IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC., ARBOR PHARMACEUTICALS, LLC, and TAKEDA PHARMACEUTICAL COMPANY LIMITED, Plaintiffs, v. ZYDUS WORLDWIDE DMCC, ZYDUS PHARMACEUTICALS (USA) INC., and ZYDUS LIFESCIENCES LIMITED, Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs Azurity Pharmaceuticals, Inc., Arbor Pharmaceuticals, LLC (together with Azurity Pharmaceuticals, Inc., "Azurity"), and Takeda Pharmaceutical Company Limited ("Takeda") (collectively, "Plaintiffs"), for their Complaint against Defendants Zydus Worldwide DMCC ("Zydus Worldwide"), Zydus Pharmaceuticals (USA) Inc. ("Zydus USA"), and Zydus Lifesciences Limited ("Zydus Lifesciences") (collectively "Defendants" or "Zydus"), hereby allege as follows:

THE PARTIES

1. Azurity Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 8 Cabot Road, Suite 2000, Woburn, MA 01801.

2. Arbor Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 6 Concourse Parkway, Suite 1800, Atlanta, GA 30328.

3. Takeda is a corporation organized and existing under the laws of Japan, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan.

4. Upon information and belief, Defendant Zydus Worldwide is a company organized and existing under the laws of the United Arab Emirates, having a principal place of business at Unit No. 908, Armada Tower 2, Plot No. JLT-PH2-P2A, Jumeriah Lakes Tower, P.O. Box 113536, Dubai, United Arab Emirates.

5. Upon information and belief, Defendant Zydus USA is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 73 Route 31 North, Pennington, New Jersey, 08534.

6. Upon information and belief, Defendant Zydus Lifesciences is a corporation organized and existing under the laws of India, with its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad, Gujarat 382481, India.

7. Upon information and belief, Zydus Worldwide submitted ANDA No. 218658 to FDA, and Zydus USA is acting as an agent for Zydus Worldwide with respect to Zydus's Azilsartan Medoxomil ANDA Product.

8. Upon information and belief, following any approval of Zydus' ANDA No. 218658, Zydus Worldwide, Zydus USA, and Zydus Lifesciences will act in concert to distribute and sell Zydus's Azilsartan Medoxomil ANDA Product through the United States, including within Delaware.

9. Upon information and belief, Zydus Worldwide submitted ANDA No. 218451 to FDA, and Zydus USA is acting as an agent for Zydus Worldwide with respect to Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product.

10. Upon information and belief, following any approval of Zydus's ANDA No. 218451, Zydus Worldwide, Zydus USA, and Zydus Lifesciences will act in concert to distribute and sell Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product through the United States, including within Delaware.

NATURE OF THE ACTION

11. This is a civil action for infringement of United States Patent Nos. 9,066,936 ("the '936 patent"), 9,169,238 ("the '238 patent"), and 9,387,249 ("the '249 patent"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq.

JURISDICTION & VENUE

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

13. This Court has personal jurisdiction over Zydus Worldwide because, *inter alia*, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Zydus Worldwide is involved in developing, manufacturing, marketing, selling, and/or distributing a broad range of generic pharmaceutical products in the United States, including in Delaware, and therefore transacts business within Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

14. On information and belief, Zydus Worldwide has been previously sued in this Judicial District and has not challenged personal jurisdiction. *See, e.g., Novo Nordisk Inc. and Novo Nordisk A/S v. Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd.*, C.A. No. 22-297-CFC (D. Del.) (filed March 4, 2022); *UCB, Inc. v. Zydus Worldwide DMCC et al.*, C.A. No. 16-1023 (D. Del.) (filed Nov. 3, 2016).

15. On information and belief, Zydus Worldwide has availed itself of the jurisdiction of this Court by previously asserting claims in this Judicial District. *See, e.g.*, *Pharmacyclics LLC v. Zydus Worldwide DMCC et al.*, C.A. No. 20-560 (D. Del. Apr. 24, 2020).

