IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACADIA PHARMACEUTICALS INC., Plaintiff, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED, Defendants.	C.A. No. 1:20-cv-01021-RGA

ZYDUS PHARMACEUTICALS (USA) INC. AND CADILA HEALTHCARE LIMITED'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO THE COMPLAINT

Zydus Pharmaceuticals (USA) Inc. ("Zydus") and Cadila Healthcare Limited ("Cadila") (collectively, "Defendants"), for their Answer, Affirmative Defenses, and Counterclaims to the Complaint of Acadia Pharmaceuticals Inc. ("Acadia" or "Plaintiff"), state as follows:

All averments not expressly admitted are denied.

THE PARTIES

1. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 1 and therefore deny them.

2. Admitted.

3. Admitted.

4. Admitted.

5. The allegations in paragraph 5 are a legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus is a wholly owned subsidiary of Cadila. Defendants deny all other allegations in paragraph 5.

6. The allegations in paragraph 6 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus is a wholly owned subsidiary of Cadila; that Cadila manufactures pharmaceutical products, including generic pharmaceutical products; that Zydus files Abbreviated New Drug Applications ("ANDAs") seeking approval from the United States Food and Drug Administration ("FDA") to market pharmaceutical products in the United States, including products manufactured by Cadila; and that Zydus sells pharmaceutical products in the United States, including pharmaceutical products manufactured by Cadila. Defendants deny all other allegations in paragraph 6.

7. Defendants admit that Zydus submitted ANDA Nos. 214493 and 214502 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively, and that Cadila is the manufacturer of the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively. Defendants deny all other allegations in paragraph 7.

NATURE OF THE ACTION

8. The allegations in paragraph 8 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiff's Complaint purports to be a civil action alleging infringement of United States Patent Nos. 7,601,740 ("the '740 patent"), 7,732,615 ("the '615 patent"), 10,449,185 ("the '185 patent"), 10,517,860 ("the '860 patent"), and 10,646,480 ("the '480 patent") (collectively, "the patents-in-suit"). Defendants deny all other allegations of paragraph 8.

JURISDICTION & VENUE

9. The allegations in paragraph 9 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest subject matter jurisdiction in this

Court solely for the purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively. Defendants deny all other allegations in paragraph 9.

10. The allegations in paragraph 10 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court solely for the purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively. Defendants deny that the commercial manufacture, use, sale, or importation of the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively, will infringe any valid and enforceable claim of the patents-in-suit. Defendants deny all other allegations in paragraph 10.

11. The allegations in paragraph 11 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction or venue in this Court solely for the purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively. Defendants admit that Zydus submitted ANDA Nos. 214493 and 214502 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively. Defendants further admit that ANDA No. 214493 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, '185, and '480 patents and that ANDA No. 214502 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)

with respect to, *inter alia*, the '740, '615, and '860 patents. Defendants deny that the commercial manufacture, use, sale, or importation of the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively, will infringe any valid and enforceable claim of the patents-in-suit. Defendants deny all other allegations in paragraph 11.

12. Defendants admit that Zydus sells pharmaceutical products, including generic pharmaceutical products, in the United States. Defendants deny all other allegations in paragraph 12.

13. Defendants admit that Zydus's website states that Zydus "currently offers more than 480 SKUs to the US market and is ranked the fourth largest unbranded generic corporation in the US" and that Zydus "is looking forward to continuing its growth in the US marketplace." *See* http://zydususa.com/overview/ (last visited October 12, 2020). Defendants further admit that Zydus's website states that "Zydus's generic products can be found across the country in most pharmacies, both in store as well as mail order." *See* http://zydususa.com/faq/ (last visited October 12, 2020). Defendants deny all other allegations in paragraph 13.

14. The allegations in paragraph 14 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court solely for the purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively. Defendants deny that the commercial manufacture, use, sale, or importation of the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively, will infringe any valid and enforceable claim of the patents-in-suit. Defendants deny all other allegations in paragraph 14.

15. The allegations in paragraph 15 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction or venue in this Court solely for the purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively. Defendants admit that Zydus submitted ANDA Nos. 214493 and 214502 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively. Defendants further admit that ANDA No. 214493 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, '185, and '480 patents and that ANDA No. 214502 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, and '860 patents. Defendants deny that the commercial manufacture, use, sale, or importation of the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively, will infringe any valid and enforceable claim of the patents-in-suit. Defendants deny all other allegations in paragraph 15.

16. Defendants admit that Cadila manufactures pharmaceutical products, including generic pharmaceutical products, and that Zydus sells pharmaceutical products, including generic pharmaceutical products manufactured by Cadila, in the United States. Defendants deny all other allegations in paragraph 16.

17. Defendants admit that Cadila's website states that "Zydus' global business has a strong presence in the regulated markets of the US," that "[t]he group has manufacturing sites and research facilities spread across five states of Gujarat, Maharashtra, Goa, Himachal Pradesh and

Sikkim in India and in the US and Brazil," and that "[i]t has more than 30 manufacturing plants worldwide including India, Brazil and USA." *See* https://zyduscadila.com/ (last visited October 12, 2020). Defendants deny all other allegations in paragraph 17.

