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.	)	
PRINSTON PHARMACEUTICAL INC., ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., and SOLCO HEALTHCARE US, LLC,	)	
Defendants.	)	

COMPLAINT

Plaintiffs, Boehringer Ingelheim Pharmaceuticals Inc.; Boehringer Ingelheim International GmbH; and Boehringer Ingelheim Corporation, by their undersigned attorneys, for their Complaint against Defendants Prinston Pharmaceutical Inc., Zhejiang Huahai Pharmaceutical Co., Ltd., and Solco Healthcare US, LLC, 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 an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiffs' GLYXAMBI® (empagliflozin/linagliptin) tablets prior to the expiration of United States Patent Nos. 8,551,957 and/or 9,949,998.

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 Prinston Pharmaceutical Inc. ("Prinston Pharma") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 2002 Eastpark Blvd., Cranbury, NJ 08512.

7. On information and belief, Prinston Pharma 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.

8. On information and belief, Defendant Solco Healthcare US, LLC ("Solco") is a Delaware corporation with a principal place of business at 2002 Eastpark Blvd., Cranbury, New Jersey 08512.

9. On information and belief, Solco is in the business of, among other things, preparing, manufacturing, marketing, and distributing pharmaceutical products, including Prinston Pharma's pharmaceutical products, throughout the United States, including in the State of Delaware. According to Prinston Pharma's website (http://www.prinstonpharm.com/Subsidiary.html) (last visited November 9, 2018), defendant Solco is the "U.S. sales and marketing division of Prinston Pharmaceutical Inc.," has "FDA-approved manufacturing capabilities," and brings "generic pharmaceutical products to the U.S. market."

10. Upon information and belief, Solco is a wholly-owned subsidiary of Prinston Pharma.

11. On information and belief, Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. ("Zhejiang Huahai") is a corporation organized and existing under the laws of China, having a principal place of business at Xunqiao, Linhai, Zhejiang 317024, China. On information and belief, Zhejiang Huahai is the ultimate parent company for Prinston and Solco, each of which are incorporated in the state of Delaware.

12. Prinston Pharma, Solco, and Zhejiang Huahai are collectively referred to hereinafter as "Prinston."

13. On information and belief, Prinston Pharma acted in concert with Solco and Zhejiang Huhai to prepare and submit ANDA No. 212264 (the "Prinston ANDA") for Prinston's 10 mg/5 mg and 25 mg/5 mg empagliflozin/linagliptin tablets ("the Prinston ANDA Products").

14. On information and belief, following FDA approval of the Prinston ANDA, Zhejiang Huahai will manufacture and supply the approved generic products to Soloco, which

will then market and sell the products throughout the United States, all at the direction, under the control, and/or for the direct benefit of Prinston Pharma.

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, each Defendant is incorporated in the State of Delaware and therefore "resides" in this judicial district and/or has committed acts of infringement in this district and has a regular and established place of business in this district and/or is foreign corporations not residing in any United States judicial district, which may be sued in any judicial district. 28 U.S.C. § 1391(c); 28 U.S.C. § 1400(b). Moreover, Prinston has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware. *See, e.g.*, *Astellas Pharma Inc. et al. v. Prinston Pharm. Inc*., C.A. No. 16-943-SLR (D. Del.) (D.I. 16); *AstraZeneca LP et al. v. Prinston Pharm. Inc.*, C.A. No. 15-1057-RGA (D. Del.) (D.I. 12); *Bayer Intell. Prop. GMBH et al. v. Aurobindo Pharma Ltd. et al*., C.A. No. 15-902-RGA (D. Del.) (D.I. 30); *Teijin Ltd. et al. v. Prinston Pharm. Inc*., C.A. No. 14-854-SLR (D. Del.) (D.I. 8).