16. This Court has personal jurisdiction over Zydus USA because, *inter alia*, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Zydus USA is involved in developing, manufacturing, marketing, selling, and/or distributing a broad range of generic pharmaceutical products in the United States, including in Delaware, and therefore transacts business within Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

17. This Court has personal jurisdiction over Zydus Lifesciences because, *inter alia*, it and through its wholly owned indirect subsidiaries Zydus Worldwide and Zydus USA, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Zydus Lifesciences, itself and through its wholly owned indirect subsidiaries Zydus Worldwide and Zydus USA, is involved in developing, manufacturing, marketing, selling, and/or distributing a broad range of generic pharmaceutical products in the United States, including in Delaware, and therefore transacts business within Delaware, and/or has engaged in systematic and continuous business contacts within Delaware. In addition, Zydus Lifesciences is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Zydus Worldwide and Zydus USA, and therefore the activities of Zydus Worldwide and Zydus USA in this jurisdiction are attributed to Zydus Lifesciences.

18. On information and belief, both Zydus USA and Zydus Lifesciences have previously been sued in this Judicial District and have not challenged personal jurisdiction. *See, e.g., Novo Nordisk Inc. and Novo Nordisk A/S v. Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd.*, C.A. No. 22-297-CFC (D. Del.) (filed March 4, 2022); *Acadia Pharmaceuticals Inc. v. Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited*, C.A. No. 22-1386-GBW (D. Del.) (filed Oct. 21, 2022); *Merck Sharp & Dohme LLC v. Zydus Worldwide DMCC et al.*, 21-315-RGA (filed Mar. 1, 2021); *Pharmacyclics LLC et al. v. Zydus Worldwide DMCC et al.*, C.A. No. 18-275-CFC (D. Del.) (filed Feb. 16, 2018).

19. On information and belief, Zydus USA and Zydus Lifesciences have previously availed themselves of the jurisdiction of this Judicial District by bringing counterclaims in this Judicial District. *See, e.g., Acadia Pharmaceuticals Inc. v. Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited*, C.A. No. 22-1386-GBW (D. Del.) (filed Oct. 21, 2022).

20. Upon information and belief, Zydus has sought approval in ANDA Nos. 218451 and 218658 to distribute Zydus's Azilsartan Medoxomil ANDA Product and Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product in the United States, including in Delaware and will do so upon approval of ANDA Nos. 218451 and 218658. The filing of ANDA Nos. 218451 and 218658 is therefore tied, in purpose and planned effect, to the deliberate making of sales in Delaware, and indicates that Zydus plans to engage in the marketing of Zydus's Azilsartan Medoxomil ANDA Product and Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product in Delaware.

21. Upon information and belief, if one or both of ANDA Nos. 218451 and 218658 is approved, Zydus will directly or indirectly market and/or sell Zydus's Azilsartan Medoxomil ANDA Product and/or Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product within

the United States, including in Delaware, consistent with Zydus's practices for the marketing and distribution of other pharmaceutical products on its own and/or through its affiliates.

22. Upon information and belief, if one or both of ANDA Nos. 218451 and 218658 is approved, Zydus's Azilsartan Medoxomil ANDA Product and/or Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product, under the direction and control of physicians practicing in Delaware, will be administered to patients in Delaware. These activities, as well as Zydus's marketing, selling, and/or distributing of Zydus's Azilsartan Medoxomil ANDA Product and/or Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product, would have a substantial effect within Delaware and would constitute infringement of the Asserted Patents in the event that Zydus's Azilsartan Medoxomil ANDA Product and/or Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product is approved before the '936 patent (Zydus's Azilsartan Medoxomil ANDA Product) or the '936, '238, and '249 patents (Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product) expire.

23. For the reasons described above, among others, the filing of ANDA Nos. 218451 and 218658 was suit-related conduct with a substantial connection to Delaware and this District, the exercise of personal jurisdiction over Zydus does not offend traditional notions of fair play and substantial justice, and this Court may properly exercise personal jurisdiction over Zydus.

24. In the alternative, this Court has personal jurisdiction over Zydus Worldwide and Zydus Lifesciences because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Plaintiffs' claims arise under federal law; (b) Zydus Worldwide and Zydus Lifesciences are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) Zydus Worldwide and Zydus Lifesciences have sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or

manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Zydus Worldwide and Zydus Lifesciences satisfies due process.

25. Venue is proper in this judicial district as to Zydus Worldwide under 28 U.S.C. §§ 1391 and 1400(b) because Zydus Worldwide is incorporated in the United Arab Emirates and may be sued in any judicial district in the United States.

