IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM CORPORATION Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD. Defendants.	C.A. No. 1:19-cv-1295-CFC

ZYDUS PHARMACEUTICALS (USA) INC. AND CADILA HEALTHCARE LTD.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Cadila Healthcare Ltd. ("Cadila") (collectively, "Zydus") hereby respond to the corresponding paragraphs of the Complaint of Plaintiffs Boehringer Ingelheim Pharmaceuticals Inc. ("BIPI"), Boehringer Ingelheim International GmbH ("BII"), and Boehringer Ingelheim Corporation ("BIC") (collectively, "Boehringer") as follows:

NATURE OF THE ACTION

1. Paragraph 1 of the Complaint contains conclusions of law to which no response is required. The Complaint speaks for itself, and no further response by Zydus is required. To the extent that a response is required, Zydus admits that the Complaint purports to be an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, which Boehringer alleges is related to United States Patent Nos. 7,579,449 ("the '449 patent"), 7,713,938 ("the '938 patent"), 8,551,957 ("the '957 patent"), 9,949,998

("the '998 patent"), and 10,258,637 ("the '637 patent") (collectively, the "Patents-in-Suit"). Zydus admits that Zydus USA submitted Abbreviated New Drug Application ("ANDA") No. 213345 to the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell empagliflozin/linagliptin tablets, 10 mg/5 mg and 25 mg/5 mg ("Zydus ANDA Products").

2. Zydus lacks sufficient knowledge to admit or deny the allegations in Paragraph 2 of the Complaint and, therefore, denies the same.

3. Zydus lacks sufficient knowledge to admit or deny the allegations in Paragraph 3 of the Complaint and, therefore, denies the same.

4. Zydus lacks sufficient knowledge to admit or deny the allegations in Paragraph 4 of the Complaint and, therefore, denies the same.

5. Paragraph 5 contains no allegations to which a response is required. To the extent a response is required, Zydus admits that the Complaint sometimes refers to BIPI, BII, and BIC collectively as "Boehringer" or "Plaintiffs."

6. Admitted.

7. Admitted.

8. Admitted.

9. Denied.

10. Paragraph 10 contains no allegations to which a response is required. To the extent a response is required, Zydus admits that the Complaint sometimes refers to Zydus USA and Cadila collectively as "Zydus."

11. Paragraph 11 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Zydus admits that Cadila develops,

manufactures, and/or distributes generic pharmaceuticals, and that certain generic pharmaceuticals developed and/or manufactured by Cadila are ultimately sold in the United States. Zydus does not contest jurisdiction in this Court for the limited purposes of this action only. Zydus denies the remaining allegations in Paragraph 11 of the Complaint.

12. Paragraph 12 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Zydus admits that Zydus USA seeks FDA approval of ANDA No. 213345. Zydus does not contest jurisdiction in this Court for the limited purposes of this action only. Zydus denies the remaining allegations in Paragraph 12 of the Complaint.

JURISDICTION AND VENUE

13. Paragraph 13 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Zydus does not contest subject matter jurisdiction in this Court for the limited purposes of this action only.

14. Paragraph 14 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Zydus admits that Zydus USA has litigated previous Hatch-Waxman patent infringement disputes in this District and that Cadila is a foreign corporation not residing in any judicial district of the United States. Although Zydus denies that venue is proper in this District, Zydus does not contest venue in this Court for the limited purposes of this action only. Zydus denies the remaining allegations in Paragraph 14 of the Complaint.

15. Paragraph 15 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Zydus admits that Zydus USA has filed counterclaims in one or more prior cases in this District and that Zydus USA did not contest venue or personal jurisdiction for the limited purposes of those actions only. Although Zydus

denies that venue is proper in this District, Zydus does not contest venue or personal jurisdiction in this Court for the limited purposes of this action only.

PERSONAL JURISDICTION OVER ZYDUS USA

16. Zydus repeats and incorporates its responses to Paragraphs 1-15 as if fully set forth herein.

17. Zydus admits that Zydus USA develops, manufactures, and/or distributes generic pharmaceuticals in the United States. Zydus denies the remaining allegations in Paragraph 17 of the Complaint.

18. Paragraph 18 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Zydus admits that Zydus USA develops, manufactures, and/or distributes generic pharmaceuticals in the United States. Zydus does not contest personal jurisdiction in this Court for the limited purpose of this action only. Zydus denies the remaining allegations in Paragraph 18 of the Complaint.