18. Denied.

19. The allegations in paragraph 19 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction or venue in this Court solely for the purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively. Defendants admit that: in *Boehringer Ingelheim Pharm. Inc. v. Zydus Pharm. (USA) Inc*., C.A. No. 19-1501-CFC (D. Del.), Defendants asserted counterclaims and stated that, "[a]lthough Zydus denies that venue is proper in this District, Zydus does not contest venue or personal jurisdiction in this Court for the limited purposes of this action only"; in *Boehringer Ingelheim Pharm. Inc. v. Zydus Pharm. (USA) Inc.,* C.A. No. 19-1295-CFC (D. Del.), Defendants asserted counterclaims and stated that, "[a]lthough Zydus denies that venue is proper in this District, Zydus does not contest venue or personal jurisdiction in this Court for the limited purposes of this action only"; in *Boehringer Ingelheim Pharm. Inc. v. Zydus Pharm. (USA) Inc*., C.A. No. 18-1763-CFC-SRF (D. Del.), Defendants asserted counterclaims and stated that, "[a]lthough Defendants deny that venue is proper in this District, Defendants do not contest venue or personal jurisdiction in this Court for the limited purposes of this action only"; in *Millennium Pharmaceuticals, Inc. v. Zydus Pharmaceuticals (USA) Inc*., No. 1:17-cv-00423 (D. Del. May 24, 2017), Defendants asserted counterclaims and stated that "Defendants do not contest personal jurisdiction in this Court for the limited purposes of this action only" and that "Defendants do not contest venue in this Court for the limited purposes of this action

only"; in *Sanofi-Aventis U.S. LLC v. Zydus Pharmaceuticals (USA) Inc*., No. 1:17-cv-00034 (D. Del. Apr. 10, 2017), Defendants asserted counterclaims and stated that "Defendants do not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to the proposed product described in ANDA No. 209668" and that "Defendants do not contest venue in this judicial district solely for purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to the proposed product described in ANDA No. 209668"; in *Amgen Inc. v. Zydus Pharm. (USA) Inc.*, C.A. No. 20-0075-CFC (D. Del.), Defendants stated that "Zydus does not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Zydus in this case and solely as they apply to the proposed product described in ANDA No. 213442" and that "Zydus does not contest venue in this Court solely for the purposes of Plaintiffs' claims against Zydus in this case and solely as they apply to the proposed product described in ANDA No. 213442"; in *Pfizer Inc. v. Zydus Pharm. (USA) Inc.*, C.A. No. 19-0760-CFC (D. Del.), Defendants stated that "Zydus USA does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Zydus USA in this case and solely as they apply to the proposed product described in ANDA No. 213098" and that "Cadila does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Cadila in this case and solely as they apply to the proposed product described in ANDA No. 213098"; in *Merck Sharp & Dohme Corp. v. Zydus Pharm. (USA) Inc.*, C.A. No. 19-0314-RGA (D. Del.), Defendants stated that "Defendants do not contest personal jurisdiction in this Court solely for the purposes of Merck's claims against Defendants in this case and solely as they apply to the sitagliptin tablets … described in ANDA Nos. 208186, 208535, and 209573, respectively," "Zydus USA does not contest venue in this Court solely for the purposes of Merck's claims against Zydus USA in this case and solely as they apply to the sitagliptin tablets … described in ANDA

Nos. 208186, 208535, and 209573, respectively," and that "Cadila does not contest venue in this Court solely for the purposes of Merck's claims against Cadila in this case and solely as they apply to the sitagliptin tablets … described in ANDA Nos. 208186, 208535, and 209573, respectively"; in *Anacor Pharm., Inc. v. Ascent Pharm., Inc.*, C.A. No. 18-1673-RGA (D. Del.), Defendants stated that "Zydus does not contest jurisdiction in this Court solely for purposes of Anacor's claims against Zydus in this case and solely as they apply to the proposed product described in ANDA No. 212294" and that "Zydus does not contest venue in this Court solely for purposes of Anacor's claims against Zydus in this case and solely as they apply to the proposed product described in ANDA No. 212294"; in *H. Lundbeck A/S v. Zydus Pharm. (USA) Inc.*, C.A. No. 18-0150-LPS (D. Del.), Defendants stated that "Defendants do not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to the vortioxetine tablets, 5 mg, 10 mg, and 20 mg, described in ANDA No. 211146" and that "Defendants do not contest venue in this Court solely for purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to the vortioxetine tablets, 5 mg, 10 mg, and 20 mg, described in ANDA No. 211146"; in *Pfizer Inc. v. Zydus Pharmaceuticals (USA) Inc.*, No. 1:17-cv-00214-LPS (D. Del. June 5, 2017), Defendants stated that "Defendants do not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to the proposed product described in ANDA No. 209829"; in *Pfizer Inc. et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, C.A. No. 17-158-GJP (D. Del.), Defendants asserted affirmative defenses and stated that "Defendants do not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to the proposed product described in ANDA No. 209829"; in *Allergan USA, Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 19-1727-RGA (D. Del.), Zydus asserted

affirmative defenses and stated that "Zydus does not contest personal jurisdiction in this Court solely for purposes of Allergan's alleged claims arising under 35 U.S.C. § 271(e)(2) against Zydus related to the patents-in-suit in this case and solely as those alleged claims apply to the proposed products described in ANDA No. 213522" and that "Zydus does not contest venue in this Court solely for purposes of Allergan's alleged claims arising under 35 U.S.C. § 271(e)(2) against Zydus related to the patents-in-suit in this case and solely as those alleged claims apply to the proposed products described in ANDA No. 213522"; and in *Biogen Int'l GmbH v. Zydus Pharm. (USA) Inc*., C.A. No. 19-0333-MN (D. Del.), Zydus stated that "Zydus does not contest subject matter jurisdiction, personal jurisdiction, or venue in this Court solely for purposes of Biogen's alleged claims arising under 35 U.S.C. § 271(e)(2) against Zydus related to the '001 patent in this case and solely as those alleged claims apply to the proposed products described in ANDA No. 210538." Defendants deny all other allegations in paragraph 19.