26. Venue is proper in this judicial district as to Zydus Lifesciences under 28 U.S.C. §§ 1391 and 1400(b) because Zydus Lifesciences is incorporated in the Republic of India and may be sued in any judicial district in the United States.

27. Venue is proper in this judicial district as to Zydus USA under 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Zydus USA is subject to personal jurisdiction in this judicial district, has previously consented to venue in this judicial district, and on information and belief is subject to venue in this judicial district for the purpose of this case. Zydus USA has consented to venue in this judicial district in numerous patent litigations, including but not limited to the following actions: *Acadia Pharmaceuticals Inc. v. Zydus Pharmaceuticals (USA) Inc. et al.*, C.A. No. 22-1386-GBW (D. Del.); *Novo Nordisk Inc., et al. v Zydus Worldwide DMCC, et al.*, C.A. No. 22-297-CFC (D. Del.); *Astrazeneca AB, et al. v. Zydus Pharmaceuticals (USA) Inc., et al.*, C.A. No. 21-550-RGA (D. Del.).

THE PATENTS-IN-SUIT

28. On June 30, 2015, the '936 patent, entitled "Solid pharmaceutical composition comprising a benzimidazole-7-carboxylate derivative and a pH control agent" was duly and legally issued. A copy of the '936 patent is attached as Exhibit A.

29. Takeda owns the '936 patent. Azurity holds an exclusive license to the '936 patent in the United States.

30. On October 27, 2015, the ’238 patent, entitled “Solid pharmaceutical composition” was duly and legally issued. A copy of the ’238 patent is attached as Exhibit B.

31. Takeda owns the ’238 patent. Azurity holds an exclusive license to the ’238 patent in the United States.

32. On July 12, 2016, the ’249 patent, entitled “Methods of treating hypertension with at least one angiotensin II receptor blocker and chlorthalidone” was duly and legally issued. A copy of the ’249 patent is attached as Exhibit C.

33. Takeda owns the ’249 patent. Azurity holds an exclusive license to the ’249 patent in the United States.

ACTS GIVING RISE TO THIS ACTION

34. Azurity holds New Drug Application (“NDA”) No. 200796 for oral tablets containing 40/80 mg azilsartan medoxomil as the active ingredient. Azurity markets and sells these oral tablets in the United States under the brand name EDARBI®.

35. Pursuant to 21 U.S.C. § 355(b)(1), the ’936 patent is listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) as covering EDARBI® or its use. United States Patent Nos. 7,157,584 (“the ’584 patent”) and 7,572,920 (“the ’920 patent”) are further listed in the Orange Book as covering EDARBI® or its use.

36. Upon information and belief, Zydus submitted ANDA No. 218658 to the FDA under 21 U.S.C. § 355(j). Upon information and belief, Zydus’s ANDA No. 218658 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 an oral tablet containing 40 mg or 80 mg of azilsartan medoxomil (“Zydus’s Azilsartan Medoxomil ANDA Product”) prior to the expiration of the ’936 patent.

37. Upon information and belief, by filing ANDA No. 218658, Zydus has certified to the FDA that Zydus's Azilsartan Medoxomil ANDA Product has the same active ingredients as EDARBI® and the same or substantially the same proposed labeling as EDARBI®.

38. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Zydus certified in ANDA No. 218658 that the claims of the '936 patent are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of Zydus's Azilsartan Medoxomil ANDA Product.

39. Upon information and belief, Zydus did not certify the claims of the '584 patent and the '920 patent to be invalid, unenforceable, or not to be infringed by the commercial manufacture, use, sale, or offer for sale of Zydus's Azilsartan Medoxomil ANDA Product in ANDA No. 218658.

40. Plaintiffs received written notification of Zydus's ANDA No. 218658 and its accompanying § 505(j)(2)(A)(vii)(IV) certifications by Federal Express, dated July 19, 2023 ("Zydus's Azilsartan Medoxomil Notice Letter").

41. To date, Zydus has not provided Plaintiffs with a copy of any portions of ANDA No. 218658 or any information regarding Zydus's Azilsartan Medoxomil ANDA Product, beyond the information set forth in Zydus's Azilsartan Medoxomil Notice Letter.