19. Paragraph 19 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Zydus admits that Zydus USA has filed counterclaims in one or more prior cases in this District and that Zydus USA did not contest personal jurisdiction for the limited purposes of those actions only. Zydus does not contest personal jurisdiction in this Court for the limited purposes of this action only.

PERSONAL JURISDICTION OVER CADILA

20. Zydus repeats and incorporates its responses to Paragraphs 1-19 as if fully set forth herein.

21. Zydus admits that Cadila develops, manufactures, and/or distributes generic pharmaceuticals, and that certain generic drugs developed or manufactured by Cadila are

ultimately sold in the United States. Zydus lacks sufficient information to admit or deny the remaining allegations in Paragraph 21 of the Complaint and, therefore, denies the same.

22. Paragraph 22 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Zydus does not contest personal jurisdiction in this Court for the limited purpose of this action only. Zydus denies the remaining allegations in Paragraph 22 of the Complaint.

23. Paragraph 23 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Zydus admits that Cadila has filed counterclaims in one or more prior cases in this District and that Cadila did not contest personal jurisdiction for the limited purposes of those actions only. Zydus does not contest personal jurisdiction in this Court for the limited purposes of this action only. Zydus denies that Cadila asserted counterclaims in *H. Lundbeck A/S v. Zydus Pharm. (USA) Inc.*, No. 18-150-LPS, D.I. 13 (D. Del. Apr. 2, 2018).

24. Paragraph 24 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Zydus does not contest personal jurisdiction in this Court for the limited purpose of this action only. Zydus denies the remaining allegations in Paragraph 24 of the Complaint.

BACKGROUND

25. Paragraph 25 of the Complaint contains conclusions of law to which no answer is required. To the extent an answer is required, Zydus admits that, on its face, the '449 patent is titled "Glucopyranosyl-Substituted Phenyl Derivatives, Medicaments Containing Such Compounds, Their Use and Process for Their Manufacture," has an issue date of August 25, 2009, is assigned to BII, and lists as inventors Matthias Eckhardt, Peter Eickelmann, Frank Himmelsbach, Edward Leon Barsoumian, and Leo Thomas. Zydus further admits that what

purports to be a copy of the '449 patent is attached to the Complaint as Exhibit 1. Zydus lacks sufficient knowledge to admit or deny the remaining allegations in Paragraph 25 of the Complaint and, therefore, denies the same.

26. Paragraph 26 of the Complaint contains conclusions of law to which no answer is required. To the extent an answer is required, Zydus admits that, on its face, the '938 patent is titled "Crystalline Form of 1-Chloro-4-(β-D-Glucopyranos-1-yl)-2-[4-((*S*)-Tetrahydrofuran-3-yloxy)-Benzyl]-Benzene, A Method for Its Preparation and the Use Thereof for Preparing Medicaments," has an issue date of May 11, 2010, is assigned to BII, and lists as inventors Frank Himmelsbach, Sandra Schmid, Martin Schuehle, Hans-Jürgen Martin, and Matthias Eckhardt. Zydus further admits that what purports to be a copy of the '938 patent is attached to the Complaint as Exhibit 2. Zydus lacks sufficient knowledge to admit or deny the remaining allegations in Paragraph 26 of the Complaint and, therefore, denies the same.

27. Paragraph 27 of the Complaint contains conclusions of law to which no answer is required. To the extent an answer is required, Zydus admits that, on its face, the '957 patent is titled "Pharmaceutical Composition Comprising a Glucopyranosyl-Substituted Benzene Derivate," has an issue date of October 8, 2013, is assigned to BII, and lists as inventors Klaus Dugi, Michel Mark, Leo Thomas, and Frank Himmelsbach. Zydus further admits that what purports to be a copy of the '957 patent is attached to the Complaint as Exhibit 3. Zydus lacks sufficient knowledge to admit or deny the remaining allegations in Paragraph 27 of the Complaint and, therefore, denies the same.

28. Paragraph 28 of the Complaint contains conclusions of law to which no answer is required. To the extent an answer is required, Zydus admits that, on its face, the '998 patent is titled "Pharmaceutical Composition, Methods for Treating and Uses Thereof," has an issue date

of April 24, 2018, is assigned to BII, and lists as inventors Uli Christian Broedl, Sreeraj Macha, Maximilian von Eynatten, and Hans-Juergen Woerle. Zydus further admits that what purports to be a copy of the '998 patent is attached to the Complaint as Exhibit 4. Zydus lacks sufficient knowledge to admit or deny the remaining allegations in Paragraph 28 of the Complaint and, therefore, denies the same.