20. The allegations in paragraph 20 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiff's Complaint purports to be a civil action alleging infringement of the '740, '615, '185, '480, and '860 patents pursuant to Title 35 of the United States Code. Defendants further admit that Cadila is an entity organized and existing under the laws of India, having a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, India. Defendants do not contest personal jurisdiction in this Court solely for the purposes of Plaintiff's claims against Defendants in this case and solely as they apply to the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively. Defendants deny all other allegations in paragraph 20.

ACADIA' S NDAS AND THE PATENTS-IN-SUIT

21. Defendants admit that FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists "ACADIA PHARMACEUTICALS INC" as the Applicant Holder; "PIMAVANSERIN TARTRATE" as the Active Ingredient; "NUPLAZID" as the Proprietary Name; "EQ 34 MG BASE" as the Strength; and "CAPSULE; ORAL" as the Dosage Form and Route of Administration for New Drug Application ("NDA") No. 210793. Defendants lack knowledge or information sufficient to form a belief about all other allegations in paragraph 21 and therefore deny them.

22. Defendants admit that FDA's Orange Book lists "ACADIA PHARMACEUTICALS INC" as the Applicant Holder; "PIMAVANSERIN TARTRATE" as the Active Ingredient; "NUPLAZID" as the Proprietary Name; "EQ 10 MG BASE" as the Strength; and "TABLET; ORAL" as the Dosage Form and Route of Administration for NDA No. 207318. Defendants lack knowledge or information sufficient to form a belief about all other allegations in paragraph 22 and therefore deny them.

23. Defendants admit on information and belief that what purports to be a copy of the '740 patent is attached to the Complaint as Exhibit A. Defendants further admit that Exhibit A is titled "Selective Serotonin 2A/2C Receptor Inverse Agonists as Therapeutics for Neurodegenerative Diseases" and lists October 13, 2009, as the Date of Patent. Defendants deny all other allegations in paragraph 23.

24. The allegations in paragraph 24 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Exhibit A lists "Acadia Pharmaceuticals, Inc." as the "Assignee." Defendants deny all other allegations in paragraph 24.

25. Defendants admit on information and belief that what purports to be a copy of the '615 patent is attached to the Complaint as Exhibit B. Defendants further admit that Exhibit B is

titled "N-(4-fluorobenzy1)-N-(1-methylpiperidin-4-y1)-N'-(4-(2-methylpropyloxy)phenylmethyl)carbamide and its Tartrate Salt and Crystalline Forms" and lists June 8, 2010, as the Date of Patent. Defendants deny all other allegations in paragraph 25.

26. The allegations in paragraph 26 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Exhibit B lists "ACADIA Pharmaceuticals Inc." as the "Assignee." Defendants deny all other allegations in paragraph 26.

27. Defendants admit on information and belief that what purports to be a copy of the '185 patent is attached to the Complaint as Exhibit C. Defendants further admit that Exhibit C is titled "Formulations of Pimavanserin" and lists October 22, 2019, as the Date of Patent. Defendants deny all other allegations in paragraph 27.

28. The allegations in paragraph 28 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Exhibit C lists "ACADIA Pharmaceuticals Inc." as the "Assignee." Defendants deny all other allegations in paragraph 28.

29. Defendants admit on information and belief that what purports to be a copy of the '860 patent is attached to the Complaint as Exhibit D. Defendants further admit that Exhibit D is titled "Combination of Pimavanserin and Cytochrome P450 Modulators" and lists December 31, 2019, as the Date of Patent. Defendants deny all other allegations in paragraph 29.

30. The allegations in paragraph 30 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Exhibit D lists "ACADIA Pharmaceuticals Inc." as the "Assignee." Defendants deny all other allegations in paragraph 30.

31. Defendants admit on information and belief that what purports to be a copy of the '480 patent is attached to the Complaint as Exhibit E. Defendants further admit that Exhibit E is

titled "Formulations of Pimavanserin" and lists May 12, 2020, as the Date of Patent. Defendants deny all other allegations in paragraph 31.

32. The allegations in paragraph 32 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Exhibit E lists "ACADIA Pharmaceuticals Inc." as the "Assignee." Defendants deny all other allegations in paragraph 32.

33. The allegations in paragraph 33 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that FDA's Orange Book lists, *inter alia*, the '740, '615, '185, and '480 patents in connection with NDA No. 210793, NUPLAZID® (pimavanserin tartrate) capsules, 34 mg. Defendants deny all other allegations in paragraph 33.

34. The allegations in paragraph 34 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that FDA's Orange Book lists, *inter alia*, the '740, '615, and '860 patents for NDA No. 207318, NUPLAZID® (pimavanserin tartrate) tablets, 10 mg. Defendants deny all other allegations in paragraph 34.

ZYDUS' ANDAS AND PARAGRAPH IV NOTIFICATIONS

35. Defendants admit that Zydus submitted ANDA No. 214493 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of the pimavanserin capsules, 34 mg, described in ANDA No. 214493. Defendants further admit that ANDA No. 214493 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, '185, and '480 patents. Defendants deny all other allegations in paragraph 35.

36. The allegations in paragraph 36 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 214493 identifies "NUPLAZID® (pimavanserin) capsules" as the "Reference-Listed Drug (RLD)" and "EQ 34MG

BASE" as the "RLD Strength(s)." Defendants further admit that the product labeling for the pimavanserin capsules, 34 mg, described in ANDA No. 214493 will comply with applicable law. Defendants deny all other allegations in paragraph 36.

