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 PHARMACEUTICALS (USA) INC. and ZYDUS LIFESCIENCES LIMITED, Defendants.	)	C.A. No. 23-cv-833-MN

ZYDUS PHARMACEUTICALS (USA) INC.'S AND
ZYDUS LIFESCIENCES LIMITED'S
ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' COMPLAINT

Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Zydus Lifesciences Limited ("Zydus Lifesciences") (collectively, "Defendants") for their Answer and Affirmative Defenses to the Complaint of Azurity Pharmaceuticals, Inc., Arbor Pharmaceuticals, LLC (together with Azurity Pharmaceuticals, Inc., "Azurity"), and Takeda Pharmaceutical Company Limited ("Takeda") (collectively, "Plaintiffs") 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. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 2 and therefore deny them.

3. Defendants lack knowledge or information sufficient to form a belief about the truth

of the allegations in paragraph 3 and therefore deny them.

4. The allegations in paragraph 4 relate to a party that has been dismissed from the case, therefore, no response is required. (D.I. 16, Oct. 6, 2023 Stipulation and Order Dismissing Without Prejudice Defendant Zydus Worldwide DMCC and Amending Case Caption to Reflect Same.)

5. Admitted.

6. Admitted.

7. Denied.

8. The allegations in paragraph 8 are legal conclusions to which no answer is required. To the extent an answer is required, denied.

9. Denied.

10. The allegations in paragraph 10 are legal conclusions to which no answer is required. To the extent an answer is required, denied.

NATURE OF THE ACTION

11. The allegations in paragraph 11 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Complaint purports to be a civil action alleging infringement of U.S. Patent Nos. 9,066,936 ("the '936 patent"), 9,169,238 ("the '238 patent"), and 9,387,249 ("the '249 patent") (collectively, the "Patents-In-Suit"). Defendants deny all other allegations in paragraph 11.

JURISDICTION & VENUE

12. The allegations in paragraph 12 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 purposes of Plaintiffs' claims against Defendants in this case and solely as

they apply to the proposed azilsartan medoxomil and chlorthalidone tablets, 40 mg/12.5 mg and 40 mg/25 mg, described in ANDA No. 218451 ("Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products") and the proposed azilsartan medoxomil, 40 mg and 80 mg, described in ANDA No. 218658 ("Zydus USA's Proposed Azilsartan Medoxomil ANDA Products). Defendants deny all other allegations in paragraph 12.

13. The allegations in paragraph 13 are directed to a party that has been dismissed from this case and are legal conclusions to which no answer is required. (D.I. 16, Oct. 6, 2023 Stipulation and Order Dismissing Without Prejudice Defendant Zydus Worldwide DMCC and Amending Case Caption to Reflect Same.) To the extent an answer is required, denied.

14. The allegations in paragraph 14 are directed to a party that has been dismissed from the case (D.I. 16, Oct. 6, 2023 Stipulation and Order Dismissing Without Prejudice Defendant Zydus Worldwide DMCC and Amending Case Caption to Reflect Same) and are legal conclusions to which no answer is required. To the extent an answer is required, denied.

15. The allegations in paragraph 15 are directed to a party that has been dismissed from the case (D.I. 16, Oct. 6, 2023 Stipulation and Order Dismissing Without Prejudice Defendant Zydus Worldwide DMCC and Amending Case Caption to Reflect Same) and are legal conclusions to which no answer is required. To the extent an answer is required, denied.

16. The allegations in paragraph 16 are legal conclusions to which no answer is required. To the extent an answer is required, 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 Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products and Zydus USA's Proposed Azilsartan Medoxomil ANDA Products. Defendants admit that Zydus USA imports pharmaceutical products, including generic pharmaceutical products, into the United

States, and that it sells pharmaceutical products in the United States. Defendants deny all other allegations in paragraph 16.

17. The allegations in paragraph 17 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus Lifesciences does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products and Zydus USA's Proposed Azilsartan Medoxomil ANDA Products. Defendants admit that Zydus Worldwide and Zydus USA are wholly owned subsidiaries of Zydus Lifesciences. Defendants admit that Zydus Lifesciences manufactures pharmaceutical products, including generic pharmaceutical products, sold in the United States. Defendants further admit that Zydus USA sells pharmaceutical products in the United States. Defendants deny all other allegations in paragraph 17.