29. Paragraph 29 of the Complaint contains conclusions of law to which no answer is required. To the extent an answer is required, Zydus admits that, on its face, the '637 patent is titled "Pharmaceutical Composition, Methods for Treating and Uses Thereof," has an issue date of April 16, 2019, is assigned to BII, and lists as inventors Uli Christian Broedl, Sreeraj Macha, Maximilian von Eynatten, and Hans-Juergen Woerle. Zydus further admits that what purports to be a copy of the '637 patent is attached to the Complaint as Exhibit 5. Zydus lacks sufficient knowledge to admit or deny the remaining allegations in Paragraph 29 of the Complaint and, therefore, denies the same.

30. Zydus admits that the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") lists BIPI as the holder of New Drug Application ("NDA") No. 206073 for empagliflozin/linagliptin, which is sold under the trade name GLYXAMBI®, for oral use in 10 mg/5 mg and 25 mg/5 mg dosages.

31. Admitted.

32. Paragraph 32 contains conclusions of law to which no response is required. To the extent a response is required, Zydus admits that the '449, '938, '957, '998, and '637 patents are among the patents listed in the Orange Book with respect to GLYXAMBI®.

33. Paragraph 33 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Zydus lacks sufficient knowledge to admit or deny the allegations of Paragraph 33 and, therefore, denies the same.

CLAIM FOR RELIEF — INFRINGEMENT OF THE '449 PATENT

34. Zydus repeats and incorporates its responses to Paragraphs 1-33 as if fully set forth herein.

35. Admitted.

36. Admitted.

37. Zydus admits that Zydus USA, by letter dated May 30, 2019, informed BII and BIPI of a certification in ANDA No. 213345, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the Patents-in-Suit are invalid, unenforceable, and/or would not be infringed by the manufacture, use, or sale of the Zydus ANDA Products. Zydus denies the remaining allegations in Paragraph 37 of the Complaint.

38. Denied.

39. Zydus admits that an actual and immediate controversy exists regarding Zydus's alleged infringement of the '449 patent. Zydus denies the remaining allegations in Paragraph 39 of the Complaint.

40. Denied.

41. Denied.

42. Denied.

43. Denied.

44. Paragraph 44 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Zydus admits having knowledge of the '449

patent when ANDA No. 213345 was submitted to FDA and denies the remaining allegations in Paragraph 44 of the Complaint.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

CLAIM FOR RELIEF — INFRINGEMENT OF THE '938 PATENT

49. Zydus repeats and incorporates its responses to Paragraphs 1-48 as if fully set forth herein.

50. Denied.

51. Zydus admits that an actual and immediate controversy exists regarding Zydus's alleged infringement of the '938 patent. Zydus denies the remaining allegations in Paragraph 51 of the Complaint.

52. Denied.

53. Denied.

54. Denied.

55. Denied.

56. Paragraph 56 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Zydus admits having knowledge of the '938 patent when ANDA No. 213345 was submitted to FDA and denies the remaining allegations in Paragraph 56 of the Complaint.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

CLAIM FOR RELIEF — INFRINGEMENT OF THE '957 PATENT

61. Zydus repeats and incorporates its responses to Paragraphs 1-60 as if fully set forth herein.

62. Denied.

63. Zydus admits that an actual and immediate controversy exists regarding Zydus's alleged infringement of the '957 patent. Zydus denies the remaining allegations in Paragraph 63 of the Complaint.

64. Denied.

65. Denied.

66. Denied.

67. Denied.

68. Paragraph 68 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Zydus admits having knowledge of the '957 patent when ANDA No. 213345 was submitted to FDA and denies the remaining allegations in Paragraph 68 of the Complaint.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

CLAIM FOR RELIEF — INFRINGEMENT OF THE '998 PATENT

73. Zydus repeats and incorporates its responses to Paragraphs 1-72 as if fully set forth herein.

74. Denied.

75. Zydus admits that an actual and immediate controversy exists regarding Zydus's alleged infringement of the '998 patent. Zydus denies the remaining allegations in Paragraph 75 of the Complaint.

