitute active inducement of the infringement of the ’827 patent.

579. On information and belief, Accord knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the ’827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

580. On information and belief, Accord knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

581. The commercial manufacture, use, sale, offer for sale, and/or importation of Accord’s Proposed ANDA Product will contribute to the actual infringement of the ’827 patent.

582. On information and belief, Accord knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

583. The foregoing actions by Accord will constitute contributory infringement of the '827 patent.

584. On information and belief, Accord intends to, and will, actively induce and contribute to the infringement of the '827 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

585. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and /or importation of Accord's Proposed ANDA Product by Accord will induce and/or contribute to infringement of the '827 patent.

586. The commercial manufacture, use, offer for sale, sale, and/or importation of Accord's Proposed ANDA Product, which will actively induce and/or contribute to the infringement of the '827 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

587. Unless Accord is enjoined from actively inducing and contributing to the infringement of the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

588. On information and belief, despite having actual notice of the '827 patent, Accord continues to prepare to actively induce and/or contribute to infringement of the '827 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT XV

Infringement of the '827 Patent Under 35 U.S.C. § 271(e)(2) by Amneal's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

589. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

590. Amneal submitted its ANDA No. 208002 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting such application, Amneal has committed an act of infringement of the '827 patent under 35 U.S.C. § 271(e)(2)(A).

591. The commercial manufacture, importation, use, sale, or offer for sale of Amneal's Proposed ANDA Product will constitute an act of infringement of the '827 patent.

592. On information and belief, Amneal became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

593. On information and belief, Amneal will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Amneal will engage in such activities upon the FDA's approval of Amneal's ANDA.

594. On information and belief, Amneal knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

595. The commercial manufacture, importation, use, sale, or offer for sale of Amneal's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

596. Unless and until Amneal is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

597. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Amneal's ANDA be a date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT XVI

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271(b) and/or (c) by Amneal's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

598. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

599. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

600. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

601. On information and belief, Amneal's Proposed ANDA Product is covered by the claims of the '827 patent.

602. Amneal has actual knowledge of the '827 patent.

603. On information and belief, Amneal became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

604. On information and belief, Amneal has acted with full knowledge of the '827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '827 patent.

605. On information and belief, Amneal will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Amneal will engage in such activities upon the FDA's approval of Amneal's ANDA.

606. The commercial manufacture, use, sale, offer for sale, and/or importation of Amneal's Proposed ANDA Product will induce the actual infringement of the '827 patent.

607. On information and belief, Amneal knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product will actively induce the actual infringement of the '827 patent.

608. On information and belief, Amneal will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the '827 patent.

609. On information and belief, Amneal will encourage another's infringement of the '827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the '827 patent.

610. Amneal's act of infringement will be done with the knowledge of the '827 patent and with the intent to encourage infringement.

611. The foregoing actions by Amneal will constitute active inducement of the infringement of the '827 patent.

612. On information and belief, Amneal knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the '827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

613. On information and belief, Amneal knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

614. The commercial manufacture, use, sale, offer for sale, and/or importation of Amneal's Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

615. On information and belief, Amneal knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

616. The foregoing actions by Amneal will constitute contributory infringement of the '827 patent.

617. On information and belief, Amneal intends to, and will, actively induce and contribute to the infringement of the '827 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

618. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and /or importation of Amneal's Proposed ANDA Product by Amneal will induce and/or contribute to infringement of the '827 patent.

619. The commercial manufacture, use, offer for sale, sale, and/or importation of Amneal's Proposed ANDA Product, which will actively induce and/or contribute to the infringement of the '827 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

620. Unless Amneal is enjoined from actively inducing and contributing to the infringement of the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

621. On information and belief, despite having actual notice of the '827 patent, Amneal continues to prepare to actively induce and/or contribute to infringement of the '827 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT XVII

Infringement of the '827 Patent Under 35 U.S.C. § 271(e)(2) by FTUG's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

622. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

623. FTUG submitted its ANDA No. 207995 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting such application, FTUG has committed an act of infringement of the '827 patent under 35 U.S.C. § 271(e)(2)(A).

624. The commercial manufacture, importation, use, sale, or offer for sale of FTUG's Proposed ANDA Product will constitute an act of infringement of the '827 patent.

