IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM CORPORATION,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Boehringer Ingelheim Pharmaceuticals Inc.; Boehringer Ingelheim International GmbH; and Boehringer Ingelheim Corporation, by their undersigned attorneys, for their Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submissions of Abbreviated New Drug Applications ("ANDAs") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Plaintiffs' JARDIANCE® (empagliflozin) tablets and/or SYNJARDY® (empagliflozin/metformin) tablets prior to the expiration of United States Patent Nos. 7,579,449, 9,949,998, and/or 7,713,938.

THE PARTIES

2. Plaintiff 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 Rd., Ridgefield, CT 06877.

3. Plaintiff 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.

4. Plaintiff Boehringer Ingelheim Corporation ("BIC") is a corporation organized and existing under the laws of Nevada, having a principal place of business at 900 Ridgebury Road, Ridgefield, CT, 06877.

5. BIPI, BII, and BIC are collectively referred to hereinafter as "Boehringer" or "Plaintiffs."

6. On information and belief, Defendant Zydus Pharmaceuticals USA, Inc. ("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 N., Pennington, New Jersey 08534.

7. On information and belief, Defendant Cadila Healthcare Limited ("Zydus 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.

8. On information and belief, Zydus USA is a wholly-owned subsidiary of Zydus Cadila.

9. On information and belief, the acts of Zydus USA complained of herein were done with the cooperation, participation, and assistance of Zydus Cadila.

10. Zydus USA and Zydus Cadila are collectively referred to hereinafter as "Zydus."

11. On information and belief, Zydus Cadila is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the state of Delaware, through its own actions and through the actions of its agents and subsidiaries, including Zydus USA, from which Zydus Cadila derives a substantial portion of its revenue.

12. On information and belief, Zydus USA acted in concert with Zydus Cadila to prepare and submit ANDA No. 212138 (the "Zydus Empagliflozin ANDA") for Zydus USA's 10 mg and 25 mg empagliflozin tablets (the "Zydus Empagliflozin ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of Zydus Cadila. Following FDA approval of the Zydus Empagliflozin ANDA, Zydus Cadila will manufacture and supply the approved generic products to Zydus USA, which will then market and sell the products throughout the United States at the direction, under the control, and for the direct benefit of Zydus Cadila.

13. On information and belief, Zydus USA acted in concert with Zydus Cadila to prepare and submit ANDA No. 212198 (the "Zydus Empagliflozin/Metformin ANDA") for Zydus USA's 5 mg/500 mg, 5 mg/1 g, 12.5 mg/500 mg, and 12.5 mg/1 g empagliflozin and metformin hydrochloride tablets ("Zydus Empagliflozin/Metformin Products"), which was done at the direction of, under the control of, and for the direct benefit of Zydus Cadila. Following

FDA approval of the Zydus Empagliflozin/Metformin ANDA, Zydus Cadila will manufacture and supply the approved generic products to Zydus USA, which will then market and sell the products throughout the United States at the direction, under the control, and for the direct benefit of Zydus Cadila.

14. The Zydus Empagliflozin Products and Zydus Empagliflozin/Metformin Products are collectively referred to herein as the "Zydus ANDA Products."

JURISDICTION AND VENUE

15. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

16. Venue is proper in this Court because, among other things, the defendants are either a foreign corporation not residing in any United States judicial district, or the agent of a foreign corporation. 28 U.S.C. § 1391(c); 28 U.S.C. § 1400(b). Moreover, Zydus has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware.

17. Zydus USA has been sued in this district previously in Hatch-Waxman patent infringement disputes, and has not contested personal jurisdiction or venue in one or more cases. *See, e.g., Bristol-Myers Squibb Company et al v. Zydus Pharmaceuticals (USA) Inc.*, 1-17-cv-00412 (D. Del); *Millennium Pharm., Inc. v. Zydus Pharm. (USA) Inc. et al.*, No. 1:17-cv-00423 (D. Del.); *Sanofi-Aventis U.S. LLC et al. v. Zydus Pharm. (USA) Inc. et al.*, No. 1:17-cv-00034 (D. Del.); *Astellas Pharma, Inc. et al. v. Zydus Pharm. (USA) Inc. et al.*, No. 1:16-cv-01167 (D. Del.); *Amgen Inc. v. Zydus Pharm. (USA) Inc. et al.*, No. 1:16-cv- 00853 (D. Del.); *Genzyme Corp. et al. v. Zydus Pharm. (USA) Inc.*, No. 1:16- cv-00540 (D. Del.); *Upsher-Smith Labs, Inc.*

v. Zydus Pharm. (USA) Inc. et al., No. 1:16-cv-00248 (D. Del.). On information and belief, Zydus also has affirmatively invoked this Court's jurisdiction by asserting counterclaims in cases it has litigated in Delaware. For example, Zydus asserted counterclaims in the cases listed above.