42. The limited information relating to Zydus's Azilsartan Medoxomil ANDA Product that was provided in Zydus's Azilsartan Medoxomil Notice Letter does not demonstrate that Zydus's Azilsartan Medoxomil ANDA Product, which Zydus has asked the FDA to approve for sale in the U.S., will not fall within the scope of issued claims of the '936 patent.

43. This action was commenced within 45 days of Plaintiffs receiving Zydus's Azilsartan Medoxomil Notice Letter.

44. Azurity holds New Drug Application ("NDA") No. 202331 for oral tablets containing 40 mg azilsartan medoxomil and 25 mg chlorthalidone, and 40 mg azilsartan medoxomil and 12.5 mg chlorthalidone, as the active ingredients. Azurity markets and sells these oral tablets in the United States under the brand name EDARBYCLOR®.

45. Pursuant to 21 U.S.C. § 355(b)(1), the '936 patent, the '238 patent, and the '249 patent are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering EDARBI® or its use. The '584 patent and the '920 patent are further listed in the Orange Book as covering EDARBYCLOR® or its use.

46. Upon information and belief, Zydus submitted ANDA No. 218451 to the FDA under 21 U.S.C. § 355(j). Upon information and belief, Zydus's ANDA No. 218451 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 an oral tablet containing 40 mg azilsartan medoxomil and 12.5 mg chlorthalidone, and 40 mg azilsartan medoxomil and 25 mg chlorthalidone ("Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product") prior to the expiration of the patents-in-suit.

47. Upon information and belief, by filing ANDA No. 218451, Zydus has certified to the FDA that Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product has the same active ingredients as EDARBYCLOR® and the same or substantially the same proposed labeling as EDARBYCLOR®.

48. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Zydus certified in ANDA No. 218451 that the claims of the '936 patent, the '238 patent, and the '249 patent are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product.

49. Upon information and belief, Zydus did not certify the claims of the '584 patent and the '920 patent to be invalid, unenforceable, or not to be infringed by the commercial manufacture, use, sale, or offer for sale of Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product in ANDA No. 218451.

50. Plaintiffs received written notification of Zydus ANDA No. 218451 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by FedEx®, dated June 19, 2023 ("Zydus's Azilsartan Medoxomil and Chlorthalidone Notice Letter").

51. To date, Zydus has not provided Plaintiffs with a copy of any portions of ANDA No. 218451 or any information regarding Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product, beyond the information set forth in Zydus's Azilsartan Medoxomil and Chlorthalidone Notice Letter.

52. The limited information relating to Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product that was provided in Zydus's Azilsartan Medoxomil and Chlorthalidone Notice Letter does not demonstrate that Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product, which Zydus has asked the FDA to approve for sale in the U.S., will not fall within the scope of issued claims of the patents-in-suit.

53. This action was commenced within 45 days of Plaintiffs receiving Zydus's Azilsartan Medoxomil and Chlorthalidone Notice Letter.

COUNT I
INFRINGEMENT BY ZYDUS OF U.S. PATENT NO. 9,066,936

54. Plaintiffs re-allege paragraphs 1-53 as if fully set forth herein.

55. Zydus's submission of ANDA No. 218658 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '936 patent under 35 U.S.C. § 271(e)(2)(A).

56. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of Zydus's Azilsartan Medoxomil ANDA Product —if approved by the FDA, prior to the expiration of the '936 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '936 patent.

57. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Zydus's ANDA No. 218658 be a date that is not earlier than the expiration of the '936 patent, or any later expiration of patent term extension, adjustment, or exclusivity for the '936 patent to which Plaintiffs are or become entitled.

58. Plaintiffs will be irreparably harmed by Zydus's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

59. Upon information and belief, Zydus was aware of the existence of the '936 patent and were aware that the filing of ANDA No. 218658 and the certification with respect to the '936 patent constituted an act of infringement of that patent.

COUNT II
INFRINGEMENT BY ZYDUS OF U.S. PATENT NO. 9,066,936

60. Plaintiffs re-allege paragraphs 1-59 as if fully set forth herein.

61. Zydus's submission of ANDA No. 218451 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '936 patent under 35 U.S.C. § 271(e)(2)(A).

62. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product —if approved by the FDA, prior to the expiration of the '936 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '936 patent.

63. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Zydus's ANDA No. 218451 be a date that is not earlier than the expiration of the '936 patent, or any later expiration of patent term extension, adjustment, or exclusivity for the '936 patent to which Plaintiffs are or become entitled.