37. Defendants admit that Zydus sent a letter dated June 22, 2020 ("Zydus's ANDA No. 214493 Notice Letter") to Plaintiff, notifying Plaintiff that Zydus submitted ANDA No. 214493 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of the pimavanserin capsules, 34 mg, described in ANDA No. 214493, and that ANDA No. 214493 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, '185, and '480 patents. Defendants deny all other allegations in paragraph 37.

38. Defendants admit that Zydus sent Zydus's ANDA No. 214493 Notice Letter to Plaintiff, notifying Plaintiff that ANDA No. 214493 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, '185, and '480 patents. Defendants deny that the allegations in paragraph 38 accurately and completely reflect Zydus's ANDA No. 214493 Notice Letter and therefore deny them. Defendants deny all other allegations in paragraph 38.

39. Defendants admit that Zydus submitted ANDA No. 214502 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of the pimavanserin tablets, 10 mg, described in ANDA No. 214502. Defendants further admit that ANDA No. 214502 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, and '860 patents. Defendants deny all other allegations in paragraph 39.

40. The allegations in paragraph 40 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 214502 identifies "NUPLAZID® (pimavanserin) Tablets" as the "Reference-Listed Drug (RLD)" and "EQ 10MG BASE" as the "RLD Strength(s)." Defendants further admit that the product labeling for the pimavanserin tablets, 10 mg, described in ANDA No. 214502 will comply with applicable law. Defendants deny all other allegations in paragraph 40.

41. Defendants admit that Zydus sent a letter dated June 22, 2020 ("Zydus's ANDA No. 214502 Notice Letter") to Plaintiff, notifying Plaintiff that Zydus submitted ANDA No. 214502 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of the pimavanserin tablets, 10 mg, described in ANDA No. 214502, and that ANDA No. 214502 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, and '860 patents. Defendants deny all other allegations in paragraph 41.

42. Defendants admit that Zydus sent Zydus's ANDA No. 214502 Notice Letter to Plaintiff, notifying Plaintiff that ANDA No. 214502 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, and '860 patents. Defendants deny that the allegations in paragraph 42 accurately and completely reflect Zydus's ANDA No. 214502 Notice Letter and therefore deny them. Defendants deny all other allegations in paragraph 42.

43. The allegations in paragraph 43 are legal conclusions to which no answer is required and do not appear to be directed to ANDA Nos. 214493 and 214502. To the extent an answer is required, Defendants admit that Zydus's ANDA No. 214493 Notice Letter and Zydus's

ANDA No. 214502 Notice Letter comply with applicable law. Defendants deny all other allegations in paragraph 43.

44. Denied.

45. The allegations in paragraph 45 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus sent Zydus's ANDA No. 214493 Notice Letter and Zydus's ANDA No. 214502 Notice Letter (collectively, "Zydus's Notice Letters") to Plaintiff on June 22, 2020, and that Plaintiff filed the Complaint alleging infringement of the patents-in-suit on July 30, 2020. Defendants deny all other allegations in paragraph 45.

46. Defendants admit that Zydus's ANDA No. 214493 Notice Letter and Zydus's ANDA No. 214502 Notice Letter comply with applicable law. Defendants further admit that, after Zydus sent Zydus's ANDA No. 214493 Notice Letter and Zydus's ANDA No. 214502 Notice Letter to Plaintiff, the parties exchanged proposed revisions to the Offers of Confidential Access ("OCAs") contained in Zydus's ANDA No. 214493 Notice Letter and Zydus's ANDA No. 214502 Notice Letter. Plaintiff's proposed revisions to the OCAs exceeded the requirements of applicable law. Defendants further admit that, on July 29, 2020, Plaintiff's counsel stated that, "[c]onsidering ACADIA's expectations for the OCA and the time remaining in the 45-day period, it is apparent that we will not reach an agreement in time." Defendants admit that Plaintiff did not agree to the terms for confidential access as of the filing of the Complaint. Defendants deny all other allegations in paragraph 46.

47. Defendants admit that Zydus's ANDA No. 214493 Notice Letter and Zydus's ANDA No. 214502 Notice Letter comply with applicable law. Defendants further admit that, after Zydus sent Zydus's ANDA No. 214493 Notice Letter and Zydus's ANDA No. 214502 Notice

Letter to Plaintiff, the parties exchanged proposed revisions to the OCAs contained in Zydus's ANDA No. 214493 Notice Letter and Zydus's ANDA No. 214502 Notice Letter. Plaintiff's proposed revisions to the OCAs exceeded the requirements of applicable law. Defendants further admit that, on July 29, 2020, Plaintiff's counsel stated that, "[c]onsidering ACADIA's expectations for the OCA and the time remaining in the 45-day period, it is apparent that we will not reach an agreement in time." Defendants admit that Plaintiff did not agree to the terms for confidential access as of the filing of the Complaint. Defendants further admit that, as of November 2, 2020, Defendants have not produced ANDA Nos. 214493 and 214502 to Plaintiff. Defendants deny all other allegations in paragraph 47.

48. Denied.

COUNT I – INFRINGEMENT BY ZYDUS USA AND CADILA

49. Defendants restate and reallege their answers to each of the preceding paragraphs 1–48, as if fully set forth herein.

50. Denied.

51. Defendants admit that ANDA No. 214493 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, '185, and '480 patents. Defendants further admit that Zydus sent Zydus's ANDA No. 214493 Notice Letter to Plaintiff, notifying Plaintiff that ANDA No. 214493 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, '185, and '480 patents. Defendants further admit that Zydus's ANDA No. 214493 Notice Letter contains a detailed statement of the factual and legal basis of Zydus's certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '740, '615, '185, and '480 patents are not valid, unenforceable, or will not be infringed. Defendants deny that the allegations in the first sentence of paragraph 51 accurately and

completely reflect Zydus's ANDA No. 214493 Notice Letter and therefore deny them. Defendants deny all other allegations of paragraph 51.