625. On information and belief, FTUG became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

626. On information and belief, FTUG will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, FTUG will engage in such activities upon the FDA's approval of FTUG's ANDA.

627. On information and belief, FTUG knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

628. The commercial manufacture, importation, use, sale, or offer for sale of FTUG's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

629. Unless and until FTUG is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

630. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for FTUG's ANDA be a date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT XVIII

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271(b) and/or (c) by FTUG's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

631. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

632. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

633. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

634. On information and belief, FTUG's Proposed ANDA Product is covered by the claims of the '827 patent.

635. FTUG has actual knowledge of the '827 patent.

636. On information and belief, FTUG became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

637. On information and belief, FTUG has acted with full knowledge of the '827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '827 patent.

638. On information and belief, FTUG will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, FTUG will engage in such activities upon the FDA's approval of FTUG's ANDA.

639. The commercial manufacture, use, sale, offer for sale, and/or importation of FTUG's Proposed ANDA Product will induce the actual infringement of the '827 patent.

640. On information and belief, FTUG knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product will actively induce the actual infringement of the '827 patent.

641. On information and belief, FTUG will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the '827 patent.

642. On information and belief, FTUG will encourage another's infringement of the '827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the '827 patent.

643. FTUG's act of infringement will be done with the knowledge of the '827 patent and with the intent to encourage infringement.

644. The foregoing actions by FTUG will constitute active inducement of the infringement of the '827 patent.

645. On information and belief, FTUG knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the '827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

646. On information and belief, FTUG knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

647. The commercial manufacture, use, sale, offer for sale, and/or importation of FTUG's Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

648. On information and belief, FTUG knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

649. The foregoing actions by FTUG will constitute contributory infringement of the '827 patent.

650. On information and belief, FTUG intends to, and will, actively induce and contribute to the infringement of the '827 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

651. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and /or importation of FTUG's Proposed ANDA Product by FTUG will induce and/or contribute to infringement of the '827 patent.

652. The commercial manufacture, use, offer for sale, sale, and/or importation of FTUG's Proposed ANDA Product, which will actively induce and/or contribute to the infringement of the '827 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

653. Unless FTUG is enjoined from actively inducing and contributing to the infringement of the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

654. On information and belief, despite having actual notice of the '827 patent, FTUG continues to prepare to actively induce and/or contribute to infringement of the '827 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT XIX

Infringement of the '827 Patent Under 35 U.S.C. § 271(e)(2) by InvaGen's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

655. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

656. InvaGen submitted its ANDA No. 208028 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting such application, InvaGen has committed an act of infringement of the '827 patent under 35 U.S.C. § 271(e)(2)(A).

657. The commercial manufacture, importation, use, sale, or offer for sale of InvaGen's Proposed ANDA Product will constitute an act of infringement of the '827 patent.

658. On information and belief, InvaGen became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

659. On information and belief, InvaGen will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, InvaGen will engage in such activities upon the FDA's approval of InvaGen's ANDA.

660. On information and belief, InvaGen knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

661. The commercial manufacture, importation, use, sale, or offer for sale of InvaGen's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

662. Unless and until InvaGen is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

663. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for InvaGen's ANDA be a date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT XX

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271(b) and/or (c) by InvaGen's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

664. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

665. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

666. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

667. On information and belief, InvaGen's Proposed ANDA Product is covered by the claims of the '827 patent.

668. InvaGen has actual knowledge of the '827 patent.

669. On information and belief, InvaGen became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

670. On information and belief, InvaGen has acted with full knowledge of the '827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '827 patent.

671. On information and belief, InvaGen will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, InvaGen will engage in such activities upon the FDA's approval of InvaGen's ANDA.

672. The commercial manufacture, use, sale, offer for sale, and/or importation of InvaGen's Proposed ANDA Product will induce the actual infringement of the '827 patent.

673. On information and belief, InvaGen knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product will actively induce the actual infringement of the '827 patent.

674. On information and belief, InvaGen will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the '827 patent.

675. On information and belief, InvaGen will encourage another's infringement of the '827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the '827 patent.

676. InvaGen's act of infringement will be done with the knowledge of the '827 patent and with the intent to encourage infringement.