18. The allegations in paragraph 18 are legal conclusions to which no answer is required. To the extent an answer is required, 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 Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products and Zydus USA's Proposed Azilsartan Medoxomil ANDA Products. Defendants admit that in *Novo Nordisk Inc. and Novo Nordisk A/S v. Zydus Worldwide DMCC et al*., C.A. No. 22-297-CFC (D. Del.), Zydus USA and Zydus Lifesciences stated "Defendants do not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against [Zydus USA and Zydus Lifesciences] in this case and solely as they apply to Zydus's Proposed ANDA Product." Defendants further admit that in *Acadia Pharmaceuticals Inc. v. Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited*, C.A. No. 22-1386-GBW, Zydus USA and Zydus

Lifesciences stated "Defendants do not contest personal jurisdiction or venue in this Court solely for the purpose of Plaintiffs' claims against Defendants in this case and solely as they apply to the pimavanserin capsules, 34 mg, described in ANDA No. 214493." Defendants further admit that in *Merck Sharp & Dohme LLC v. Zydus Worldwide DMCC et al*., 21-315-RGA, Zydus USA and Zydus Lifesciences stated "[Zydus USA and Zydus Lifesciences] do not contest personal jurisdiction in this Court solely for the limited purpose of Merck's claims against [Zydus USA and Zydus Lifesciences] in this case and solely as they apply to the sitagliptin tablets, 25 mg, 50 mg, and 100 mg, described in NDA No. 211566." Defendants further admit that in *Pharmacyclics LLC and Janssen Biotech, Inc. v. Zydus Worldwide DMCC et al*., C.A. No. 18-275-GMS (D. Del.), Zydus USA and Zydus Lifesciences stated "[Zydus USA and Zydus Lifesciences] admits it has been named in a patent litigation in this District and avers that it does not contest this Court's personal jurisdiction over [Zydus USA and Zydus Lifesciences] solely for the limited purposes of this action only, and reserves the right to contest personal jurisdiction in any other case." Defendants deny all other allegations in paragraph 18.

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 in this Court solely for purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products and Zydus USA's Proposed Azilsartan Medoxomil ANDA Products. Defendants admit that in *Acadia Pharmaceuticals Inc. v. Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited*, C.A. No. 22-1386-GBW, Zydus USA and Zydus Lifesciences filed counterclaims against plaintiff Acadia Pharmaceuticals Inc. 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 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 Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products and Zydus USA's Proposed Azilsartan Medoxomil ANDA Products. Defendants admit that Zydus USA submitted ANDA No. 218451 to FDA seeking approval to engage in the commercial manufacture, use, sale, or importation of Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products in or into the United States and submitted ANDA No. 218658 to FDA seeking approval to engage in the commercial manufacture, use, sale, or importation of Zydus USA's Proposed Azilsartan Medoxomil ANDA Products in or into the United States. Defendants deny all other allegations in paragraph 20.

21. The allegations in paragraph 21 are legal conclusions to which no answer is required. To the extent an answer is required, 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 Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products and Zydus USA's Proposed Azilsartan Medoxomil ANDA Products. Defendants admit that Zydus USA submitted ANDA No. 218451 to FDA seeking approval to engage in the commercial manufacture, use, sale, or importation of Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products in or into the United States and submitted ANDA No. 218658 to FDA seeking approval to engage in the commercial manufacture, use, sale, or importation of Zydus USA's Proposed Azilsartan Medoxomil ANDA Products in or into the United States. Defendants deny all other allegations in paragraph 21.

22. The allegations in paragraph 22 are legal conclusions to which no answer is required. To the extent an answer is required, 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 Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products and Zydus USA's Proposed Azilsartan Medoxomil ANDA Products. Defendants admit that Zydus USA submitted ANDA No. 218451 to FDA seeking approval to engage in the commercial manufacture, use, sale, or importation of Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products in or into the United States and submitted ANDA No. 218658 to FDA seeking approval to engage in the commercial manufacture, use, sale, or importation of Zydus USA's Proposed Azilsartan Medoxomil ANDA Products in or into the United States. Defendants lack knowledge or information sufficient to form a belief regarding the truth of the allegations in the first sentence of paragraph 22 and therefore deny them. Defendants deny all other allegations in paragraph 22.

23. The allegations in paragraph 23 are legal conclusions to which no answer is required. To the extent an answer is required, 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 Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products and Zydus USA's Proposed Azilsartan Medoxomil ANDA Products. Defendants deny all other allegations in paragraph 23.