52. Defendants deny that the allegations in paragraph 52 accurately and completely reflect Zydus's ANDA No. 214493 Notice Letter, which states that Zydus "does not waive, and expressly reserves, the right to raise additional defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '740, … '615, … '185, or '480 patents in any ensuing litigation or other proceeding that may result from receipt of [Zydus's ANDA No. 214493 Notice Letter]." *See Abbott Labs., Inc. v. Apotex Inc.*, 725 F. Supp. 2d 724, 728 (N.D. Ill. 2010) (refusing to strike defense theories not raised in defendant's notice letter because an ANDA filer is "not limited to the invalidity and noninfringement theories raised in its paragraph IV [notice] letter"); *Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99 Civ. 8928 (BSJ), 2000 WL 257125, at *1 (S.D.N.Y. Mar. 8, 2000) ("There is no language in the relevant statutory provisions, legislative history or cases barring [an ANDA filer] from raising defenses and counterclaims not noticed in [its] ANDA."). Zydus denies all other allegations in paragraph 52.

53. Defendants deny that the allegations in paragraph 53 accurately and completely reflect Zydus's ANDA No. 214493 Notice Letter, which states that Zydus "does not waive, and expressly reserves, the right to raise additional defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '740, … '615, … '185, or '480 patents in any ensuing litigation or other proceeding that may result from receipt of [Zydus's ANDA No. 214493 Notice Letter]." *See Abbott Labs.*, 725 F. Supp. 2d at 728 (refusing to strike defense theories not raised in defendant's notice letter because an ANDA filer is "not limited to the invalidity and noninfringement theories raised in its paragraph IV [notice] letter"); *Astra Aktiebolag*, 2000 WL 257125 at *1 ("There is no language in the relevant statutory provisions,

legislative history or cases barring [an ANDA filer] from raising defenses and counterclaims not noticed in [its] ANDA."). Defendants deny all other allegations in paragraph 53.

54. The allegations in paragraph 54 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 54. Defendants admit that Zydus submitted ANDA No. 214493 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of the pimavanserin capsules, 34 mg, described in ANDA No. 214493. Defendants further admit that ANDA No. 214493 identifies Cadila as the manufacturer of the pimavanserin capsules, 34 mg, described in ANDA No. 214493. Defendants further admit that ANDA No. 214493 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, '185, and '480 patents. Defendants deny all other allegations in paragraph 54.

55. The allegations in paragraph 55 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 214493 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, '185, and '480 patents. Defendants deny that the commercial manufacture, use, sale, or importation of the pimavanserin capsules, 34 mg, described in ANDA No. 214493 will infringe any valid and enforceable claim of the '740, '615, '185, and '480 patents. Defendants deny all other allegations in paragraph 55.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

COUNT II – INFRINGEMENT BY ZYDUS USA AND CADILA

60. Defendants restate and reallege their answers to each of the preceding paragraphs 1–59, as if fully set forth herein.

61. Denied.

62. Defendants admit that ANDA No. 214502 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, and '860 patents. Defendants further admit that Zydus sent Zydus's ANDA No. 214502 Notice Letter to Plaintiff, notifying Plaintiff that ANDA No. 214502 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, and '860 patents. Defendants further admit that Zydus's ANDA No. 214502 Notice Letter contains a detailed statement of the factual and legal basis of Zydus's certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '740, '615, and '860 patents are not valid, unenforceable, or will not be infringed. Defendants deny that the allegations in the first sentence of paragraph 62 accurately and completely reflect Zydus's ANDA No. 214502 Notice Letter and therefore deny them. Defendants deny all other allegations of paragraph 62.

63. Defendants deny that the allegations in paragraph 63 accurately and completely reflect Zydus's ANDA No. 214502 Notice Letter, which states that Zydus "does not waive, and expressly reserves, the right to raise additional defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '740, … '615, … and '860 patents in any ensuing litigation or other proceeding that may result from receipt of [Zydus's ANDA No. 214502 Notice Letter]." *See Abbott Labs.*, 725 F. Supp. 2d at 728 (refusing to strike defense theories not raised in defendant's notice letter because an ANDA filer is "not limited to the invalidity and noninfringement theories raised in its paragraph IV [notice] letter"); *Astra Aktiebolag*, 2000 WL

257125 at *1 ("There is no language in the relevant statutory provisions, legislative history or cases barring [an ANDA filer] from raising defenses and counterclaims not noticed in [its] ANDA."). Defendants deny all other allegations in paragraph 63.

64. Defendants deny that the allegations in paragraph 64 accurately and completely reflect Zydus's ANDA No. 214502 Notice Letter, which states that Zydus "does not waive, and expressly reserves, the right to raise additional defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '740, … '615, … and '860 patents in any ensuing litigation or other proceeding that may result from receipt of [Zydus's ANDA No. 214502 Notice Letter]." *See Abbott Labs.*, 725 F. Supp. 2d at 728 (refusing to strike defense theories not raised in defendant's notice letter because an ANDA filer is "not limited to the invalidity and noninfringement theories raised in its paragraph IV [notice] letter"); *Astra Aktiebolag*, 2000 WL 257125 at *1 ("There is no language in the relevant statutory provisions, legislative history or cases barring [an ANDA filer] from raising defenses and counterclaims not noticed in [its] ANDA."). Defendants deny all other allegations in paragraph 64.