76. Denied.

77. Denied.

78. Denied.

79. Denied.

80. Paragraph 80 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Zydus admits having knowledge of the '998 patent when ANDA No. 213345 was submitted to FDA and denies the remaining allegations in Paragraph 80 of the Complaint.

81. Denied.

82. Denied.

83. Denied.

CLAIM FOR RELIEF — INFRINGEMENT OF THE '637 PATENT

84. Zydus repeats and incorporates its responses to Paragraphs 1-83 as if fully set forth herein.

85. Denied.

86. Zydus admits that an actual and immediate controversy exists regarding Zydus's alleged infringement of the '637 patent. Zydus denies the remaining allegations in Paragraph 86 of the Complaint.

87. Denied.

88. Denied.

89. Denied.

90. Denied.

91. Paragraph 91 of the Complaint contains conclusions of law to which no response is required. To the extent a response is required, Zydus admits having knowledge of the '637 patent after ANDA No. 213345 was submitted to FDA and denies the remaining allegations in Paragraph 91 of the Complaint.

92. Denied.

93. Denied.

94. Denied.

PRAYER FOR RELIEF

WHEREFORE, Zydus denies that Boehringer is entitled to the relief requested in the Complaint. Zydus specifically denies that Boehringer is 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 its Answer or to its ability to seek and allege any and all defenses not presently known or that are revealed during the course of discovery, Zydus asserts the following affirmative defenses in response to the Complaint:

First Affirmative Defense

Each claim of the Patents-in-Suit that Boehringer asserts against Zydus is invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112, and/or the judicial doctrine barring double-patenting.

Second Affirmative Defense

Zydus has not infringed, is not infringing, and will not infringe, either directly or by contribution or inducement, literally or by doctrine of equivalents, any valid and enforceable claim of the Patents-in-Suit under 35 U.S.C. § 271(a), (b), or (c).

Third Affirmative Defense

Zydus has not infringed and is not infringing any valid and enforceable claim of the Patents-in-Suit under 35 U.S.C. § 271(e) by submission of ANDA No. 213345.

Reservation of Rights

Zydus hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. patent laws and any other defenses, in law or equity, which may now exist or become available as a result of discovery and further factual investigation during this litigation.

COUNTERCLAIMS

For their counterclaims against Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Corporation (collectively, "Boehringer"), Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Cadila Healthcare Ltd. ("Cadila") (collectively, "Zydus") allege upon knowledge with respect to their own acts, and upon information and belief as to other matters, as follows:

The Parties

1. Counterclaimant 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.

2. Counterclaimant Cadila is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India.

3. On information and belief, Counterdefendant Boehringer Ingelheim Pharmaceuticals Inc. ("BIPI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

4. On information and belief, Counterdefendant Boehringer Ingelheim International GmbH ("BII") is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

5. On information and belief, Counterdefendant Boehringer Ingelheim Corporation ("BIC") is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

Jurisdiction and Venue

6. Zydus repeats and realleges Paragraphs 1-5 of the Counterclaims as if fully stated herein.

7. These are counterclaims for declaratory judgment of noninfringement and/or invalidity of one or more claims of United States Patent Nos. 7,579,449 ("the '449 patent"), 7,713,938 ("the '938 patent"), 8,551,957 ("the '957 patent"), 9,949,998 ("the '998 patent"), and 10,258,637 ("the '637 patent") (collectively, the "Patents-in-Suit"), pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, 35 U.S.C. § 271(e)(5), and 21 U.S.C. § 355(j) for the purpose of determining an

actual and justiciable controversy between the parties. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

8. Personal jurisdiction over Boehringer exists because Boehringer has submitted to the personal jurisdiction of the Court by asserting the Patents-in-Suit against Zydus in this District.

9. Venue is proper because Boehringer has submitted to the jurisdiction of the Court by asserting the Patents-in-Suit against Zydus in this District.

Acts Giving Rise to the Action

10. Zydus repeats and realleges Paragraphs 1-9 of the Counterclaims as if fully stated herein.

11. In its Complaint, Boehringer alleges that BII owns the Patents-in-Suit.

12. In its Complaint, Boehringer alleges that BIPI is the holder of the New Drug Application ("NDA") No. 206073 for empagliflozin/linagliptin for oral use, in 10 mg/5 mg and 25 mg/5 mg dosages, which is marketed under the trade name GLYXAMBI®.