677. The foregoing actions by InvaGen will constitute active inducement of the infringement of the '827 patent.

678. On information and belief, InvaGen knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the '827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

679. On information and belief, InvaGen knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

680. The commercial manufacture, use, sale, offer for sale, and/or importation of InvaGen's Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

681. On information and belief, InvaGen knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

682. The foregoing actions by InvaGen will constitute contributory infringement of the '827 patent.

683. On information and belief, InvaGen intends to, and will, actively induce and contribute to the infringement of the '827 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

684. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and /or importation of InvaGen's Proposed ANDA Product by InvaGen will induce and/or contribute to infringement of the '827 patent.

685. The commercial manufacture, use, offer for sale, sale, and/or importation of InvaGen's Proposed ANDA Product, which will actively induce and/or contribute to the infringement of the '827 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

686. Unless InvaGen is enjoined from actively inducing and contributing to the infringement of the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

687. On information and belief, despite having actual notice of the '827 patent, InvaGen continues to prepare to actively induce and/or contribute to infringement of the '827 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT XXI

Infringement of the '827 Patent Under 35 U.S.C. § 271(e)(2) by Par's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

688. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

689. Par submitted its ANDA No. 207948 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting such application, Par has committed an act of infringement of the '827 patent under 35 U.S.C. § 271(e)(2)(A).

690. The commercial manufacture, importation, use, sale, or offer for sale of Par's Proposed ANDA Product will constitute an act of infringement of the '827 patent.

691. On information and belief, Par became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

692. On information and belief, Par will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Par will engage in such activities upon the FDA's approval of Par's ANDA.

693. On information and belief, Par knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

694. The commercial manufacture, importation, use, sale, or offer for sale of Par's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

695. Unless and until Par is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

696. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Par's ANDA be a

date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT XXII

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271(b) and/or (c) by Par's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

697. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

698. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

699. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

700. On information and belief, Par's Proposed ANDA Product is covered by the claims of the '827 patent.

701. Par has actual knowledge of the '827 patent.

702. On information and belief, Par became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

703. On information and belief, Par has acted with full knowledge of the '827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '827 patent.

704. On information and belief, Par will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Par will engage in such activities upon the FDA's approval of Par's ANDA.

705. The commercial manufacture, use, sale, offer for sale, and/or importation of Par's Proposed ANDA Product will induce the actual infringement of the '827 patent.

706. On information and belief, Par knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product will actively induce the actual infringement of the '827 patent.

707. On information and belief, Par will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the '827 patent.

708. On information and belief, Par will encourage another's infringement of the '827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the '827 patent.

709. Par's act of infringement will be done with the knowledge of the '827 patent and with the intent to encourage infringement.

710. The foregoing actions by Par will constitute active inducement of the infringement of the '827 patent.

711. On information and belief, Par knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the '827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

712. On information and belief, Par knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

713. The commercial manufacture, use, sale, offer for sale, and/or importation of Par's Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

714. On information and belief, Par knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

715. The foregoing actions by Par will constitute contributory infringement of the '827 patent.

716. On information and belief, Par intends to, and will, actively induce and contribute to the infringement of the '827 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

717. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and /or importation of Par's Proposed ANDA Product by Par will induce and/or contribute to infringement of the '827 patent.

718. The commercial manufacture, use, offer for sale, sale, and/or importation of Par's Proposed ANDA Product, which will actively induce and/or contribute to the infringement of the '827 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

719. Unless Par is enjoined from actively inducing and contributing to the infringement of the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

720. On information and belief, despite having actual notice of the '827 patent, Par continues to prepare to actively induce and/or contribute to infringement of the '827 patent in

disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT XXIII

Infringement of the '827 Patent Under 35 U.S.C. § 271(e)(2) by Torrent's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

721. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

722. Torrent submitted its ANDA No. 208055 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting such application, Torrent has committed an act of infringement of the '827 patent under 35 U.S.C. § 271(e)(2)(A).

723. The commercial manufacture, importation, use, sale, or offer for sale of Torrent's Proposed ANDA Product will constitute an act of infringement of the '827 patent.

724. On information and belief, Torrent became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

725. On information and belief, Torrent will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Torrent will engage in such activities upon the FDA's approval of Torrent's ANDA.