24. The allegations in paragraph 24 directed to Zydus Worldwide relate to a party that has been dismissed from the case (D.I. 16, Oct. 6, 2023 Stipulation and Order Dismissing Without Prejudice Defendant Zydus Worldwide DMCC and Amending Case Caption to Reflect Same) and are legal conclusions to which no answer is required. To the extent an answer is required, 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 Zydus USA's Proposed

Azilsartan Medoxomil and Chlorthalidone ANDA Products and Zydus USA's Proposed Azilsartan Medoxomil ANDA Products. Defendants deny all other allegations in paragraph 24.

25. The allegations in paragraph 25 relate to a party that has been dismissed from the case (D.I. 16, Oct. 6, 2023 Stipulation and Order Dismissing Without Prejudice Defendant Zydus Worldwide DMCC and Amending Case Caption to Reflect Same) and are legal conclusions to which no answer is required. To the extent an answer is required, denied.

26. The allegations in paragraph 26 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus Lifesciences does not contest venue in this Court solely for purposes of Plaintiffs' claims arising under 28 U.S.C. §§ 1391 and 1400(b) against Zydus Lifesciences in this case and solely as they apply to Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products and Zydus USA's Proposed Azilsartan Medoxomil ANDA Products. Defendants deny all other allegations in paragraph 26.

27. The allegations in paragraph 27 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus USA does not contest venue in this judicial district solely for the limited purpose of Plaintiffs' claims arising under 28 U.S.C. §§ 1391 and 1400(b) against Zydus USA solely as they apply to Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products and Zydus USA's Proposed Azilsartan Medoxomil ANDA Products. Defendants deny all other allegations in paragraph 27.

THE PATENTS-IN-SUIT

28. Defendants admit that on its face, the '936 patent lists June 30, 2015 as the "Date of Patent" and is titled "Solid pharmaceutical composition comprising a benzimidazole-7-carboxylate derivative and a pH control agent." Defendants further admit on information and belief that what purports to be a copy of the '936 patent is attached to the Complaint as Exhibit A.

Defendants deny all other allegations in paragraph 28.

29. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 29 and therefore deny them.

30. Defendants admit that on its face, the ’238 patent lists October 27, 2015 as the “Date of Patent” and is titled “Solid pharmaceutical composition.” Defendants further admit on information and belief that what purports to be a copy of the ’238 patent is attached to the Complaint as Exhibit B. Defendants deny all other allegations in paragraph 30.

31. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 31 and therefore deny them.

32. Defendants admit that on its face, the ’249 patent lists July 12, 2016 as the “Date of Patent” and is titled “Methods of treating hypertension with at least one angiotensin II receptor blocker and chlorthalidone.” Defendants further admit on information and belief that what purports to be a copy of the ’249 patent is attached to the Complaint as Exhibit C. Defendants deny all other allegations in paragraph 32.

33. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 33 and therefore deny them.

ACTS GIVING RISE TO THIS ACTION

34. Defendants admit that FDA’s Electronic Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) lists Azurity Pharmaceuticals Inc. as the Applicant Holder for New Drug Application (“NDA”) No. 200796 for azilsartan medoxomil, 40 mg and 80 mg tablets, and the Proprietary Name as “EDARBI.” Defendants deny all other allegations in paragraph 34.

35. The allegations in paragraph 35 are legal conclusions to which no answer is

required. To the extent an answer is required, Defendants admit that the FDA's Orange Book lists the '936, '584 and '920 patents and "EDARBI" as the Proprietary Name in connection with NDA No. 200796. 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 Zydus USA submitted ANDA No. 218658 to FDA seeking approval to engage in the commercial manufacture, use, sale, or importation of Zydus USA's Proposed Azilsartan Medoxomil ANDA Products. Defendants deny all other allegations in paragraph 36.

37. The allegations in paragraph 37 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 218658 identifies EDARBI (azilsartan medoxomil) tablets, 40 mg and 80 mg, as the Reference Listed Drug. Defendants further admit that the product labeling for Zydus USA's Proposed Azilsartan Medoxomil ANDA Products will comply with applicable law. Defendants deny all other allegations in paragraph 37.

38. Defendants admit that ANDA No. 218658 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '936 patent. Defendants deny all other allegations in paragraph 38.

39. Admitted.

40. Defendants admit that Zydus USA sent a letter dated July 19, 2023, to Plaintiffs notifying them that Zydus USA submitted ANDA No. 218658 to the FDA and that ANDA No. 218658 included a § 505(j)(2)(A)(vii)(IV) certification with respect to the '936 patent. Defendants admit that Plaintiffs received Zydus's July 19, 2023 letter on July 24, 2023. Defendants deny all

other allegations in paragraph 40.