13. The '449 patent on its face is titled "Glucopyranosyl-Substituted Phenyl Derivatives, Medicaments Containing Such Compounds, Their Use and Process for Their Manufacture" and lists an issue date of August 25, 2009. The face of the '449 patent identifies BII as the assignee.

14. The '938 patent on its face is titled "Crystalline Form of 1-Chloro-4-(β-D-Glucopyranos-1-yl)-2-[4-((*S*)-Tetrahydrofuran-3-yloxy)-Benzyl]-Benzene, A Method for Its Preparation and the Use Thereof for Preparing Medicaments" and lists an issue date of May 11, 2010. The face of the '938 patent identifies BII as the assignee.

15. The '957 patent on its face is titled "Pharmaceutical Composition Comprising a Glucopyranosyl-Substituted Benzene Derivate" and lists an issue date of October 8, 2013. The face of the '957 patent identifies BII as the assignee.

16. The '998 patent on its face is titled "Pharmaceutical Composition, Methods for Treating and Uses Thereof" and lists an issue date of April 24, 2018. The face of the '998 patent identifies BII as the assignee.

17. The '637 patent on its face is titled "Pharmaceutical Composition, Methods for Treating and Uses Thereof" and lists an issue date of April 16, 2019. The face of the '637 patent identifies BII as the assignee.

18. On information and belief, Boehringer caused the Patents-in-Suit, allegedly covering GLYXAMBI® and its use, to be listed in the United States Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for GLYXAMBI®.

19. Abbreviated New Drug Application ("ANDA") No. 213345 was submitted to FDA pursuant to 21 U.S.C. § 355(j)(2)(A) in order to obtain approval to sell empagliflozin/linagliptin for oral use, in 10 mg/5 mg and 25 mg/5 mg dosages ("Zydus ANDA Products"), in the United States. Zydus USA is the named applicant on ANDA No. 213345.

20. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Zydus USA certified in ANDA No. 213345, *inter alia*, that the Patents-in-Suit are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, and/or sale of the Zydus ANDA Products.

21. On May 30, 2019, Zydus USA sent a notice letter to BII and BIPI, providing notice that ANDA No. 213345 was filed with FDA and contained a Paragraph IV certification,

inter alia, that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, and/or sale of the Zydus ANDA Products. This notice letter included a detailed statement of the factual and legal bases for the Paragraph IV certification and an Offer of Confidential Access to ANDA No. 213345 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

22. In a letter dated June 6, 2019, Boehringer accepted the Offer of Confidential Access to ANDA No. 213345.

23. The Offer of Confidential Access accepted by Boehringer limited Boehringer's use of the disclosed information to determining whether to bring an action under 35 U.S.C. § 271(e)(2)(A) for infringing the patents referred to in the Paragraph IV certification of ANDA No. 213345.

24. At Boehringer's request, Zydus produced copies of ANDA No. 213345 and the Drug Master File for the Zydus ANDA Products.

The Presence of a Case or Controversy

25. Zydus repeats and realleges Paragraphs 1-24 of the Counterclaims as if fully stated herein.

26. By maintaining the listing of the Patents-in-Suit in the Orange Book, Boehringer represents that the Patents-in-Suit claim the approved drug GLYXAMBI® and/or a method of use of GLYXAMBI®, and that a claim for patent infringement "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(G).

27. On July 11, 2019, in response to Zydus USA's ANDA filings and Paragraph IV certifications directed to the Patents-in-Suit, Boehringer filed a Complaint alleging, *inter alia*, infringement of the Patents-in-Suit.

28. Actual and justiciable controversies exist between Zydus and Boehringer relating to the Patents-in-Suit.

29. A declaration of rights between the parties is both appropriate and necessary to establish that Zydus will not infringe any valid and/or enforceable claim of the Patents-in-Suit.

COUNT I
DECLARATION OF NONINFRINGEMENT OF THE '449 PATENT

30. Zydus repeats and realleges Paragraphs 1-29 of the Counterclaims as if fully stated herein.

31. The submission of ANDA No. 213345 to FDA does not infringe any valid and enforceable claim of the '449 patent, either literally or under the doctrine of equivalents, or directly, through contribution or inducement.

32. The commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Products does not and will not infringe any valid and enforceable claim of the '449 patent, either literally or under the doctrine of equivalents, or directly, through contribution or inducement.

33. An actual and justiciable controversy exists between Zydus and Boehringer regarding the noninfringement of the '449 patent.

