IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INC., BIOGEN SWISS MANUFACTURING GMBH, and ALKERMES PHARMA IRELAND LIMITED,	)	C.A. No. 23-732-GBW
Plaintiffs,	)	
v.	)	
ZYDUS WORLDWIDE DMCC, ZYDUS PHARMACEUTICALS (USA) INC., and ZYDUS LIFESCIENCES LIMITED,	)	
Defendants.	)	

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

Defendants Zydus Worldwide DMCC ("Zydus Worldwide"), Zydus Pharmaceuticals (USA) Inc. ("Zydus USA"), and Zydus Lifesciences Limited ("Zydus Lifesciences") (collectively "Zydus" or "Defendants") for their Answer and Affirmative Defenses to the Complaint of Biogen Inc., Biogen Swiss Manufacturing GmbH ("BSM") (together "Biogen"), and Alkermes Pharma Ireland Limited ("Alkermes") (collectively, "Plaintiffs") state as follows:

All averments not expressly admitted are denied.

NATURE OF THE ACTION

1. The allegations in paragraph 1 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Plaintiffs' Complaint purports to be a civil action alleging infringement under the patent laws of the United States, Title 35 of the United States Code, of United States Patent Nos. 8,669,281 ("the '281 patent"), 9,090,558 ("the '558 patent"), and 10,080,733 ("the '733 patent") (collectively "the patents-in-suit"). Zydus further admits that Zydus Worldwide submitted Abbreviated New Drug Application ("ANDA") No.

218596 to the United States Food and Drug Administration ("FDA"), seeking FDA approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of diroximel fumarate delayed-release capsules, 231 mg ("Zydus's Proposed ANDA Product") in or into the United States. Zydus further admits that ANDA No. 218596 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications") with respect to the '281, '558, and '733 patents. Zydus further admits that pursuant to 21 U.S.C. § 355(j), Zydus sent a letter dated May 25, 2023 ("Zydus's Notice Letter") to Biogen Inc. and Alkermes Pharma Ireland Limited notifying them that Zydus Worldwide submitted ANDA No. 218596. Zydus further admits that ANDA No. 218596 identifies Vumerity® (diroximel fumarate) delayed-release capsules, 231 mg, as the Reference Listed Drug. Zydus further admits that the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") lists in connection with New Drug Application ("NDA") No. 211855: "BIOGEN INC" as the Applicant Holder and "VUMERITY" as the Proprietary Name. Zydus further admits that the prescribing information for Vumerity®, dated February 10, 2023, under "INDICATIONS AND USAGE" states that "VUMERITY is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults." Zydus denies all other allegations in paragraph 1.

PARTIES

2. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 2 and therefore denies them.

3. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 3 and therefore denies them.

4. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 4 and therefore denies them.

5. Admitted.

6. Admitted.

7. Admitted.

8. The allegations in paragraph 8 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus Worldwide submitted ANDA No. 218596 to the FDA. Zydus further admits that Zydus USA is the U.S. Liaison Agent to FDA for Zydus Worldwide listed in ANDA No. 218596. Zydus denies all other allegations in paragraph 8.

9. The allegations in paragraph 9 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus Worldwide submitted ANDA No. 218596 to FDA seeking FDA approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA and Zydus Worldwide are wholly owned subsidiaries of Zydus Lifesciences and that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants further admit that ANDA No. 218596 identifies Zydus Lifesciences as the manufacturer of Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 9.

JURISDICTION AND VENUE

10. The allegations in paragraph 10 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus does not contest subject matter jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to the diroximel fumarate delayed-release capsules, 231 mg described in ANDA No. 218596. Zydus denies 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, Zydus does not contest personal jurisdiction in this

Court solely for the limited purpose of Plaintiffs' claims against Zydus Worldwide in this case and solely as they apply to the diroximel fumarate delayed-release capsules, 231 mg described in ANDA No. 218596. Zydus denies all other allegations in paragraph 11.

12. The allegations in paragraph 12 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA in this case and solely as they apply to the diroximel fumarate delayed-release capsules, 231 mg described in ANDA No. 218596. Zydus further admits that Zydus USA sells pharmaceutical products, including generic pharmaceutical products, in the United States. Zydus denies all other allegations in paragraph 12.

13. The allegations in paragraph 13 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to the diroximel fumarate delayed-release capsules, 231 mg described in ANDA No. 218596. Zydus admits that Zydus Lifesciences manufactures pharmaceutical products, including generic pharmaceutical products, that are sold in the United States. Zydus further admits that Zydus USA and Zydus Worldwide are wholly owned subsidiaries of Zydus Lifesciences and that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Zydus denies 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, Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as

they apply to the diroximel fumarate delayed-release capsules, 231 mg described in ANDA No. 218596. Zydus further admits that Zydus Worldwide submitted ANDA No. 218596 to FDA seeking FDA approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus denies 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, Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to the diroximel fumarate delayed-release capsules, 231 mg described in ANDA No. 218596. Zydus admits that Zydus Worldwide submitted ANDA No. 218596 to FDA seeking FDA approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus denies all other allegations in paragraph 15.