PERSONAL JURISDICTION OVER PRINSTON PHARMA

17. Plaintiffs reallege paragraphs 1-16 as if fully set forth herein.

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

19. This Court has personal jurisdiction over Prinston Pharma because, *inter alia*, Prinston Pharma, on information and belief: (1) is a Delaware corporation; (2) has substantial, continuous, and systematic contacts with this State, either directly or through at least one of its wholly-owned subsidiaries or agents; (3) intends to market, sell, and/or distribute infringing Prinston ANDA Products to residents of this State upon approval of ANDA No. 212264, either directly or through at least one of its wholly-owned subsidiaries or agents; and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State.

20. On information and belief, Prinston Pharma 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.*, *Astellas Pharma Inc. et al. v. Prinston Pharm. Inc*., C.A. No. 16-943-SLR (D. Del.) (D.I. 16); *AstraZeneca LP et al. v. Prinston Pharm. Inc.*, C.A. No. 15-01057-RGA (D. Del.) (D.I. 12); *Bayer Intell. Prop. GMBH et al. v. Aurobindo Pharma Ltd. et al*., C.A. No. 15-902-RGA (D. Del.) (D.I. 30); *Teijin Ltd. et al. v. Prinston Pharm. Inc*., C.A. No. 14-854-SLR (D. Del.) (D.I. 8).

PERSONAL JURISDICTION OVER SOLCO

21. Plaintiffs reallege paragraphs 1-20 as if fully set forth herein.

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

23. This Court has personal jurisdiction over Solco because, *inter alia*, Solco, on information and belief: (1) is a Delaware corporation and is registered to do business in Delaware under File Number 4582086; (2) has substantial, continuous, and systematic contacts with this State; (3) intends to market, sell, and/or distribute infringing Prinston ANDA Products

to residents of this State upon approval of ANDA No. 212264; and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State.

PERSONAL JURISDICTION OVER ZHEJIANG HUAHAI

24. Plaintiffs reallege paragraphs 1-23 as if fully set forth herein.

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

26. This Court has personal jurisdiction over Zhejiang Huahai because, *inter alia*, Zhejiang Huahai, on information and belief: (1) has substantial, continuous, and systematic contacts with this State; (2) intends to market, sell, and/or distribute infringing Prinston ANDA Products to residents of this State upon approval of ANDA No. 212264; (3) enjoys substantial income from sales of its generic pharmaceutical products in this State; and (4) makes its generic drug products available in this State.

27. Alternatively, to the extent the above facts do not establish personal jurisdiction over Zhejiang Huahai, this Court may exercise jurisdiction over Zhejiang Huahai pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Zhejiang Huahai would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Zhejiang Huahai has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Zhejiang Huahai satisfies due process.

BACKGROUND

U.S. PATENT NO. 8,551,957

28. On October 8, 2013, the USPTO duly and legally issued United States Patent No. 8,551,957 ("the '957 patent") entitled "Pharmaceutical Composition Comprising a Glucopyranosyl-Substituted Benzene Derivate" to inventors Klaus Dugi, Michael Mark, Leo Thomas and Frank Himmelsbach. A true and correct copy of the '957 patent is attached as Exhibit 1. The '957 patent is assigned to BII. BIC and BIPI are licensees of the '957 patent.

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

29. 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.

GLYXAMBI®

30. BIPI is the holder of 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 sold under the trade name GLYXAMBI®.

31. GLYXAMBI® is listed in 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 '957 and '998 patents are among the patents listed in the Orange Book with respect to GLYXAMBI®.

33. The '957 and '998 patents cover the GLYXAMBI® product and its use.

ACTS GIVING RISE TO THIS ACTION

COUNT I —INFRINGEMENT OF THE '957 PATENT

34. Plaintiffs reallege paragraphs 1-33 as if fully set forth herein.

35. On information and belief, Prinston submitted the Prinston ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Prinston ANDA Products.

36. Prinston has represented that the Prinston refers to and relies upon the GLYXAMBI® NDA, and contains data that, according to Prinston, demonstrate the bioavailability or bioequivalence of the Prinston ANDA Products to GLYXAMBI®.

37. Plaintiffs received a letter from Prinston on or about October 5, 2018 stating that Prinston had included a certifications in the Prinston ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '957 and '998 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Prinston ANDA Products (the "Prinston Paragraph IV Certification"). Prinston intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Prinston ANDA Products prior to the expiration of the '957 and/or '998 patents.