34. Zydus is entitled to a declaration that the submission of ANDA No. 213345 to FDA does not infringe any valid and enforceable claim of the '449 patent.

35. Zydus is entitled to a declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Products does not and will not infringe any valid and enforceable claim of the '449 patent.

COUNT II
DECLARATION OF INVALIDITY OF THE '449 PATENT

36. Zydus repeats and realleges Paragraphs 1-35 of the Counterclaims as if fully stated herein.

37. The claims of the '449 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112, and/or the judicial doctrine barring double-patenting. In particular, the claims of the '449 patent are invalid under 35 U.S.C. § 103 because the claims would have been obvious to one of ordinary skill in the art in view of the prior art, including, for example: U.S. Patent Publication No. 2002/0137903 by Ellsworth; U.S. Patent Publication No. 2001/0044435 by Himmelsbach; U.S. Patent Publication No. 2001/0041674 by Tomiyama; International Patent Publication No. WO 01/27128 A1 by Ellsworth; International Patent Publication No. WO 98/31697 by Sato; *Remington's Pharmaceutical Sciences*; the *Encyclopedia of Pharmaceutical Technology*; C.J. Torrance et al., *Combinational Chemoprevention of Intestinal Neoplasia*, 6 Nature Med. 1024 (2000); J.D. McKinney et al., *Forum: The Practice of Structural Activity Relationships (SAR) in Toxicology*, 56 Toxicological Sci. 8 (2000); C. Hansch, *Use of Quantitative Structure-Activity Relationships (QSAR) in Drug Design*, 14 Pharmaceutical Chemistry J. 678 (1980); S. Wielert-Badt et al., *Probing the Conformation of the Sugar Transport Inhibitor Phlorizin by 2D-NMR, Molecular Dynamics Studies, and Pharmacore Analysis*, 43 J. Medicinal Chemistry 1692 (2000); and S. Wielert-Badt et al., *Single Molecule Recognition of Protein Binding Epitopes in Brush Border Membranes by Force Microscopy*, 82 Biophysical J. 2767 (2002).

38. An actual and justiciable controversy exists between Zydus and Boehringer regarding the validity of the ’449 patent.

39. Zydus is entitled to a declaration that the ’449 patent is invalid.

COUNT III
DECLARATION OF NONINFRINGEMENT OF THE ’938 PATENT

40. Zydus repeats and realleges Paragraphs 1-39 of the Counterclaims as if fully stated herein.

41. The submission of ANDA No. 213345 to FDA does not infringe any valid and enforceable claim of the ’938 patent, either literally or under the doctrine of equivalents, or directly, through contribution or inducement.

42. The commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Products does not and will not infringe any valid and enforceable claim of the ’938 patent, either literally or under the doctrine of equivalents, or directly, through contribution or inducement.

43. An actual and justiciable controversy exists between Zydus and Boehringer regarding the noninfringement of the ’938 patent.

44. Zydus is entitled to a declaration that the submission of ANDA No. 213345 to FDA does not infringe any valid and enforceable claim of the ’938 patent.

45. Zydus is entitled to a declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Products does not and will not infringe any valid and enforceable claim of the ’938 patent.

COUNT IV
DECLARATION OF INVALIDITY OF THE ’938 PATENT

46. Zydus repeats and realleges Paragraphs 1-45 of the Counterclaims as if fully stated herein.

47. The claims of the '938 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112, and/or the judicial doctrine barring double-patenting. In particular, the claims of the '938 patent are invalid under 35 U.S.C. § 103 because the claims would have been obvious to one of ordinary skill in the art in view of the prior art, including, for example: J. K. Guillory, *Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids, in* Polymorphism in Pharmaceutical Solids 183 (Harry G. Brittain ed., 1999); C.-H. Gu et al., *Polymorph Screening: Influence of Solvents on the Rate of Solvent-Mediated Polymorphic Transformation*, 90 J. Pharmaceutical Sci. 1878 (2001); and the '449 patent.

48. An actual and justiciable controversy exists between Zydus and Boehringer regarding the validity of the '938 patent.

49. Zydus is entitled to a declaration that the '938 patent is invalid.

COUNT V
DECLARATION OF NONINFRINGEMENT OF THE '957 PATENT

50. Zydus repeats and realleges Paragraphs 1-49 of the Counterclaims as if fully stated herein.

51. The submission of ANDA No. 213345 to FDA does not infringe any valid and enforceable claim of the '957 patent, either literally or under the doctrine of equivalents, or directly, through contribution or inducement.