726. On information and belief, Torrent knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

727. The commercial manufacture, importation, use, sale, or offer for sale of Torrent's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

728. Unless and until Torrent is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

729. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Torrent's ANDA be a date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT XXIV

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271(b) and/or (c) by Torrent's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

730. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

731. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

732. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

733. On information and belief, Torrent's Proposed ANDA Product is covered by the claims of the '827 patent.

734. Torrent has actual knowledge of the '827 patent.

735. On information and belief, Torrent became aware of the ’827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

736. On information and belief, Torrent has acted with full knowledge of the ’827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the ’827 patent.

737. On information and belief, Torrent will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Torrent will engage in such activities upon the FDA’s approval of Torrent’s ANDA.

738. The commercial manufacture, use, sale, offer for sale, and/or importation of Torrent’s Proposed ANDA Product will induce the actual infringement of the ’827 patent.

739. On information and belief, Torrent knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product will actively induce the actual infringement of the ’827 patent.

740. On information and belief, Torrent will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the ’827 patent.

741. On information and belief, Torrent will encourage another’s infringement of the ’827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the ’827 patent.

742. Torrent’s act of infringement will be done with the knowledge of the ’827 patent and with the intent to encourage infringement.

743. The foregoing actions by Torrent will constitute active inducement of the infringement of the ’827 patent.

744. On information and belief, Torrent knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the ’827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

745. On information and belief, Torrent knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

746. The commercial manufacture, use, sale, offer for sale, and/or importation of Torrent’s Proposed ANDA Product will contribute to the actual infringement of the ’827 patent.

747. On information and belief, Torrent knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the ’827 patent.

748. The foregoing actions by Torrent will constitute contributory infringement of the ’827 patent.

749. On information and belief, Torrent intends to, and will, actively induce and contribute to the infringement of the ’827 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

750. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and /or importation of Torrent’s Proposed ANDA Product by Torrent will induce and/or contribute to infringement of the ’827 patent.

751. The commercial manufacture, use, offer for sale, sale, and/or importation of Torrent’s Proposed ANDA Product, which will actively induce and/or contribute to the

infringement of the ’827 patent, in violation of Plaintiffs’ patent rights, will cause harm to Plaintiffs for which damages are inadequate.

752. Unless Torrent is enjoined from actively inducing and contributing to the infringement of the ’827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

753. On information and belief, despite having actual notice of the ’827 patent, Torrent continues to prepare to actively induce and/or contribute to infringement of the ’827 patent in disregard of Plaintiffs’ rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

COUNT XXV

Infringement of the ’827 Patent Under 35 U.S.C. § 271(e)(2) by Watson’s Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

754. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

755. Watson submitted its ANDA No. 208016 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting such application, Watson has committed an act of infringement of the ’827 patent under 35 U.S.C. § 271(e)(2)(A).

756. The commercial manufacture, importation, use, sale, or offer for sale of Watson’s Proposed ANDA Product will constitute an act of infringement of the ’827 patent.

757. On information and belief, Watson became aware of the ’827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

758. On information and belief, Watson will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Watson will engage in such activities upon the FDA's approval of Watson's ANDA.

759. On information and belief, Watson knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

760. The commercial manufacture, importation, use, sale, or offer for sale of Watson's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

761. Unless and until Watson is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

762. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Watson's ANDA be a date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT XXVI

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271(b) and/or (c) by Watson's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

763. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

764. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

765. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

766. On information and belief, Watson's Proposed ANDA Product is covered by the claims of the '827 patent.

767. Watson has actual knowledge of the '827 patent.

768. On information and belief, Watson became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

769. On information and belief, Watson has acted with full knowledge of the '827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '827 patent.

770. On information and belief, Watson will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Watson will engage in such activities upon the FDA's approval of Watson's ANDA.

771. The commercial manufacture, use, sale, offer for sale, and/or importation of Watson's Proposed ANDA Product will induce the actual infringement of the '827 patent.

772. On information and belief, Watson knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product will actively induce the actual infringement of the '827 patent.

773. On information and belief, Watson will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA

approval, a label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the '827 patent.

774. On information and belief, Watson will encourage another's infringement of the '827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the '827 patent.

775. Watson's act of infringement will be done with the knowledge of the '827 patent and with the intent to encourage infringement.