38. Prinston has infringed at least one claim of the '957 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Prinston ANDA, by which Prinston seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Prinston ANDA Products prior to the expiration of the '957 patent.

39. Prinston has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Prinston ANDA Products in the event that the FDA approves the Prinston ANDA. Accordingly, an actual and immediate controversy exists regarding Prinston's infringement of the '957 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

40. Prinston's manufacture, use, offer to sell, or sale of the Prinston ANDA Products in the United States or importation of the Prinston ANDA Products into the United States during the term of the '957 patent would further infringe at least one claim of the '957 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

41. On information and belief, the Prinston 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 '957 patent either literally or under the doctrine of equivalents.

42. On information and belief, the use of the Prinston ANDA Products each constitute a material part of at least one of the claims of the '957 patent; Prinston knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '957 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.

43. On information and belief, the offering to sell, sale, and/or importation of the Prinston ANDA Products would contributorily infringe at least one of the claims of the '957 patent, either literally or under the doctrine of equivalents.

44. On information and belief, Prinston had knowledge of the '957 patent and, by its promotional activities and package inserts for the Prinston 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 '957 patent, either literally or under the doctrine of equivalents.

45. On information and belief, the offering to sell, sale, and/or importation of the Prinston ANDA Products by Prinston would actively induce infringement of at least one of the claims of the ’957 patent, either literally or under the doctrine of equivalents.

46. On information and belief, Prinston does not deny that the Prinston ANDA Products will infringe the claims of the ’957 patent and in the Prinston Paragraph IV Certification, Prinston did not deny that the Prinston ANDA Products will infringe the claims of the ’957 patent.

47. Plaintiffs will be substantially and irreparably harmed if Prinston is not enjoined from infringing the ’957 patent.

48. 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

49. Plaintiffs reallege paragraphs 1-48 as if fully set forth herein.

50. Prinston 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 Prinston ANDA, by which Prinston seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Prinston ANDA Products prior to the expiration of the ’998 patent.

51. Prinston has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Prinston ANDA Products in the event that the FDA approves the Prinston ANDA. Accordingly, an actual and immediate controversy exists regarding Prinston’s infringement of the ’998 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

52. Prinston’s manufacture, use, offer to sell, or sale of the Prinston ANDA Products in the United States or importation of the Prinston ANDA 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).

53. On information and belief, the Prinston 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 ’998 patent either literally or under the doctrine of equivalents.

54. On information and belief, the use of the Prinston ANDA Products constitutes a material part of at least one of the claims of the ’998 patent; Prinston knows that its ANDA 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 its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

55. On information and belief, the offering to sell, sale, and/or importation of the Prinston ANDA Products would contributorily infringe at least one of the claims of the ’998 patent, either literally or under the doctrine of equivalents.

56. On information and belief, Prinston had knowledge of the ’998 patent and, by its promotional activities and package inserts for the Prinston 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 ’998 patent, either literally or under the doctrine of equivalents.

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

58. On information and belief, Prinston does not deny that the Prinston ANDA Products will infringe the claims of the ’998 patent and in the Prinston Paragraph IV Certification, Prinston did not deny that the Prinston ANDA Products will infringe the claims of the ’998 patent.

59. Plaintiffs will be substantially and irreparably harmed if Prinston is not enjoined from infringing the ’998 patent.

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

PRAYER FOR RELIEF

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

a. A Judgment be entered that Prinston has infringed at least one claim of the ’957 and/or ’998 patents by submitting the Prinston;

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 Prinston, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them 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 ’957 and/or ’998 patents, and (ii) seeking, obtaining or maintaining approval of ANDA until the expiration of the ’957 and/or ’998 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 Prinston's ANDA 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 '957 and/or '998 patents, including any extensions;

e. That Boehringer be awarded monetary relief if Prinston commercially uses, offers to sell, or sells its proposed generic version of GLYXAMBI® or any other product that infringes or induces or contributes to the infringement of the '957 and/or '998 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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