65. The allegations in paragraph 65 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence. Defendants admit that Zydus submitted ANDA No. 214502 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of the pimavanserin tablets, 10 mg, described in ANDA No. 214502. Defendants further admit that ANDA No. 214502 identifies Cadila as the manufacturer of the pimavanserin tablets, 10 mg, described in ANDA No. 214502. Defendants further admit that ANDA No. 214502 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, and '860 patents. Defendants deny all other allegations in paragraph 65.

66. Denied.

67. The allegations in paragraph 67 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 214502 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to, *inter alia*, the '740, '615, and '860 patents. Defendants deny that the commercial manufacture, use, sale, or importation of the pimavanserin tablets, 10 mg, described in ANDA No. 214502 will infringe any valid and enforceable claim of the '740, '615, and '860 patents. Defendants deny all other allegations in paragraph 67.

68. Denied.

69. Denied.

70. Denied.

PRAYER FOR RELIEF

Defendants specifically deny that Plaintiff is entitled to the general or specific relief requested against Defendants, or to any relief whatsoever, and pray for judgment in favor of Defendants, dismissing this action with prejudice and awarding Defendants their reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in their Answer and without admitting any allegations of the Complaint not otherwise admitted, Defendants aver and assert the following Affirmative Defenses to Plaintiff's Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 7,601,740)

Plaintiff will not and cannot meet the burden of proof required to show that the commercial manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively, will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '740 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 7,601,740)

Upon information and belief, the claims of the '740 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

THIRD AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 7,732,615)

Plaintiff will not and cannot meet the burden of proof required to show that the commercial manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively, will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '615 patent.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 7,732,615)

Upon information and belief, the claims of the '615 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

FIFTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,449,185)

Plaintiff will not and cannot meet the burden of proof required to show that the commercial manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the pimavanserin capsules, 34 mg, described in ANDA No. 214493 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '185 patent.

SIXTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,449,185)

Upon information and belief, the claims of the '185 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

SEVENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,517,860)

Plaintiff will not and cannot meet the burden of proof required to show that the commercial manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the pimavanserin tablets, 10 mg, described in ANDA No. 214502 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '860 patent.

EIGHTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,517,860)

Upon information and belief, the claims of the '860 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

NINTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,646,480)

Plaintiff will not and cannot meet the burden of proof required to show that the commercial manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the

pimavanserin capsules, 34 mg, described in ANDA No. 214493 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '480 patent.

TENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,646,480)

Upon information and belief, the claims of the '480 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

RESERVATION OF DEFENSES

Defendants hereby reserve any and all defenses that are available under the Federal Rules of Civil Procedure and the United States Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this investigation.

COUNTERCLAIMS

Zydus Pharmaceuticals (USA) Inc. ("Zydus") and Cadila Healthcare Limited ("Cadila") (collectively, "Defendants" or "Counterclaimant"), by their attorneys, allege the following Counterclaims against Acadia Pharmaceuticals Inc. ("Acadia" or "Counterclaim Defendant").

THE PARTIES

1. Zydus is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

2. Cadila is an entity organized and existing under the laws of India, having a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, India.

3. On information and belief, Acadia is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3611 Valley Centre Drive Suite 300, San Diego, California 92130.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202; 35 U.S.C. § 1 *et seq*.; 21 U.S.C. § 355(j)(5)(C)(i); and 35 U.S.C. § 271(e)(5).

5. This Court has personal jurisdiction over Acadia because Acadia commenced and continues to maintain this action against Zydus in this district.

6. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and 21 U.S.C. § 355(j)(5)(C)(i)(II) and because Acadia commenced and continues to maintain this action against Zydus in this district.

REGULATORY FRAMEWORK

7. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271), a pharmaceutical company seeking approval from the U.S. Food and Drug Administration ("FDA") to sell a new drug must file a New Drug Application ("NDA"), which includes specific data concerning the safety and effectiveness of the drug referenced in the NDA, i.e., the reference-listed drug or RLD.

8. The Hatch-Waxman Act provides that NDA holders shall submit to FDA the patent number and expiration date of any patent that the NDA holder believes "claims the drug for which

the applicant submitted the [NDA] … and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the [NDA] owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). FDA lists the patent number(s) and expiration date(s) in its publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book").

ACADIA'S ORANGE-BOOK-LISTED PATENTS FOR NUPLAZID®

9. On information and belief, Acadia is the holder of NDA No. 210793 for NUPLAZID® (pimavanserin tartrate) capsules, 34 mg, and NDA No. 207318 for NUPLAZID® (pimavanserin tartrate) tablets, 10 mg.

10. On information and belief, on October 13, 2009, United States Patent No. 7,601,740 ("the '740 patent"), titled "Selective Serotonin 2A/2C Receptor Inverse Agonists as Therapeutics for Neurodegenerative Diseases" was issued to Acadia as assignee. FDA's Orange Book lists the expiration date of the '740 patent as June 17, 2027.

11. On information and belief, on June 8, 2010, United States Patent No. 7,732,615 ("the '615 patent"), titled "N-(4-fluorobenzy1)-N-(1-methylpiperidin-4-y1)-N'-(4-(2-methylpropyloxy)phenylmethyl)carbamide and its Tartrate Salt and Crystalline Forms" was issued to Acadia as assignee. FDA's Orange Book lists the expiration date of the '615 patent as June 3, 2028.

12. On information and belief, on October 22, 2019, United States Patent No. 10,449,185 ("the '185 patent"), titled "Formulations of Pimavanserin" was issued to Acadia as assignee. FDA's Orange Book lists the expiration date of the '185 patent as August 27, 2038.

13. On information and belief, on December 31, 2019, United States Patent No. 10,517,860 ("the '860 patent"), titled "Combination of Pimavanserin and Cytochrome P450

Modulators" was issued to Acadia as assignee. FDA's Orange Book lists the expiration date of the '860 patent as March 23, 2037.