52. The commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Products does not and will not infringe any valid and enforceable claim of the '957 patent, either literally or under the doctrine of equivalents, or directly, through contribution or inducement.

53. An actual and justiciable controversy exists between Zydus and Boehringer regarding the noninfringement of the ’957 patent.

54. Zydus is entitled to a declaration that the submission of the ANDA No. 213345 to FDA does not infringe any valid and enforceable claim of the ’957 patent.

55. Zydus is entitled to a declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Products does not and will not infringe any valid and enforceable claim of the ’957 patent.

COUNT VI
DECLARATION OF INVALIDITY OF THE ’957 PATENT

56. Zydus repeats and realleges Paragraphs 1-55 of the Counterclaims as if fully stated herein.

57. The claims of the ’957 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112, and/or the judicial doctrine barring double-patenting. In particular, the claims of the ’957 patent are invalid under 35 U.S.C. § 103 because the claims would have been obvious to one of ordinary skill in the art in view of the prior art, including, for example: U.S. Patent Publication No. 2005/0209166 by Eckhardt; U.S. Patent Publication No. 2004/0097510 by Himmelsbach; U.S. Patent No. 9,198,925; U.S. Patent No. 7,094,763; and K.M. Utzschneider & S.E. Kahn, *The Role of Insulin Resistance in Nonalcoholic Fatty Liver Disease*, 19 J. Clinical Endocrinology & Metabolism 4753 (2006).

58. An actual and justiciable controversy exists between Zydus and Boehringer regarding the validity of the ’957 patent.

59. Zydus is entitled to a declaration that the ’957 patent is invalid.

COUNT VII
DECLARATION OF NONINFRINGEMENT OF THE '998 PATENT

60. Zydus repeats and realleges Paragraphs 1-59 of the Counterclaims as if fully stated herein.

61. The submission of ANDA No. 213345 to FDA does not infringe any valid and enforceable claim of the '998 patent, either literally or under the doctrine of equivalents, or directly, through contribution or inducement.

62. The commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Products does not and will not infringe any valid and enforceable claim of the '998 patent, either literally or under the doctrine of equivalents, or directly, through contribution or inducement.

63. An actual and justiciable controversy exists between Zydus and Boehringer regarding the noninfringement of the '998 patent.

64. Zydus is entitled to a declaration that the submission of ANDA No. 213345 to FDA does not infringe any valid and enforceable claim of the '998 patent.

65. Zydus is entitled to a declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Products does not and will not infringe any valid and enforceable claim of the '998 patent.

COUNT VIII
DECLARATION OF INVALIDITY OF THE '998 PATENT

66. Zydus repeats and realleges Paragraphs 1-65 of the Counterclaims as if fully stated herein.

67. The claims of the '998 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112, and/or the judicial doctrine barring double-patenting. In particular, the claims of the '998 patent are invalid

under 35 U.S.C. § 103 because the claims would have been obvious to one of ordinary skill in the art in view of the prior art, including, for example: International Patent Publication No. WO 2010/092126 by Eisenreich; *Remington's Pharmaceutical Sciences*; the *Encyclopedia of Pharmaceutical Technology*; J.-F. Yale et al., *Efficacy and Safety of Canagliflozin in Subjects with Type 2 Diabetes and Chronic Kidney Disease*, 15 Diabetes, Obesity & Metabolism 463 (2013); J. Rosenstock et al., *Efficacy and Safety of BI10773, a New Sodium Glucose Cotransporter-2 (SGLT-2) Inhibitor, in Type 2 Diabetes Inadequately Controlled on Metformin*, Clinical Therapeutics/New Technology—Glucose Monitoring and Sensing, Poster Session 989-P (2011); and Boehringer Ingelheim Pharmaceuticals, *Efficacy and Safety of BI 10773 in Patients with Type 2 Diabetes and Renal Impairment*, Clinical Trial NCT01164501, July 15, 2010.