41. Denied.

42. Denied.

43. Defendants admit that Zydus USA sent Zydus's Azilsartan Medoxomil Notice Letter on July 19, 2023, that Plaintiffs received the letter on July 24, 2023, and that Plaintiffs filed the Complaint alleging infringement of the '936 patent on August 2, 2023. Defendants deny all other allegations in paragraph 43.

44. Defendants admit that FDA's Orange Book lists Azurity Pharmaceuticals, Inc as the Applicant Holder for NDA No. 202331 for azilsartan medoxomil and chlorthalidone tablets, 40/25 mg and 40/12.5 mg tablets, and the Proprietary Name as "EDARBYCLOR." Defendants deny all other allegations in paragraph 44.

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 the FDA's Orange Book lists the '936 patent, the '238 patent, the '249 patent, the '584 patent, and the '920 patent and "EDARBYCLOR" as the Proprietary Name in connection with NDA No. 202331. Defendants further admit that FDA's Orange Book lists the '936 patent, the '584 patent, and the '920 patent and "EDARBI" as the Proprietary Name in connection with NDA No. 200796. Defendants deny all other allegations in paragraph 45.

46. The allegations in paragraph 46 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218451 to FDA seeking approval to engage in the commercial manufacture, use, sale, or importation of Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA

Products. Defendants deny all other allegations in paragraph 46.

47. The allegations in paragraph 47 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 218451 identifies EDARBYCLOR (azilsartan medoxomil and chlorthalidone) tablets, 40 mg/12.5 mg and 40 mg/25 mg, as the Reference Listed Drug. Defendants further admit that the product labeling for Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products, will comply with applicable law. Defendants deny all other allegations in paragraph 47.

48. Defendants admit that ANDA No. 218451 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '936 patent, the '238 patent, and the '249 patent. Defendants deny all other allegations in paragraph 48.

49. Admitted.

50. Defendants admit that Zydus USA sent a letter dated June 19, 2023 to Plaintiffs notifying them that Zydus USA submitted ANDA No. 218451 to the FDA and that ANDA No. 218451 included a § 505(j)(2)(A)(vii)(IV) certification with respect to the '936 patent, the '238 patent, and the '249 patent. Defendants admit that Plaintiffs received Zydus's June 19, 2023 letter on June 22, 2023. Defendants deny all other allegations in paragraph 50.

51. Denied.

52. Denied.

53. Defendants admit that Zydus USA sent a letter to Plaintiffs on June 19, 2023, that Plaintiffs received the letter on June 22, 2023, and that Plaintiffs filed their Complaint alleging infringement of the Patents-In-Suit on August 2, 2023. Defendants deny all other allegations in

paragraph 53.

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

54. Defendants re-allege their answers to each of the preceding paragraphs 1-53, as if fully set forth herein.

55. Denied.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

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

60. Defendants re-allege their answers to each of the preceding paragraphs 1-59, as if fully set forth herein.

61. Denied.

62. Denied.

63. Denied.

64. Denied.

65. Denied.

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

66. Defendants re-allege their answers to each of the preceding paragraphs 1-65, as if

fully set forth herein.

67. Denied.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

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

72. Defendants re-allege their answers to each of the preceding paragraphs 1-71, as if fully set forth herein.

73. Denied.

74. Denied.

75. Denied.

76. Denied.

77. Denied.

PRAYER FOR RELIEF

Defendants specifically deny that Plaintiffs are 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 attorney's 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 Plaintiffs' Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 9,066,936)

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218658 and ANDA No. 218451 and/or the manufacture, use, sale, or offer to sell within, and/or importation in or into the United States of Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products and Zydus USA's Proposed Azilsartan Medoxomil ANDA Products will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '936 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,066,936)

Upon information and belief, the claims of the '936 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 obviousness-type double patenting.

THIRD AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 9,169,238)

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218451 and/or the manufacture, use, sale, or offer to sell within, and/or importation in or into the United States of Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '238.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,169,238)

Upon information and belief, the claims of the '238 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 obviousness-type double patenting.

FIFTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 9,387,249)

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218451 and/or the manufacture, use, sale, or offer to sell within, and/or importation in or into the United States of Zydus USA's Proposed Azilsartan Medoxomil and Chlorthalidone ANDA Products will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '249 patent.

SIXTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,387,249)

Upon information and belief, the claims of the '249 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 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 U.S. 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 litigation.

Dated: April 25, 2024

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on April 25, 2024, a copy of the foregoing document was served on the counsel listed below in the manner indicated:

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