PERSONAL JURISDICTION OVER ZYDUS USA

18. Plaintiffs reallege paragraphs 1-17 as if fully set forth herein.

19. On information and belief, Zydus USA develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

20. This Court has personal jurisdiction over Zydus USA because, *inter alia*, Zydus USA, on information and belief: (1) has substantial, continuous, and systematic contacts with this State; (2) intends to market, sell, and/or distribute Zydus' infringing ANDA products to residents of this State; (3) enjoys substantial income from sales of its generic pharmaceutical products in this State; and (4) has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in this judicial district.

21. On information and belief, Zydus USA has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *See, e.g., Bristol-Myers Squibb Company et al v. Zydus Pharmaceuticals (USA) Inc*., 1-17-cv-00412 (D. Del); *Millennium Pharm., Inc. v. Zydus Pharm. (USA) Inc. et al.*, No. 1:17-cv-00423 (D. Del.); *Sanofi-Aventis U.S. LLC et al. v. Zydus Pharm. (USA) Inc. et al.*, No. 1:17-cv-00034 (D. Del.); *Astellas Pharma, Inc. et al. v. Zydus Pharm. (USA) Inc. et al.*, No. 1:16-cv-01167 (D. Del.); *Amgen Inc. v. Zydus Pharm. (USA) Inc. et al.*, No. 1:16-cv- 00853 (D. Del.);

Genzyme Corp. et al. v. Zydus Pharm. (USA) Inc., No. 1:16- cv-00540 (D. Del.); *Upsher-Smith Labs, Inc. v. Zydus Pharm. (USA) Inc. et al.*, No. 1:16-cv-00248 (D. Del.)

PERSONAL JURISDICTION OVER ZYDUS CADILA

22. Plaintiffs reallege paragraphs 1-21 as if fully set forth herein.

23. On information and belief, Zydus Cadila develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

24. This Court has personal jurisdiction over Zydus Cadila because, *inter alia*, Zydus Cadila, on information and belief: (1) intends to market, sell, or distribute Zydus's ANDA Products to residents of this State; (2) controls Defendant Zydus USA to distribute the infringing ANDA products that it manufactures; (3) makes its generic drug products available in this State; and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State.

25. Additionally, on information and belief, Zydus Cadila has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g., H. Lundbeck A/S v. Zydus Pharma. (USA) Inc.*, No. 18-150-LPS, D.I. 13 (D. Del. Apr. 2, 2018); *Millennium Pharma., Inc. v. Zydus Pharma. (USA) Inc*., No. 17-423-CFC, D.I. 9 (D. Del. May 24, 2017).

26. Alternatively, to the extent the above facts do not establish personal jurisdiction over Zydus Cadila, this Court may exercise jurisdiction over Zydus Cadila pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Zydus Candila would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c)

Zydus Cadila has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Zydus Cadila satisfies due process.

BACKGROUND

U.S. PATENT NO. 7,579,449

27. On August 25, 2009, the USPTO duly and legally issued United States Patent No. 7,579,449 ("the '449 patent") entitled "Glucopyranosyl-substituted phenyl derivatives, medicaments containing such compounds, their use and process for their manufacture" to inventors Matthias Eckhardt, Peter Eickelmann, Frank Himmelsbach, Edward Leon Baroumian, and Leo Thomas. A true and correct copy of the '449 patent is attached as Exhibit 1. The '449 patent is assigned to BII. BIC and BIPI are licensees of the '449 patent.

U.S. PATENT NO. 9,949,998

28. On April 24, 2018, the USPTO duly and legally issued United States Patent No. 9,949,998 ("the '998 patent") entitled "Pharmaceutical Composition, Methods for Treating and Uses Thereof" to inventors Uli Christian Broedl, Sreeraj Macha, Maximilian von Eynatten, and Hans-Juergen Woerle. A true and correct copy of the '998 patent is attached as Exhibit 2. The '998 patent is assigned to BII. BIC and BIPI are licensees of the '998 patent.

U.S. PATENT NO. 7,713,938

29. On May 11, 2010, the USPTO duly and legally issued United States Patent No. 7,713,938 ("the '938 patent") entitled "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" to inventors Frank Himmelsbach, Sandra Schmid, Martin Schuehle, Hans-Jürgen Martin, and Matthis Eckhardt. A true and correct copy of the '938 patent is attached as Exhibit 3. The '938 patent is assigned to BII. BIC and BIPI are licensees of the '938 patent.