16. The allegations in paragraph 16 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to the diroximel fumarate delayed-release capsules, 231 mg described in ANDA No. 218596. Zydus admits that Zydus Worldwide submitted ANDA No. 218596 to FDA seeking FDA approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus denies 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 does not contest personal jurisdiction in this

Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to the diroximel fumarate delayed-release capsules, 231 mg described in ANDA No. 218596. Zydus denies 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, Zydus does not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Worldwide in this case and solely as they apply to the diroximel fumarate delayed-release capsules, 231 mg described in ANDA No. 218596. Zydus admits that Zydus Worldwide is incorporated in the United Arab Emirates. Zydus denies 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, Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to the diroximel fumarate delayed-release capsules, 231 mg described in ANDA No. 218596. Zydus admits that Zydus Lifesciences is incorporated in the Republic of India. Zydus denies 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, Zydus does not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA in this case and solely as they apply to the diroximel fumarate delayed-release capsules, 231 mg described in ANDA No. 218596. Zydus USA admits that in *Acadia Pharmaceuticals Inc. v. Zydus Pharmaceuticals (USA) Inc. et al.*, C.A. No. 22-01386-GBW (D. Del.), Zydus USA stated "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, described in ANDA No. 214493;" that in *Novo*

Nordisk Inc., et al. v Zydus Worldwide DMCC, et al., C.A. No. 22-297-CFC (D. Del.), Zydus USA stated "Defendants do not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Defendants in this case and solely as they apply to Zydus's Proposed ANDA Product;" and that in *Astrazeneca AB, et al. v. Zydus Pharmaceuticals (USA) Inc., et al*., C.A. No. 21-550-RGA (D. Del.), Zydus USA stated "Zydus does not contest venue in this Court solely for purposes of Plaintiffs' claims against Zydus in this case and solely as they apply to the osimertinib tablets, 40 mg and 80 mg, described in ANDA No. 214263." Zydus denies all other allegations in paragraph 20.

BACKGROUND

21. Zydus admits that the prescribing information for Vumerity®, dated February 10, 2023, under "INDICATIONS AND USAGE" states that "VUMERITY is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults." Zydus denies all other allegations in paragraph 21.

22. Zydus admits that the Orange Book lists in connection with NDA No. 211855: "BIOGEN INC" as the Applicant Holder and "VUMERITY" as the Proprietary Name. Zydus denies all other allegations in paragraph 22.

23. Zydus admits that the Orange Book lists in connection with NDA No. 211855: "BIOGEN INC" as the Applicant Holder. Zydus denies 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, Zydus admits that the '281 patent lists March 11, 2014 as the "Date of Patent," and is titled "Prodrugs of Fumarates and Their Use in Treating Various Diseases." Zydus further admits that, on information and belief, what purports to be a

copy of the '281 patent is attached to the Complaint as Exhibit A. Zydus denies all other allegations in paragraph 24.

25. Zydus admits that according to the United States Patent and Trademark Office's ("PTO") Patent Assignment Search Database, Reel No. 031431, Frame No. 0160, the '281 patent is assigned to Alkermes. Zydus denies all other allegations in paragraph 25.

26. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 26 and therefore denies them.

27. The allegations in paragraph 27 are legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that Plaintiffs' Complaint against Zydus purports to be a civil action alleging infringement of the '281 patent. Zydus denies 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, Zydus admits that the '558 patent lists July 28, 2015 as the "Date of Patent," and is titled "Prodrugs of Fumarates and Their Use in Treating Various Diseases." Zydus further admits that, on information and belief, what purports to be a copy of the '558 patent is attached to the Complaint as Exhibit B. Zydus denies all other allegations in paragraph 28.

29. Zydus admits that according to the PTO's Patent Assignment Search Database, Reel No. 035094, Frame No. 0630, the '558 patent is assigned to Alkermes. Zydus denies all other allegations in paragraph 29.

30. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 30 and therefore denies them.

31. The allegations in paragraph 31 are legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that Plaintiffs' Complaint against Zydus purports to be a civil action alleging infringement of the '558 patent. Zydus denies 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, Zydus admits that the '733 lists September 25, 2018 as the "Date of Patent," and is titled "Prodrugs of Fumarates and Their Use in Treating Various Diseases." Zydus further admits that, on information and belief, what purports to be a copy of the '733 patent is attached to the Complaint as Exhibit C. Zydus denies all other allegations in paragraph 32.

33. Zydus admits that according to the PTO's Patent Assignment Search Database, Reel No. 051354, Frame No. 0700, the '733 patent is assigned to Alkermes. Zydus denies all other allegations in paragraph 33.

34. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 34 and therefore denies them.

35. The allegations in paragraph 35 are legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that Plaintiffs' Complaint against Zydus purports to be a civil action alleging infringement of the '733 patent. Zydus denies 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, Zydus admits that Biogen Inc. received Zydus's Notice Letter on May 26, 2023, Alkermes received Zydus's Notice Letter on May 29, 2023, and

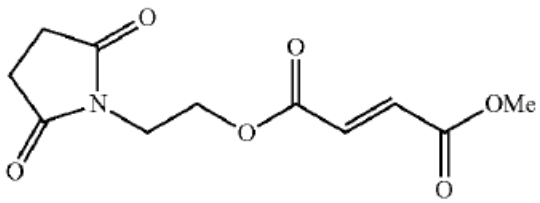
that Plaintiffs commenced an action by filing its Complaint on July 6, 2023. Zydus denies all other allegations in paragraph 36.

COUNT I
(Infringement of the '281 Patent)

37. Zydus restates and realleges its answers to each of the preceding paragraphs 1-36 as if fully set forth herein.

38. The allegations in paragraph 38 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that claim 1 of the '281 patent reads:

1. A compound having the formula:



or a pharmaceutically acceptable salt thereof.

Zydus denies all other allegations in paragraph 38.

39. Denied.

40. Denied.

41. The allegations in paragraph 41 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus's Notice Letter states in part that "Zydus does not waive, and expressly reserves, the right to raise additional defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '281, '558, and '733 patents in any ensuing litigation or other proceeding that may result from receipt of this letter. *See Abbott Labs, Inc. v. Apotex Inc.*, 725 F. Supp. 2d 724, 727 (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 letters"); *Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99 Civ. 8928 (BSJ), 2000 U.S. Dist. LEXIS 2511, *4 (S.D.N.Y. Mar. 6, 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 41.

42. Zydus admits that ANDA No. 218596 includes a Paragraph IV Certification with respect to the '281 patent, stating that in the opinion of Zydus Worldwide and to the best of its knowledge, no valid and enforceable claim of the '281 patent will be infringed by the manufacture, use, sale, or offer to sell within, or importation into, the United States of Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 42.

43. Zydus admits that Zydus Worldwide submitted ANDA No. 218596 to the FDA, seeking FDA approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218596 includes a Paragraph IV Certification with respect to the '281 patent. Zydus denies all other allegations in paragraph 43.

44. Denied.

45. Zydus admits that Zydus Worldwide submitted ANDA No. 218596 to the FDA, seeking FDA approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218596 includes a Paragraph IV Certification with respect to the '281 patent. Zydus denies 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, Zydus admits that the FDA's Orange Book lists the

'281 patent in connection with NDA No. 211855 and that ANDA No. 218596 includes a Paragraph IV Certification with respect to the '281 patent. Zydus further admits that Zydus Worldwide submitted ANDA No. 218596 to the FDA, seeking FDA approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus denies all other allegations in paragraph 46.

47. Denied.

48. Denied.

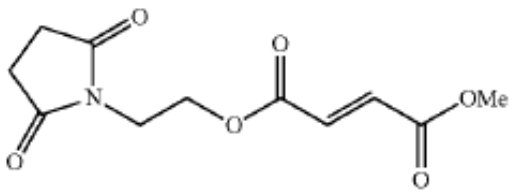
49. Denied.

COUNT II
(Infringement of the '558 Patent)

50. Zydus restates and realleges its answers to each of the preceding paragraphs 1-49 as if fully set forth herein.

51. The allegations in paragraph 51 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that claim 1 of the '558 patent reads:

> 1. A method of treating multiple sclerosis in a subject in need thereof, comprising administering to the subject a therapeutically effective amount of a compound having the formula:



> or a pharmaceutically acceptable salt thereof.

Zydus denies all other allegations in paragraph 51.

52. Denied.

53. Denied.

54. The allegations in paragraph 54 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus's Notice Letter states in part that "Zydus does not waive, and expressly reserves, the right to raise additional defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '281, '558, and '733 patents in any ensuing litigation or other proceeding that may result from receipt of this letter. *See Abbott Labs, Inc. v. Apotex Inc.*, 725 F. Supp. 2d 724, 727 (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 letters"); *Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99 Civ. 8928 (BSJ), 2000 U.S. Dist. LEXIS 2511, *4 (S.D.N.Y. Mar. 6, 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 54.

55. Zydus admits that ANDA No. 218596 includes a Paragraph IV Certification with respect to the '558 patent, stating that in the opinion of Zydus Worldwide and to the best of its knowledge, no valid and enforceable claim of the '558 patent will be infringed by the manufacture, use, sale, or offer to sell within, or importation into, the United States of Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 55.