14. On information and belief, on May 12, 2020, United States Patent No. 10,646,480 ("the '480 patent"), titled "Formulations of Pimavanserin" was issued to Acadia as assignee. FDA's Orange Book lists the expiration date of the '480 patent as August 27, 2038.

15. On information and belief, on February 9, 2010, United States Patent No. 7,659,285 ("the '285 patent"), titled "Selective Serotonin 2A/2C Receptor Inverse Agonists As Therapeutics for Neurodegenerative Diseases"—a copy of which is attached hereto as Exhibit A—was issued to Acadia as assignee. FDA's Orange Book lists the expiration date of the '285 patent as August 24, 2026.

16. On information and belief, on April 12, 2011, United States Patent No. 7,923,564 ("the '564 patent"), titled "Synthesis of N-(4-fluorobenzyl)-N-(1-methylpiperidin-4-yl)-N′-(4-(2-methylpropyloxy)phenylmethyl)carbamide and its Tartrate Salt and Crystalline Forms"—a copy of which is attached hereto as Exhibit B—was issued to Acadia as assignee. FDA's Orange Book lists the expiration date of the '564 patent as September 26, 2025.

17. On information and belief, Acadia submitted the '740, '615, '185, '860, '480, '285, and '564 patents to FDA for listing in FDA's Orange Book. Accordingly, Acadia maintains and has affirmatively represented that the '740, '615, '185, '860, '480, '285, and '564 patents claim the approved drug NUPLAZID® or a method of using that drug. Therefore, any ANDA applicant, including Zydus, attempting to market pimavanserin capsules, 34 mg, or pimavanserin tablets, 10 mg, before the expiration of the '740, '615, '185, '860, '480, '285, and '564 patents has a reasonable apprehension of suit with respect to all of the '740, '615, '185, '860, '480, '285, and '564 patents.

18. On information and belief, Acadia owns each of the '740, '615, '185, '860, '480, '285, and '564 patents.

ZYDUS'S ANDAS

19. In April 2020, Zydus submitted ANDA Nos. 214493 and 214502 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively ("Zydus's proposed ANDA products").

20. Because Zydus seeks FDA approval to engage in the commercial manufacture, use, sale, and importation of Zydus's proposed ANDA products before the expiration of the '740, '615, '185, '860, '480, '285, and '564 patents, ANDA No. 214493 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications") with respect to the '740, '615, '185, '480, '285, and '564 patents and ANDA No. 214502 includes paragraph IV certifications with respect to the '740, '615, '860, '285, and '564 patents.

21. Zydus sent a letter dated June 22, 2020 ("Zydus's ANDA No. 214493 Notice Letter") to Acadia pursuant to 21 U.S.C. § 355(j)(2)(B), notifying Acadia that Zydus submitted ANDA No. 214493 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of the pimavanserin capsules, 34 mg, described in ANDA No. 214493. Zydus's ANDA No. 214493 Notice Letter further notified Acadia that ANDA No. 214493 includes paragraph IV certifications with respect to the '740, '615, '185, '480, '285, and '564 patents, in which Zydus certified that, to the best of Zydus's knowledge, no valid claim of the '740, '615, '185, '480, '285, and '564 patents would be infringed by the manufacture, use, sale, and importation of the pimavanserin capsules, 34 mg, described in ANDA No. 214493. Zydus's ANDA No. 214493 Notice Letter contains a detailed statement of the factual

and legal basis of Zydus's paragraph IV certifications that the '740, '615, '185, '480, '285, and '564 patents are invalid, unenforceable, or will not be infringed.

22. Zydus sent a letter dated June 22, 2020 ("Zydus's ANDA No. 214502 Notice Letter") to Acadia pursuant to 21 U.S.C. § 355(j)(2)(B), notifying Acadia that Zydus submitted ANDA No. 214502 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of the pimavanserin tablets, 10 mg, described in ANDA No. 214502. Zydus's ANDA No. 214502 Notice Letter further notified Acadia that ANDA No. 214502 includes paragraph IV certifications with respect to the '740, '615, '860, '285, and '564 patents, in which Zydus certified that, to the best of Zydus's knowledge, no valid claim of the '740, '615, '860, '285, and '564 patents would be infringed by the manufacture, use, sale, and importation of the pimavanserin tablets, 10 mg, described in ANDA No. 214502. Zydus's ANDA No. 214502 Notice Letter contains a detailed statement of the factual and legal basis of Zydus's paragraph IV certifications that the '740, '615, '860, '285, and '564 patents are invalid, unenforceable, or will not be infringed.

23. On information and belief, Acadia received Zydus's ANDA No. 214493 Notice Letter and Zydus's ANDA No. 214502 Notice Letter on or around June 23, 2020.

24. Zydus's ANDA No. 214493 Notice Letter and Zydus's ANDA No. 214502 Notice Letter contained Offers of Confidential Access ("OCAs") to Zydus's ANDA No. 214493 and 214502, respectively, pursuant to 21 U.S.C. § 355(j)(5)(C), which included a confidential disclosure agreement. Acadia did not agree to the terms for confidential access before the filing of the Complaint.

25. Acadia filed its Complaint against Defendants on July 30, 2020, alleging that Zydus's proposed ANDA products would infringe the '740, '615, '185, '860, and '480 patents.

26. To date, Acadia has not sued Zydus for infringement of the ’285 and ’564 patents.

27. By listing and maintaining the ’285 and ’564 patents in the Orange Book, Acadia represents that the patents “claim[] the drug for which the applicant submitted the application [NUPLAZID®] … and with respect to which a claim for patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” *See* 21 U.S.C. § 355(b)(1).