JARDIANCE®

30. BIPI is the holder of New Drug Application ("NDA") No. 204629 for empagliflozin, for oral use, in 10 mg and 25 mg dosages, which is sold under the trade name JARDIANCE®.

31. JARDIANCE® is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") as having New Chemical Exclusivity until August 1, 2019.

32. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '449, '998, and '938 patents are among the patents listed in the Orange Book with respect to JARDIANCE®.

33. The '449, '998, and '938 patents cover the JARDIANCE® product and its use.

SYNJARDY®

34. BIPI is the holder of New Drug Application ("NDA") No. 206111 for empagliflozin and metformin hydrochloride, for oral use, in 5 mg/500 mg, 5 mg/1 g, 12.5 mg/500 mg, and 12.5 mg/1 g dosages, which is sold under the trade name SYNJARDY®.

35. SYNJARDY® is listed in Orange Book as having New Chemical Exclusivity until August 1, 2019.

36. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '449 and '938 patents are among the patents listed in the Orange Book with respect to SYNJARDY ®.

37. The '449 and '938 patents cover the SYNJARDY ® product and its use.

ACTS GIVING RISE TO THIS ACTION

COUNT I — INFRINGEMENT OF THE '449 PATENT

38. Plaintiffs reallege paragraphs 1-37 as if fully set forth herein.

39. On information and belief, Zydus submitted the Zydus Empagliflozin ANDA and the Zydus Empagliflozin/Metformin ANDA (collectively, the "Zydus ANDAs") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Zydus ANDA Products.

40. Zydus has represented that the Zydus ANDAs refer to and rely upon the JARDIANCE® NDA and the SYNJARDY® NDA and contain data that, according to Zydus, demonstrate the bioavailability or bioequivalence of the Zydus ANDA Products to JARDIANCE® and/or SYNJARDY®.

41. Plaintiffs received a letter from Zydus on or about September 28, 2018 stating that Zydus had included a certification in the Zydus Empagliflozin ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '449, '998, and '938 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Zydus ANDA Products (the "Zydus Empagliflozin Paragraph IV Certification"). Zydus intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Zydus Empagliflozin Products prior to the expiration of the '449, '998, and '938 patents.

42. Plaintiffs received a letter from Zydus on or about September 28, 2018 stating that Zydus had included a certification in the Zydus Empagliflozin/Metformin ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '449 and '938 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Zydus Empagliflozin/Metformin Products (the "Zydus Empagliflozin/Metformin Paragraph IV Certification"). Zydus intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Zydus Empagliflozin/Metformin Products prior to the expiration of the '449, and '938 patents.

43. The Zydus Empagliflozin Paragraph IV Certification and Zydus Empagliflozin/Metformin Paragraph IV Certification are collectively referred to herein as the "Zydus Paragraph IV Certifications."

44. Zydus has infringed at least one claim of the '449 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Zydus ANDAs, by which Zydus seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Zydus ANDA Products prior to the expiration of the '449 patent.

45. Zydus has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Zydus ANDA Products in the event that the FDA approves the Zydus ANDAs. Accordingly, an actual and immediate controversy exists regarding Zydus infringement of the '449 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

46. Zydus's manufacture, use, offer to sell, or sale of the Zydus ANDA Products in the United States or importation of the Zydus ANDA Products into the United States during the

term of the ’449 patent would further infringe at least one claim of the ’449 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

47. On information and belief, Zydus’s ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ’449 patent either literally or under the doctrine of equivalents.

48. On information and belief, the use of Zydus’s ANDA Products constitutes a material part of at least one of the claims of the ’449 patent; Zydus knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the ’449 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

49. On information and belief, the offering to sell, sale, and/or importation of Zydus’s ANDA Products would contributorily infringe at least one of the claims of the ’449 patent, either literally or under the doctrine of equivalents.

50. On information and belief, Zydus had knowledge of the ’449 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that they will aid and abet another’s direct infringement of at least one of the claims of the ’449 patent, either literally or under the doctrine of equivalents.

51. On information and belief, the offering to sell, sale, and/or importation of Zydus's ANDA Products by Zydus would actively induce infringement of at least one of the claims of the '449 patent, either literally or under the doctrine of equivalents.

52. On information and belief, Zydus does not deny that the Zydus ANDA Products will infringe at least certain claims of the '449 patent and in the Zydus Paragraph IV Certifications, Zydus did not deny that the Zydus ANDA Products will infringe certain claims of the '449 patent.

53. Plaintiffs will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '449 patent.

54. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT II — INFRINGEMENT OF THE '998 PATENT

55. Plaintiffs reallege paragraphs 1-54 as if fully set forth herein.

56. Zydus has infringed at least one claim of the '998 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Zydus Empagliflozin ANDA, by which Zydus seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Zydus Empagliflozin Products prior to the expiration of the '998 patent.

57. Zydus has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Zydus Empagliflozin Products in the event that the FDA approves the Zydus Empagliflozin ANDA. Accordingly, an actual and immediate

controversy exists regarding Zydus's infringement of the '998 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

58. Zydus's manufacture, use, offer to sell, or sale of the Zydus Empagliflozin Products in the United States or importation of the Zydus Empagliflozin Products into the United States during the term of the '998 patent would further infringe at least one claim of the '998 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

59. On information and belief, the Zydus Empagliflozin Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '998 patent either literally or under the doctrine of equivalents.

60. On information and belief, the use of the Zydus Empagliflozin Products constitutes a material part of at least one of the claims of the '998 patent; Zydus knows that the Zydus Empagliflozin Products are especially made or adapted for use in infringing at least one of the claims of the '998 patent, either literally or under the doctrine of equivalents; and the Zydus Empagliflozin Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

61. On information and belief, the offering to sell, sale, and/or importation of the Zydus Empagliflozin Products would contributorily infringe at least one of the claims of the '998 patent, either literally or under the doctrine of equivalents.

62. On information and belief, Zydus had knowledge of the '998 patent and, by its promotional activities and package inserts for the Zydus Empagliflozin ANDA Products, know

or should know that they will aid and abet another's direct infringement of at least one of the claims of the '998 patent, either literally or under the doctrine of equivalents.

63. On information and belief, the offering to sell, sale, and/or importation of the Zydus Empagliflozin Products by Zydus would actively induce infringement of at least one of the claims of the '998 patent, either literally or under the doctrine of equivalents.

64. Plaintiffs will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '998 patent.

65. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT III — INFRINGEMENT OF THE '938 PATENT

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

67. Zydus has infringed at least one claim of the '938 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Zydus ANDAs, by which Zydus seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Zydus ANDA Products prior to the expiration of the '938 patent.

68. Zydus has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Zydus ANDA Products in the event that the FDA approves the Zydus ANDAs. Accordingly, an actual and immediate controversy exists regarding Zydus's infringement of the '938 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

69. Zydus's manufacture, use, offer to sell, or sale of the Zydus ANDA Products in the United States or importation of the Zydus ANDA Products into the United States during the

term of the ’938 patent would further infringe at least one claim of the ’938 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

70. On information and belief, Zydus’s ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ’938 patent either literally or under the doctrine of equivalents.

71. On information and belief, the use of Zydus’s ANDA Products constitutes a material part of at least one of the claims of the ’938 patent; Zydus knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the ’938 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

72. On information and belief, the offering to sell, sale, and/or importation of Zydus’s ANDA Products would contributorily infringe at least one of the claims of the ’938 patent, either literally or under the doctrine of equivalents.

73. On information and belief, Zydus had knowledge of the ’938 patent and, by its promotional activities and package inserts for its ANDA Products, know or should know that they will aid and abet another’s direct infringement of at least one of the claims of the ’938 patent, either literally or under the doctrine of equivalents.

74. On information and belief, the offering to sell, sale, and/or importation of Zydus's ANDA Products by Zydus would actively induce infringement of at least one of the claims of the '938 patent, either literally or under the doctrine of equivalents.

75. Plaintiffs will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '938 patent.

76. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

77. On information and belief, the factual contentions in paragraphs 67-76 will likely have evidentiary support after a reasonable opportunity for further investigation or discovery.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against Zydus and for the following relief:

a. A Judgment be entered that Zydus has infringed at least one claim of the '449, '998, and '938 patents by submitting the Zydus ANDAs;

b. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

c. That Zydus, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or methods of administering drugs claimed in the '449, '998, and/or '938 patents, and (ii) seeking, obtaining or

maintaining approval of ANDAs until the expiration of the ’449, ’998, and/or ’938 patents or such other later time as the Court may determine;

d. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Zydus’s ANDAs under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the ’449, ’998, and ’938 patents, including any extensions;

e. That Boehringer be awarded monetary relief if Zydus commercially uses, offers to sell, or sells its respective proposed generic versions of JARDIANCE®, SYNJARDY® or any other product that infringes or induces or contributes to the infringement of the ’449, ’998, and/or ’938 patents, within the United States, prior to the expiration of those patents, including any extensions, and that any such monetary relief be awarded to Boehringer with prejudgment interest;

f. Costs and expenses in this action; and

g. Such other and further relief as the Court deems just and appropriate.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Brian P. Egan

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November 8, 2018