56. Zydus admits that Zydus Worldwide submitted ANDA No. 218596 to the FDA, seeking FDA approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218596 includes a Paragraph IV Certification with respect to the '558 patent. Zydus denies all other allegations in paragraph 56.

57. Denied.

58. Zydus admits that Zydus Worldwide submitted ANDA No. 218596 to the FDA, seeking FDA approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218596 includes a Paragraph IV Certification with respect to the '558 patent. Zydus denies all other allegations in paragraph 58.

59. The allegations in paragraph 59 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the FDA's Orange Book lists the '558 patent in connection with NDA No. 211855 and that ANDA No. 218596 includes a Paragraph IV Certification with respect to the '558 patent. Zydus further admits that Zydus Worldwide submitted ANDA No. 218596 to the FDA, seeking FDA approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus denies all other allegations in paragraph 59.

60. Denied.

61. Denied.

62. Denied.

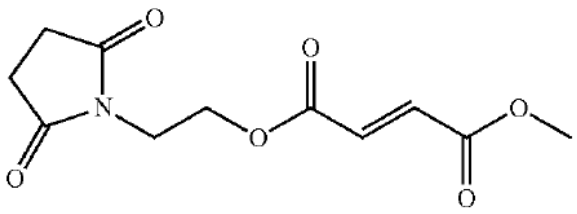
63. Denied.

COUNT III
(Infringement of the '733 Patent)

64. Zydus restates and realleges its answers to each of the preceding paragraphs 1-63 as if fully set forth herein.

65. The allegations in paragraph 65 are legal conclusions to which no answer is required. Zydus admits that claim 1 of the '773 patent reads:

1. A crystalline form of a compound having the formula:



having an X-ray powder diffraction pattern comprising peaks, in terms of degrees 2-theta±0.2 degrees, at 11.6, 21.0, 24.3, 27.4, and 27.9 when using a Cu X-ray source.

Zydus denies all other allegations in paragraph 65.

66. Denied.

67. Denied.

68. The allegations in paragraph 68 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus's Notice Letter states in part that "Zydus does not waive, and expressly reserves, the right to raise additional defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '281, '558, and '733 patents in any ensuing litigation or other proceeding that may result from receipt of this letter. *See Abbott Labs, Inc. v. Apotex Inc.*, 725 F. Supp. 2d 724, 727 (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 letters"); *Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99 Civ. 8928 (BSJ), 2000 U.S. Dist. LEXIS 2511, *4 (S.D.N.Y. Mar. 6, 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 68.

69. Zydus admits that ANDA No. 218596 includes a Paragraph IV Certification with respect to the '773 patent, stating that in the opinion of Zydus Worldwide and to the best of its knowledge, no valid and enforceable claim of the '773 patent will be infringed by the manufacture, use, sale, or offer to sell within, or importation into, the United States of Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 69.

70. Zydus admits that Zydus Worldwide submitted ANDA No. 218596 to the FDA, seeking FDA approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218596 includes a Paragraph IV Certification with respect to the '773 patent. Zydus denies all other allegations in paragraph 70.

71. Denied.

72. Zydus admits that Zydus Worldwide submitted ANDA No. 218596 to the FDA, seeking FDA approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218596 includes a Paragraph IV Certification with respect to the '773 patent. Zydus denies all other allegations in paragraph 72.

73. The allegations in paragraph 73 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the FDA's Orange Book lists the '773 patent in connection with NDA No. 211855 and that ANDA No. 218596 includes a Paragraph IV Certification with respect to the '773 patent. Zydus further admits that Zydus Worldwide submitted ANDA No. 218596 to the FDA, seeking FDA approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus denies all other allegations in paragraph 73.

74. Denied.

75. Denied.

76. Denied.

77. Denied.

PRAYER FOR RELIEF

Zydus specifically denies that Plaintiffs are entitled to the general or specific relief requested against Zydus, or to any relief whatsoever, and prays for judgment in favor of Zydus dismissing this action with prejudice and awarding Zydus its 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, Zydus avers and asserts the following Affirmative Defenses to Plaintiffs' Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,669,281)

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218596 to FDA and the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of Zydus's Proposed ANDA Product will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '281 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,669,281)

Upon information and belief, the claims of the '281 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. 9,090,558)

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218596 to FDA and the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of Zydus's Proposed ANDA Product will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '558 patent.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,090,558)

Upon information and belief, the claims of the '558 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. 10,080,733)

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218596 to FDA and the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of Zydus's Proposed ANDA Product will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '733 patent.

SIXTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,080,733)

Upon information and belief, the claims of the '733 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.

Dated: October 11, 2023

YOUNG CONAWAY STARGATT & TAYLOR, LLP

By: */s/ Pilar G. Kraman*
Pilar G. Kraman (#5199)
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CERTIFICATE OF SERVICE

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