28. Accordingly, by virtue of listing and maintaining the ’285 and ’564 patents in the Orange Book, Acadia represents that an infringement suit based on any of these patents could be asserted against Zydus because Zydus is seeking approval to market Zydus’s proposed ANDA products before the expiration of the ’285 and ’564 patents.

29. Unless and until Zydus obtains a court decision of invalidity and/or noninfringement of the ’285 and ’564 patents, Zydus potentially faces infringement liability if it commences marketing Zydus’s proposed ANDA products before the expiration of the ’285 and ’564 patents.

30. A judicial determination of invalidity and/or noninfringement of the ’285 and ’564 patents in Zydus’s favor could affect the timing of Zydus’s commercial manufacture, use, sale, or importation of Zydus’s proposed ANDA products.

31. Accordingly, there is an actual, substantial, and continuing justiciable controversy between Zydus and Acadia regarding the ’285 and ’564 patents over which the Court can and should exercise jurisdiction and declare the rights of the parties.

COUNT I
(Declaratory Judgment of Noninfringement of United States Patent No. 7,659,285)

32. Zydus repeats and realleges the allegations in paragraphs 1–31 above as though fully set forth herein.

33. The manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively, would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '285 patent.

COUNT II
(Declaratory Judgment of Invalidity of United States Patent No. 7,659,285)

34. Zydus repeats and realleges the allegations in paragraphs 1–33 above as though fully set forth herein.

35. The claims of the '285 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

36. By way of example and not limitation, the claims of the '285 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, §§ 102 and/or 103, at least over International Patent Publication No. WO 2001/066521 and the knowledge of a person of ordinary skill in the art, optionally in view of one or more of S. A. Factor et al., *Clozapine for the Treatment of Drug-Induced Psychosis in Parkinson's Disease: Results of the 12 Week Open Label Extension in the PSYCLOPS Trial*, 16 MOVEMENT DISORDERS 135 (2001); D.M. Weiner et al., *5-Hydroxytryptamine2A Receceptor Inverse Agonists as Antipsychotics*, 299 J. PHARMACOLOGY & EXPERIMENTAL THER. 268 (2001); International Patent Publication No. WO 01/29008; International Patent Publication No. WO 99/52927; United States Patent No. 6,358,698; B. K. Park et al., *Metabolism of Fluorine-Containing Drugs*, 41 ANNU. REV. PHARMACOL. TOXICOL. 443 (2001); and Silverman, *Chapter 2: Drug Discovery, Design, and Development* in THE ORGANIC CHEMISTRY OF DRUG DESIGN AND DRUG ACTION (1992).

37. Zydus reserves the right to provide additional prior art and bases for invalidity in its contentions, responses to discovery requests, expert reports, and pleadings filed or served later in this action.

38. Zydus is entitled to a declaration that the claims of the '285 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

COUNT III
(Declaratory Judgment of Noninfringement of United States Patent No. 7,923,564)

39. Zydus repeats and realleges the allegations in paragraphs 1–38 above as though fully set forth herein.

40. The manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the pimavanserin capsules, 34 mg, and pimavanserin tablets, 10 mg, described in ANDA Nos. 214493 and 214502, respectively, would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '564 patent.

COUNT IV
(Declaratory Judgment of Invalidity of United States Patent No. 7,923,564)

41. Zydus repeats and realleges the allegations in paragraphs 1–40 above as though fully set forth herein.

42. The claims of the '564 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

43. By way of example and not limitation, the claims of the '564 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, §§ 102 and/or 103, at least over International

Patent Publication No. WO 2004/064738 or International Patent Publication No. WO 04/064753 and the knowledge of a person of ordinary skill in the art, optionally in view of one or more of S. M. Berge et al., *Pharmaceutical Salts*, 66 J. PHARM. SCI. 1 (1977) and S. R. Byrn et al., *Pharmaceutical Solids: A Strategic Approach to Regulatory Considerations*, 12(7) PHARM. RES. 945 (1995).

44. Zydus reserves the right to provide additional prior art and bases for invalidity in its contentions, responses to discovery requests, expert reports, and pleadings filed or served later in this action.

45. Zydus is entitled to a declaration that the claims of the ’564 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

PRAYER FOR RELIEF

WHEREFORE, Zydus respectfully requests the Court to enter judgment against Acadia as follows:

A. A declaration that Zydus has not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’285 patent;

B. A declaration that the claims of the ’285 patent are invalid;

C. A declaration that Zydus has not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’564 patent;

D. A declaration that the claims of the ’564 patent are invalid;

E. An award to Zydus of its reasonable costs and attorneys’ fees incurred in this action pursuant to 35 U.S.C. § 285; and

F. An award of any other and further relief that this Court may deem just and proper.

Dated: November 2, 2020

Respectfully submitted,

/s/ John C. Phillips, Jr.
John C. Phillips, Jr. (# 110)
David A. Bilson (#4986)
PHILLIPS, MCLAUGHLIN & HALL, P.A. 1200
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pmhdelaw.com
dab@pmhdelaw.com

Of Counsel
Michael J. Gaertner (to be admitted *pro hac vice*)
James T. Peterka (to be admitted *pro hac vice*)
Timothy F. Peterson (to be admitted *pro hac vice*)
Christopher J. Cassella (to be admitted *pro hac vice*)
Amy Lange (to be admitted *pro hac vice*)
LOCKE LORD LLP
111 South Wacker Drive
Chicago, Illinois 60606
Telephone: (312) 443-0700
Facsimile: (312) 443-0336

Attorneys for Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited