IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACADIA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. _____
v.	)	
	)	
ZYDUS LIFESCIENCES LTD., ET AL.,	)	
	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff ACADIA Pharmaceuticals Inc. ("ACADIA" or "Plaintiff"), for its Complaint against Defendants Zydus Lifesciences Limited ("Zydus Lifesciences"), Zydus Worldwide DMCC ("Zydus DMCC"), and Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") (collectively "Zydus" or "Defendants"), hereby alleges as follows:

THE PARTIES

1. ACADIA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 12830 El Camino Real, Suite 400, San Diego, California 92130.

2. Upon information and belief, Zydus Lifesciences 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. Upon information and belief, Zydus DMCC is a company organized and existing under the laws of the United Arab Emirates with a principal place of business at Unit No. 908, Armada Tower 2, Plot No. JLT-PH2-P2A, Jumeirah Lakes Towers, Dubai, United Arab Emirates.

4. Upon information and belief, Zydus DMCC is a wholly owned subsidiary of Zydus Lifesciences.

5. Upon information and belief, Zydus DMCC acts at the direction, and for the benefit, of Zydus Lifesciences and is controlled and/or dominated by Zydus Lifesciences.

6. Upon information and belief, Zydus USA 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.

7. Upon information and belief, Zydus USA is a wholly owned subsidiary of Zydus Lifesciences.

8. Upon information and belief, Zydus USA acts at the direction, and for the benefit, of Zydus Lifesciences and is controlled and/or dominated by Zydus Lifesciences.

9. Upon information and belief, Zydus Lifesciences, Zydus DMCC, and Zydus USA work in concert, either directly or indirectly, with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in the State of Delaware.

10. Upon information and belief, Zydus Lifesciences, Zydus DMCC, and Zydus USA have participated and collaborated in the preparation, filing, and seeking FDA approval of Abbreviated New Drug Application ("ANDA") No. 214502 for pimavanserin tablets, 34 mg ("the Zydus Generic Product"); continue to participate and collaborate in seeking FDA approval of ANDA No. 214502; and intend to participate and collaborate in the commercial manufacture, marketing, offer for sale, and/or sale of the Zydus Generic Product throughout the United States including in the State of Delaware.

NATURE OF THE ACTION

11. This is a civil action for infringement of United States Patent Nos. 7,601,740 ("the '740 patent"), 7,659,285 ("the '285 patent"), 7,732,615 ("the '615 patent"), 10,517,860 ("the '860 patent") and 10,953,000 ("the '000 patent") (collectively "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*.

JURISDICTION AND VENUE

12. The Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), 2201, 2202, and 35 U.S.C. § 271. The Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court's jurisdiction.

13. Venue is proper in this Court as to Zydus USA under 28 U.S.C. §§ 1391(b), (c), (d), and/or 1400(b) because, *inter alia*, Zydus USA has committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

14. The Court has personal jurisdiction over Zydus USA and venue is proper in this Judicial District, by virtue of the facts that, *inter alia*, Zydus USA: (1) maintains pervasive, continuous, and systematic contacts with the State of Delaware and availed itself of the privilege of doing business in this Judicial District, including by the marketing, distributing, and/or sale of generic pharmaceutical drugs in the State of Delaware; (2) has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led to and/or will lead to foreseeable harm and injury to ACADIA, a Delaware corporation, including in the State of Delaware; and (3) has indicated that it intends to engage in the commercial manufacture, use, or sale of the Zydus Generic Product under ANDA

No. 214502 before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware.

15. Upon information and belief, Zydus USA is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions and through the actions of its agents and affiliates.

16. Zydus USA's website states that it "currently offers more than 500 SKUs to the US market and is ranked the fifth largest unbranded generic corporation in the US" and "remains diligent in ensuring a quality and affordable supply of our products in the US." Overview, http://www.zydususa.com/overview/ (last visited Feb. 14, 2025). The website also states that "Zydus's generic products can be found across the country in most pharmacies, both in store as well as mail order." FAQ – How to Get Zydus Products: Where can I find Zydus Products?, http://www.zydususa.com/faq/ (last visited Feb. 14, 2025).

17. Venue is proper in this Court as to Zydus Lifesciences under 28 U.S.C. §§ 1391(b), (c), (d), and/or 1400(b) because, *inter alia*, Zydus Lifesciences, directly or indirectly through its subsidiaries, agents, and/or alter egos, has committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

18. The Court has personal jurisdiction over Zydus Lifesciences, and venue is proper in this Judicial District, by virtue of the facts that, *inter alia*, Zydus Lifesciences, directly or indirectly through its subsidiaries, agents, and/or alter egos: (1) maintains pervasive, continuous, and systematic contacts with the State of Delaware and availed itself of the privilege of doing business in this Judicial District, including by the marketing, distributing, and/or sale of generic

pharmaceutical drugs in the State of Delaware; (2) has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led to and/or will lead to foreseeable harm and injury to ACADIA, a Delaware corporation, including in the State of Delaware; and (3) has indicated that it intends to engage in the commercial manufacture, use, or sale of the Zydus Generic Product under ANDA No. 214502 before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware.

19. Upon information and belief, Zydus Lifesciences is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions and through the actions of its agents and affiliates, including, at least, Zydus USA and Zydus DMCC.

20. Zydus Lifescience's website states that its "global business has a strong presence in the regulated markets of the US" and that it has "manufacturing sites and research facilities spread across . . . India and in the US" with "more than 30 manufacturing plants worldwide including India, Brazil and USA." *Homepage*, http://www.zyduslife.com/index (last visited Feb. 14, 2025).

21. Venue is proper in this Court as to Zydus DMCC under 28 U.S.C. §§ 1391(b), (c), (d), and/or 1400(b) because, *inter alia*, Zydus DMCC, directly or indirectly through its subsidiaries, agents, and/or alter egos, has committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

22. The Court has personal jurisdiction over Zydus DMCC, and venue is proper in this Judicial District, by virtue of the facts that, *inter alia*, Zydus DMCC, directly or indirectly through

its subsidiaries, agents, and/or alter egos: (1) maintains pervasive, continuous, and systematic contacts with the State of Delaware and availed itself of the privilege of doing business in this Judicial District, including by the marketing, distributing, and/or sale of generic pharmaceutical drugs in the State of Delaware; (2) has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led to and/or will lead to foreseeable harm and injury to ACADIA, a Delaware corporation, including in the State of Delaware; and (3) has indicated that it intends to engage in the commercial manufacture, use, or sale of the Zydus Generic Product under ANDA No. 214502 before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware.

23. Upon information and belief, Zydus DMCC is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions and through the actions of its agents and affiliates, including, at least, Zydus USA.

24. Zydus' infringing actions with respect to the filing of ANDA No. 214502 and intent to commercialize the Zydus Generic Product have led and/or will lead to foreseeable harm and injury to ACADIA.

25. The Court also has personal jurisdiction over Zydus Lifesciences (f/k/a Cadila Healthcare Ltd., or "Cadila"), Zydus USA, and Zydus DMCC, and venue is proper in this Court because, *inter alia*, they have previously been sued in this Judicial District and have not challenged personal jurisdiction or venue, and have purposefully availed themselves of the rights and benefits of the jurisdiction of this Court by filing counterclaims in this Judicial District. *See*, *e.g.*, *UCB, Inc. v. Zydus Worldwide DMCC et al.*, C.A. No. 16-1023-LPS (D. Del) (Zydus DMCC and Zydus USA did not contest jurisdiction); *Boehringer Ingelheim Pharm. Inc. v. Zydus Pharm. (USA) Inc.*,

C.A. No. 19-1501-CFC (D. Del.) (Zydus USA and Cadila did not contest jurisdiction and filed counterclaims); *Boehringer Ingelheim Pharm. Inc. v. Zydus Pharm. (USA) Inc.*, C.A. No. 19-1295-CFC (D. Del.) (same); *Boehringer Ingelheim Pharm. Inc. v. Zydus Pharm. (USA) Inc.*, C.A. No. 18-1763-CFC-SRF (D. Del.) (same); *Millennium Pharm., Inc. v. Zydus Pharm. (USA) Inc.,* C.A. No. 17-423-CFC (D. Del.) (same); *Sanofi-Aventis US LLC v. Zydus Pharm. (USA) Inc.*, C.A. No. 17-34-GMS (D. Del.) (same); *Amgen Inc. v. Zydus Pharm. (USA) Inc.*, C.A. No. 20-0075-CFC (D. Del.) (Zydus USA and Cadila did not contest jurisdiction); *Pfizer Inc. v. Zydus Pharm. (USA) Inc.*, C.A. No. 19-760-CFC (D. Del.) (same); *Merck Sharp & Dohme Corp. v. Zydus Pharm. (USA) Inc.*, C.A. No. 19-314-RGA (D. Del.) (same); *Anacor Pharm., Inc. v. Ascent Pharm., Inc.*, C.A. No. 18-1673-RGA (D. Del.) (same); *H. Lundbeck A/S v. Zydus Pharm. (USA) Inc.*, C.A. No. 18-150-LPS (D. Del.) (same); *Pfizer Inc. v. Zydus Pharm. (USA) Inc.*, C.A. No. 17-214 (D. Del.) (same); *Pfizer Inc. v. Zydus Pharm. (USA) Inc.*, C.A. No. 17-158-GJP (D. Del.) (same); *Allergan USA, Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 19-1727-RGA (D. Del.) (Zydus USA did not contest jurisdiction); *Biogen Int'l GmbH v. Zydus Pharm. (USA) Inc.*, C.A. No. 19-333-MN (D. Del.) (same); *Novo Nordisk Inc. et al v. Zydus Worldwide DMCC et al.*, C.A. No. 22-cv-297-CFC (D. Del.) (same); *Biogen Inc. et al v. Zydus Worldwide DMCC et al.*, C.A. No. 23-732-GBW (D. Del.) (same).

26. Further, the Court may exercise jurisdiction over Zydus Lifesciences pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) ACADIA's claims arise under federal law; (b) Zydus Lifesciences is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Zydus Lifesciences has sufficient contacts with the United States as a whole, including, but not limited to, submitting various ANDAs to the FDA, and manufacturing and selling active

pharmaceutical ingredients that are used in the products distributed throughout the United States, such that the Court's exercise of jurisdiction over Zydus Lifesciences satisfies due process.

27. Further, the Court may exercise jurisdiction over Zydus DMCC pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) ACADIA's claims arise under federal law; (b) Zydus DMCC is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Zydus DMCC has sufficient contacts with the United States as a whole, including, but not limited to, submitting various ANDAs to the FDA, and manufacturing and selling active pharmaceutical ingredients that are used in the products distributed throughout the United States, such that the Court's exercise of jurisdiction over Zydus DMCC satisfies due process.

ACADIA'S NDA AND THE PATENTS-IN-SUIT

28. ACADIA holds New Drug Application ("NDA") No. 207318 for oral tablets containing pimavanserin tartrate, Eq. 10 mg base as the active ingredient. ACADIA exclusively manufactures, markets and sells these oral tablets in the United States under the brand name NUPLAZID®.

29. On October 13, 2009, the '740 patent, entitled "Selective Serotonin 2A/2C Receptor Inverse Agonists as Therapeutics for Neurodegenerative Diseases" was duly and legally issued. A copy of the '740 patent is attached as Exhibit A.

30. ACADIA owns the '740 patent.

31. On February 9, 2010, the '285 patent, entitled "Selective Serotonin 2A/2C Receptor Inverse Agonists as Therapeutics for Neurodegenerative Diseases" was duly and legally issued. A copy of the '285 patent is attached as Exhibit B.

32. ACADIA owns the '285 patent.

33. On June 8, 2010, the '615 patent, entitled "N-(4-fluorobenzyl)-N-(1-methylpiperidin-4-yl)-N′-(4-(2-methylpropyloxy)phenylmethyl)carbamide and its tartrate salt and crystalline forms" was duly and legally issued. A copy of the '615 patent is attached as Exhibit C.

34. ACADIA owns the '615 patent.

35. On December 31, 2019, the '860 patent, entitled "Combination of Pimavanserin and Cytochrome P450 Modulators" was duly and legally issued. A copy of the '860 patent is attached as Exhibit D.

36. ACADIA owns the '860 patent.

37. On March 23, 2021, the '000 patent, entitled "Combination of Pimavanserin and Cytochrome P450 Modulators" was duly and legally issued. A copy of the '000 patent is attached as Exhibit E.

38. ACADIA owns the '000 patent.

39. Pursuant to 21 U.S.C. § 355(b)(1), the '740, '285, '615, '860 and '000 patents are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering NUPLAZID® Eq. 10 mg base or its use.

ZYDUS' ANDA AND PARAGRAPH IV NOTIFICATION

40. Zydus' ANDA No. 214502 Notice Letter represents that Zydus certified in ANDA No. 214502 that the claims of the '740, '285, '615, '860 and '000 patents are invalid or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Zydus Generic Product.

41. Upon information and belief, Zydus submitted ANDA No. 214502 to the FDA under 21 U.S.C. § 355(j). Upon information and belief, Zydus' ANDA No. 214502 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale within the United

States, or importation into the United States, of the Zydus Generic Product prior to the expiration of the patents-in-suit.

42. Upon information and belief, by filing ANDA No. 214502, Zydus has certified to the FDA that the Zydus Generic Product has the same active ingredient as NUPLAZID® Eq. 10 mg base and the same or substantially the same proposed labeling as NUPLAZID® Eq. 10 mg base.

43. ACADIA received written notification of Zydus' ANDA No. 214502, and its accompanying § 505(j)(2)(A)(vii)(IV) certification by letter dated January 2, 2025 ("Zydus' ANDA Notice Letter").

44. Zydus' ANDA Notice Letter represents that Zydus certified in ANDA No. 214502 that the claims of the patents-in-suit are either invalid and/or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Zydus Generic Product.

45. According to applicable regulations, Notice Letters such as Zydus' ANDA Notice Letter must contain a detailed statement of the factual and legal bases for the applicant's opinion that the patent is invalid, unenforceable, or not infringed, which includes a claim-by-claim analysis, describing "[f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

46. For at least one claim of the '740 patent, Zydus' ANDA No. 214502 Notice Letter failed to provide a claim-by-claim analysis on the full and detailed explanation of the grounds supporting Zydus' allegation that the claims of the '740 patents are alleged to be invalid and/or not infringed.

47. For at least one claim of the ’285 patent, Zydus’ ANDA No. 214502 Notice Letter failed to provide a claim-by-claim analysis on the full and detailed explanation of the grounds supporting Zydus’ opinion that the claims of the ’285 patents are alleged to be invalid and/or not infringed.

48. For at least one claim of the ’615 patent, Zydus’ ANDA No. 214502 Notice Letter failed to provide a claim-by-claim analysis on the full and detailed explanation of the grounds supporting Zydus’ opinion that the claims of the ’615 patents are alleged to be invalid and/or not infringed.

49. For at least one claim of the ’860 patent, Zydus’ ANDA No. 214502 Notice Letter failed to provide a claim-by-claim analysis on the full and detailed explanation of the grounds supporting Zydus’ opinion that the claims of the ’860 patents are alleged to be invalid and/or not infringed.

50. For at least one claim of the ’000 patent, Zydus’ ANDA No. 214502 Notice Letter failed to provide a claim-by-claim analysis on the full and detailed explanation of the grounds supporting Zydus’ opinion that the claims of the ’000 patents are alleged to be invalid and/or not infringed.

51. The limited information relating to the Zydus Generic Product that was provided in Zydus’ ANDA Notice Letter does not demonstrate that the Zydus Generic Product, which Zydus has asked the FDA to approve for sale in the United States, will not fall within the scope of issued claims of the patents-in-suit.

52. This action is being commenced by ACADIA within 45 days of its receipt of Zydus’ Notice Letter.

COUNT I – INFRINGEMENT BY ZYDUS

53. ACADIA incorporates paragraphs 1-52 as if fully set forth herein.

54. Zydus' submission of ANDA No. 214502 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '740, '285, '615, '860 and '000 patents under 35 U.S.C. § 271(e)(2)(A).

55. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Zydus certified in ANDA No. 214502 that the claims of the patents-in-suit are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Zydus Generic Product. Zydus notified ACADIA of that certification and provided a statement of the alleged bases for its claims.

56. Zydus' ANDA No. 214502 Notice Letter does not identify any factual basis for, or any opinion of, invalidity regarding claims 2-10, 20-21, and 24-25 of the '740 patent, claims 1-3 and 6-9 of the '285 patent, and the claims of the '615 patent.

57. Separate and apart from certain contentions regarding patent validity, Zydus' ANDA No. 214502 Notice Letter does not identify any factual basis for, or any opinion of, noninfringement regarding claims 1, 11-19, and 22-23 of the '740 patent, claims 1-3 and 6-9 of the '285 patent, the claims of the '860 patent, and the claims of the '000 patent.

58. Defendants are jointly and severally liable for infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A). Upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 214502 seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the Zydus Generic Product prior to the expiration of the patents-in-suit.

59. Moreover, if Zydus manufactures, uses, offers for sale, or imports into the United States any of the Zydus Generic Product, or induces or contributes to any such conduct, prior to the expiration of the patents-in-suit, including any applicable exclusivities or extensions, they would infringe one or more claims of the patents-in-suit under 35 U.S.C. § 271(a), (b), and/or (c).

60. Upon information and belief, Zydus was aware of the existence of the patents-in-suit and was aware that the filing of ANDA No. 214502 and certification with respect to the patents-in-suit constituted an act of infringement of those patents.

61. Zydus filed ANDA No. 214502 without adequate justification for asserting that the patents-in-suit are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Zydus Generic Product.

62. ACADIA is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of the Court that the effective date of the approval of Zydus' ANDA No. 214502 be a date that is not earlier than the expiration of the '740, '285, '615, '860 and '000 patents, or any later expiration of exclusivity for the patents-in-suit to which ACADIA is or becomes entitled.

63. ACADIA will be irreparably harmed by Zydus' infringing activities unless those activities are enjoined by the Court. ACADIA does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, ACADIA requests that the Court grant the following relief:

A. A Judgment that Zydus has infringed the '740, '285, '615, '860 and '000 patents by submitting ANDA No. 214502 to the FDA;

B. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Zydus' ANDA No. 214502 will not be earlier than the expiration date of the '740, '285, '615, '860 and '000 patents, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which ACADIA is or becomes entitled;

C. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Zydus' ANDA No. 214502 will not be earlier than the expiration date of the '740, '285, '615, '860 and '000 patents, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which ACADIA is or becomes entitled;

D. An Order permanently enjoining Zydus, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with Zydus, from commercially manufacturing, using, offering to sell, selling, marketing, distributing, or importing the Zydus Generic Product identified in this Complaint, or any product that infringes or induces or contributes to the infringement of one or more of the patents-in-suit, prior to the expiration of the patents-in-suit, including any exclusivities or extensions to which ACADIA is or becomes entitled;

E. That ACADIA be awarded monetary relief to the extent Zydus commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, any product that infringes or induces or contributes to the infringement of the patents-in-suit, within the United States prior to the expiration of the patents-in-suit, including any later expiration of any patent term extensions or exclusivities for the patents-in-suit to which ACADIA is or will become entitled, and that any such monetary relief be awarded to ACADIA with prejudgment interest;

F. A finding that this case is an exceptional case and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

G. That ACADIA be awarded the costs and expenses that they incur in prosecuting this action; and

H. Such other and further relief as the Court may deem just and proper.

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Dated: February 14, 2025

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