776. The foregoing actions by Watson will constitute active inducement of the infringement of the '827 patent.

777. On information and belief, Watson knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the '827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

778. On information and belief, Watson knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

779. The commercial manufacture, use, sale, offer for sale, and/or importation of Watson's Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

780. On information and belief, Watson knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

781. The foregoing actions by Watson will constitute contributory infringement of the '827 patent.

782. On information and belief, Watson intends to, and will, actively induce and contribute to the infringement of the '827 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

783. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and /or importation of Watson's Proposed ANDA Product by Watson will induce and/or contribute to infringement of the '827 patent.

784. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's Proposed ANDA Product, which will actively induce and/or contribute to the infringement of the '827 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

785. Unless Watson is enjoined from actively inducing and contributing to the infringement of the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

786. On information and belief, despite having actual notice of the '827 patent, Watson continues to prepare to actively induce and/or contribute to infringement of the '827 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT XXVII

Infringement of the '827 Patent Under 35 U.S.C. § 271(e)(2) by Zydus's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

787. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

788. Zydus submitted its ANDA No. 208052 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting such

application, Zydus has committed an act of infringement of the '827 patent under 35 U.S.C. § 271(e)(2)(A).

789. The commercial manufacture, importation, use, sale, or offer for sale of Zydus's Proposed ANDA Product will constitute an act of infringement of the '827 patent.

790. On information and belief, Zydus became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

791. On information and belief, Zydus will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Zydus will engage in such activities upon the FDA's approval of Zydus's ANDA.

792. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

793. The commercial manufacture, importation, use, sale, or offer for sale of Zydus's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

794. Unless and until Zydus is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

795. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Zydus's ANDA be a date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT XXVIII

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271(b) and/or (c) by Zydus's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

796. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

797. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

798. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

799. On information and belief, Zydus's Proposed ANDA Product is covered by the claims of the '827 patent.

800. Zydus has actual knowledge of the '827 patent.

801. On information and belief, Zydus became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

802. On information and belief, Zydus has acted with full knowledge of the '827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '827 patent.

803. On information and belief, Zydus will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Zydus will engage in such activities upon the FDA's approval of Zydus's ANDA.

804. The commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's Proposed ANDA Product will induce the actual infringement of the '827 patent.

805. On information and belief, Zydus knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product will actively induce the actual infringement of the '827 patent.

806. On information and belief, Zydus will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the '827 patent.

807. On information and belief, Zydus will encourage another's infringement of the '827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the '827 patent.

808. Zydus's act of infringement will be done with the knowledge of the '827 patent and with the intent to encourage infringement.

809. The foregoing actions by Zydus will constitute active inducement of the infringement of the '827 patent.

810. On information and belief, Zydus knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the '827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

811. On information and belief, Zydus knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

812. The commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

813. On information and belief, Zydus knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the ’827 patent.

814. The foregoing actions by Zydus will constitute contributory infringement of the ’827 patent.

815. On information and belief, Zydus intends to, and will, actively induce and contribute to the infringement of the ’827 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

816. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and /or importation of Zydus’s Proposed ANDA Product by Zydus will induce and/or contribute to infringement of the ’827 patent.

817. The commercial manufacture, use, offer for sale, sale, and/or importation of Zydus’s Proposed ANDA Product, which will actively induce and/or contribute to the infringement of the ’827 patent, in violation of Plaintiffs’ patent rights, will cause harm to Plaintiffs for which damages are inadequate.

818. Unless Zydus is enjoined from actively inducing and contributing to the infringement of the ’827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

819. On information and belief, despite having actual notice of the ’827 patent, Zydus continues to prepare to actively induce and/or contribute to infringement of the ’827 patent in disregard of Plaintiffs’ rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

COUNT XXIX

Infringement of the '827 Patent Under 35 U.S.C. § 271(e)(2) by Jubilant's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

820. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

821. Jubilant submitted its ANDA No. 210388 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting such application, Jubilant has committed an act of infringement of the '827 patent under 35 U.S.C. § 271(e)(2)(A).

822. The commercial manufacture, importation, use, sale, or offer for sale of Jubilant's Proposed ANDA Product will constitute an act of infringement of the '827 patent.

823. On information and belief, Jubilant became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

824. On information and belief, Jubilant will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Jubilant will engage in such activities upon the FDA's approval of Jubilant's ANDA.