68. An actual and justiciable controversy exists between Zydus and Boehringer regarding the validity of the '998 patent.

69. Zydus is entitled to a declaration that the '998 patent is invalid.

COUNT IX
DECLARATION OF NONINFRINGEMENT OF THE '637 PATENT

70. Zydus repeats and realleges Paragraphs 1-69 of the Counterclaims as if fully stated herein.

71. The submission of ANDA No. 213345 to FDA does not infringe any valid and enforceable claim of the '637 patent, either literally or under the doctrine of equivalents, or directly, through contribution or inducement.

72. The commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Products does not and will not infringe any valid and enforceable claim of the '637 patent, either literally or under the doctrine of equivalents, or directly, through contribution or inducement.

73. An actual and justiciable controversy exists between Zydus and Boehringer regarding the noninfringement of the ’637 patent.

74. Zydus is entitled to a declaration that the submission of ANDA No. 213345 to FDA does not infringe any valid and enforceable claim of the ’637 patent.

75. Zydus is entitled to a declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Products does not and will not infringe any valid and enforceable claim of the ’637 patent.

COUNT X
DECLARATION OF INVALIDITY OF THE ’637 PATENT

76. Zydus repeats and realleges Paragraphs 1-75 of the Counterclaims as if fully stated herein.

77. The claims of the ’637 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112, and/or the judicial doctrine barring double-patenting. In particular, the claims of the ’637 patent are invalid under 35 U.S.C. § 103 because the claims would have been obvious to one of ordinary skill in the art in view of the prior art, including, for example: International Patent Publication No. WO 2010/092126 by Eisenreich; *Remington’s Pharmaceutical Sciences*; the *Encyclopedia of Pharmaceutical Technology*; J.-F. Yale et al., *Efficacy and Safety of Canagliflozin in Subjects with Type 2 Diabetes and Chronic Kidney Disease*, 15 Diabetes, Obesity & Metabolism 463 (2013); J. Rosenstock et al., *Efficacy and Safety of BI10773, a New Sodium Glucose Cotransporter-2 (SGLT-2) Inhibitor, in Type 2 Diabetes Inadequately Controlled on Metformin*, Clinical Therapeutics/New Technology—Glucose Monitoring and Sensing, Poster Session 989-P (2011); Boehringer Ingelheim Pharmaceuticals, *Efficacy and Safety of BI 10773 in Patients with Type 2 Diabetes and Renal Impairment*, Clinical Trial NCT01164501, July 15, 2010; and

Boehringer Ingelheim Pharmaceuticals, *Bioavailability of a Fixed Dose Combination Tablet with Empagliflozin (BI 10773) and Metformin Compared with the Monocomponents and Effect of Food on Bioavailability*, Clinical Trial NCT01211197, Sept. 29, 2010.

78. An actual and justiciable controversy exists between Zydus and Boehringer regarding the validity of the '637 patent.

79. Zydus is entitled to a declaration that the '637 patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, Zydus respectfully requests this Court to enter judgment for Zydus and against Boehringer as follows:

A. That the Complaint be dismissed with prejudice, and that Boehringer takes nothing by its Complaint;

B. Declaring that the manufacture, use, offer for sale, sale, and importation of the Zydus ANDA Products does not and will not infringe any valid claim of the Patents-in-Suit;

C. Declaring that the submission of ANDA No. 213345 by Zydus does not infringe any valid and enforceable claim of the Patents-in-Suit;

D. Declaring that the claims of the '449, '938, '957, '998, and '637 patents are invalid;

E. Declaring that this is an exceptional case under 35 U.S.C. § 285;

F. Awarding Zydus its costs, expenses, and attorneys' fees pursuant to 35 U.S.C. § 285, other applicable statutes or rules, or the general power of the Court;

G. Preliminarily and permanently enjoining Boehringer, its officers, agents, servants, employees, attorneys, successors, and any person who acts in concert or participation with

Boehringer from using the '449, '938, '957, '998, or '637 patents to block, hamper, hinder, or obstruct FDA approval of the products described in ANDA No. 213345; and

H. Awarding to Zydus such further relief as this Court may deem necessary, just, and proper.

Dated: July 17, 2019

Respectfully submitted,

/s/ John C. Phillips, Jr.

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

OF COUNSEL:

Chad A. Landmon
Ted Mathias
Ryan A. Cook
AXINN, VELTROP & HARKRIDER LLP
90 State House Square
Hartford, CT 06103
(860) 275-8100

Jonathan M. Knowles
AXINN, VELTROP & HARKRIDER LLP
114 West 47th Street, Floor 22
New York, NY 10036
(212) 728-2200