64. Plaintiffs will be irreparably harmed by Zydus's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

65. Upon information and belief, Zydus was aware of the existence of the '936 patent and were aware that the filing of ANDA No. 218451 and the certification with respect to the '936 patent constituted an act of infringement of that patent.

COUNT III
INFRINGEMENT BY ZYDUS OF U.S. PATENT NO. 9,169,238

66. Plaintiffs re-allege paragraphs 1-65 as if fully set forth herein.

67. Zydus's submission of ANDA No. 218451 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '238 patent under 35 U.S.C. § 271(e)(2)(A).

68. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product —if approved by the FDA, prior to the expiration of the '238 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '238 patent.

69. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Zydus's ANDA No. 218451 be a date that is not earlier than the expiration of the '238 patent, or any later expiration of patent term

extension, adjustment, or exclusivity for the ’238 patent to which Plaintiffs are or become entitled.

70. Plaintiffs will be irreparably harmed by Zydus’s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

71. Upon information and belief, Zydus was aware of the existence of the ’238 patent and were aware that the filing of ANDA No. 218451 and the certification with respect to the ’238 patent constituted an act of infringement of that patent.

COUNT IV
INFRINGEMENT BY ZYDUS OF U.S. PATENT NO. 9,387,249

72. Plaintiffs re-allege paragraphs 1-71 as if fully set forth herein.

73. Zydus’s submission of ANDA No. 218451 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the ’249 patent under 35 U.S.C. § 271(e)(2)(A).

74. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of Zydus’s Azilsartan Medoxomil and Chlorthalidone ANDA Product —if approved by the FDA, prior to the expiration of the ’249 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the ’249 patent.

75. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Zydus’s ANDA No. 218451 be a date that is not earlier than the expiration of the ’249 patent, or any later expiration of patent term extension, adjustment, or exclusivity for the ’249 patent to which Plaintiffs are or become entitled.

76. Plaintiffs will be irreparably harmed by Zydus's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

77. Upon information and belief, Zydus was aware of the existence of the '249 patent and were aware that the filing of ANDA No. 218451 and the certification with respect to the '249 patent constituted an act of infringement of that patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment that:

A. Zydus has infringed one or more claims of the '936 patent;

B. Zydus has infringed one or more claims of the '238 patent;

C. Zydus has infringed one or more claims of the '249 patent;

D. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Zydus's ANDA No. 218658 will not be earlier than the expiration date of the '936 patent, or any later expiration of any patent term extension, adjustment, or exclusivity for the '936 patent to which Plaintiffs are or become entitled;

E. Zydus, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling, marketing, distributing, or importing Zydus's Azilsartan Medoxomil ANDA Product and any other product that infringes or induces or contributes to the infringement of the '936 patent, prior to the expiration of the '936 patent, including any exclusivity, adjustment, or extension to which Plaintiffs are or become entitled;

F. Plaintiffs 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 '936 patent

within the United States prior to its expiration, including any later expiration of any patent term extension, adjustment, or exclusivity for the '936 patent to which Plaintiffs are or will become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

G. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Zydus's ANDA No. 218451 will not be earlier than the expiration date of the '936 patent, '238 patent, and/or '249 patent, or any later expiration of any patent term extension, adjustment, or exclusivity for the '936 patent, '238 patent, and/or '249 patent to which Plaintiffs are or become entitled;

H. Zydus, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling, marketing, distributing, or importing Zydus's Azilsartan Medoxomil and Chlorthalidone ANDA Product and any other product that infringes or induces or contributes to the infringement of the '936 patent, '238 patent, and/or '249 patent, prior to the expiration of the '936 patent, '238 patent, and/or '249 patent, including any exclusivity, adjustment, or extension to which Plaintiffs are or become entitled;

I. Plaintiffs 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 '936 patent, '238 patent, and/or '249 patent within the United States prior to its expiration, including any later expiration of any patent term extension, adjustment, or exclusivity for the '936 patent, '238 patent, and/or '249 patent to which Plaintiffs are or will become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

J. Plaintiffs be awarded the attorneys' fees, costs, and expenses that they incur in litigating this action; and

K. Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated: August 2, 2023

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