825. On information and belief, Jubilant knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

826. The commercial manufacture, importation, use, sale, or offer for sale of Jubilant's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

827. Unless and until Jubilant is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

828. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Jubilant's ANDA be a date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT XXX

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271(b) and/or (c) by Jubilant's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

829. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

830. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

831. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

832. On information and belief, Jubilant's Proposed ANDA Product is covered by the claims of the '827 patent.

833. Jubilant has actual knowledge of the '827 patent.

834. On information and belief, Jubilant became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

835. On information and belief, Jubilant has acted with full knowledge of the '827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '827 patent.

836. On information and belief, Jubilant will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Jubilant will engage in such activities upon the FDA's approval of Jubilant's ANDA.

837. The commercial manufacture, use, sale, offer for sale, and/or importation of Jubilant's Proposed ANDA Product will induce the actual infringement of the '827 patent.

838. On information and belief, Jubilant knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product will actively induce the actual infringement of the '827 patent.

839. On information and belief, Jubilant will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the '827 patent.

840. On information and belief, Jubilant will encourage another's infringement of the '827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the '827 patent.

841. Jubilant's act of infringement will be done with the knowledge of the '827 patent and with the intent to encourage infringement.

842. The foregoing actions by Jubilant will constitute active inducement of the infringement of the '827 patent.

843. On information and belief, Jubilant knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the '827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

844. On information and belief, Jubilant knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

845. The commercial manufacture, use, sale, offer for sale, and/or importation of Jubilant's Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

846. On information and belief, Jubilant knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

847. The foregoing actions by Jubilant will constitute contributory infringement of the '827 patent.

848. On information and belief, Jubilant intends to, and will, actively induce and contribute to the infringement of the '827 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

849. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and /or importation of Jubilant's Proposed ANDA Product by Jubilant will induce and/or contribute to infringement of the '827 patent.

850. The commercial manufacture, use, offer for sale, sale, and/or importation of Jubilant's Proposed ANDA Product, which will actively induce and/or contribute to the infringement of the '827 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

851. Unless Jubilant is enjoined from actively inducing and contributing to the infringement of the ’827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

852. On information and belief, despite having actual notice of the ’827 patent, Jubilant continues to prepare to actively induce and/or contribute to infringement of the ’827 patent in disregard of Plaintiffs’ rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

RELIEF SOUGHT

WHEREFORE, Plaintiffs request:

A) That a judgment be entered that Defendants have infringed the ’827 patent under 35 U.S.C. § 271(e)(2)(A) by submitting their ANDAs under Section 505(j) of the FFDCA, and the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Defendants’ Proposed ANDA Products will constitute an act of infringement of the ’827 patents;

B) That a judgment be entered declaring that the ’827 patent has not been proven invalid or unenforceable;

C) That an Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Defendants’ ANDAs shall be a date which is not earlier than the expiration date of the ’827 patent as extended by any applicable period of exclusivity;

D) That an injunction be granted pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with Defendants or acting on Defendants’ behalf, from engaging in the commercial manufacture, use,

offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '827 patent;

E) That a judgment be entered declaring that if Defendants engage in the commercial manufacture, use, offer to sell, sale, or importation of Defendants' generic products disclosed in their ANDAs prior to the expiration of the '827 patent, as extended by any applicable period of exclusivity, a preliminary injunction and/or permanent injunction will be entered enjoining such conduct pursuant to 35 U.S.C. § 283;

F) That a judgment be entered declaring that if Defendants engage in the commercial manufacture, use, offer to sell, sale, or importation of the Proposed ANDA Products disclosed in their ANDAs prior to the expiration of the '827 patent, as extended by any applicable period of exclusivity, Plaintiffs are entitled to damages or other monetary relief resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

G) That a judgment be issued pursuant to 28 U.S.C. § 2201 declaring that if Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with Defendants or acting on Defendants' behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed ANDA Products prior to the expiration of the '827 patent, it will constitute an act of infringement of the '827 patent under 35 U.S.C. §§ 271(b) and/or (c);

H) That a judgment be entered that this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs;

I) An accounting for infringing sales not presented at trial and an award by the Court

of additional damages for any such infringing sales; and

J) Such other and further relief as the Court may deem just and proper.

Dated: February 23, 2018

By: *s/* David E. De Lorenzi

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