IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PF PRISM C.V., and C.P. PHARMACEUTICALS INTERNATIONAL C.V.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
PRINSTON PHARMACEUTICAL INC., ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., HUAHAI US INC., and SOLCO HEALTHCARE US, LLC,	)	
Defendants.	)	

COMPLAINT

Pfizer Inc., PF PRISM C.V., and C.P. Pharmaceuticals International C.V. (collectively "Plaintiffs" or "Pfizer"), for their Complaint against Defendants Prinston Pharmaceutical Inc., Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai US Inc., and Solco Healthcare US, LLC (collectively "Prinston"), allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Prinston for infringement of United States Patent No. 6,965,027 (the "'027 patent") and United States Patent No. 7,301,023 (the "'023 patent").

2. This action arises out of Prinston Pharmaceutical Inc.'s filing of Abbreviated New Drug Application ("ANDA") No. 209923 seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's Xeljanz® prior to the expiration of the '027 and '023 patents.

THE PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017.

4. Plaintiff PF PRISM C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and registered at the Trade Register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456. Pfizer Inc. is the ultimate parent company of PF PRISM C.V.

5. Plaintiff C.P. Pharmaceuticals International C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the ultimate parent company of C.P. Pharmaceuticals International C.V.

6. On information and belief, defendant Prinston Pharmaceutical Inc. is a company organized and existing under the laws of Delaware, having its principal place of business at 2002 Eastpark Blvd., Cranbury, NJ 08512.

7. On information and belief, defendant Zhejiang Huahai Pharmaceutical Co., Ltd., is a corporation organized and existing under the laws of the People's Republic of China, with a place of business at Xunqiao, Linhai, Zhejiang 317024, China. On information and belief, Prinston Pharmaceutical Inc. is a wholly-owned subsidiary of Zhejiang Huahai Pharmaceutical Co., Ltd. On information and belief, Prinston Pharmaceutical Inc. is the U.S. agent for Zhejiang Huahai Pharmaceutical Co., Ltd.

8. On information and belief, Defendant Huahai US Inc. is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 2001 Eastpark

Blvd., Cranbury, New Jersey 08512. On information and belief, Huahai US Inc. is a wholly-owned subsidiary of Zhejiang Huahai Pharmaceutical Co., Ltd.

9. On information and belief, defendant Solco Healthcare US, LLC is a company organized and existing under the laws of Delaware, having its principal place of business at 2002 Eastpark Blvd., Cranbury, NJ 08512. On information and belief, Solco Healthcare US, LLC is a wholly-owned subsidiary of Prinston Pharmaceutical Inc.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

12. This Court has personal jurisdiction over Prinston.

13. This Court has personal jurisdiction over Prinston by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including in Delaware. In particular, this suit arises out of Prinston Pharmaceutical Inc.'s filing of ANDA No. 209923 seeking FDA approval to sell 5 mg tofacitinib tablets ("Prinston Generic Tablets") prior to the expiration of the '027 and '023 patents, throughout the United States, including in Delaware.

14. This Court has personal jurisdiction over Prinston Pharmaceutical Inc. and Huahai US Inc. because they are Delaware entities.

15. On information and belief, Prinston Pharmaceutical Inc., Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai US Inc., and Solco Healthcare US, LLC are agents of each other and/or work in concert with each other on the development, obtaining of regulatory

approval, marketing, sale, and/or distribution of generic drugs, including Prinston Generic Tablets, throughout the United States, including in or into Delaware. On information and belief, Zhejiang Huahai Pharmaceutical Co., Ltd., directly or through its subsidiaries Prinston Pharmaceutical Inc., Huahai US Inc., and Solco Healthcare US, LLC, manufactures, markets, imports, and sells generic drugs for distribution in Delaware and throughout the United States.

16. On information and belief, if ANDA No. 209923 is approved, Prinston Generic Tablets will, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and/or used by patients in Delaware.

17. Prinston's infringing activities with respect to its filing of ANDA No. 209923 and its intent to commercialize and sell Prinston Generic Tablets has led and/or will lead to foreseeable harm and injury to Plaintiffs, including Pfizer Inc., which is incorporated in Delaware.

18. On information and belief, Prinston maintains substantial, systematic, and continuous and systemic contacts throughout the United States, including with Delaware. Prinston's website states that it "meets market needs through innovation" by "rapidly bringing cost-effective quality products to the US market." (http://www.prinstonpharm.com/about_us.html (last accessed Feb. 28, 2017)). Prinston's website indicates that it distributes fourteen generic products in the United States. (*See* http://www.prinstonpharm.com/Products_List.html (last accessed Feb. 28, 2017)).

19. On information and belief, defendant Huahai US Inc. "ha[s] filed 50 DMFs with the US FDA; 12 COS and 36 EDMFs filed and/or approved." (http://www.huahaius.com/about%20us.html (last accessed Feb. 28, 2017)).

20. Prinston has previously availed itself of the United States District Court for the District of Delaware by consenting to the court's jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Astellas Pharma Inc. et al. v. Prinston Pharm. Inc.*, No. 1:16-cv-00943-SLR (D. Del.) (D.I. 16); *AstraZeneca LP et al. v. Prinston Pharm. Inc.*, No. 1:15-cv-01057-RGA (D. Del.) (D.I. 12); *Bayer Intell. Prop. GMBH et al. v. Aurobindo Pharma Ltd. et al.*, No. 1:15-cv-00902-RGA (D. Del.) (D.I. 30); *Teijin Ltd. et al. v. Prinston Pharm. Inc.*, No. 1:14-cv-00854-SLR (D. Del.) (D.I. 8).

21. In the alternative, this Court has jurisdiction over Zhejiang Huahai Pharmaceutical Co., Ltd. under Federal Rule of Civil Procedure 4(k)(2). Zhejiang Huahai Pharmaceutical Co., Ltd. has contacts with the United States by, *inter alia*, having caused the filing of Prinston Pharmaceutical Inc.'s ANDA with the FDA.

BACKGROUND

Xeljanz®

22. Tofacitinib citrate is an inhibitor of Janus kinases ("JAKs") and is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.

23. The active ingredient in Xeljanz® is tofacitinib citrate. Xeljanz® contains tofacitinib citrate in an amount equivalent to 5 mg of tofacitinib base in a tablet formulated for twice-daily administration.

24. The FDA-approved Prescribing Information for Xeljanz® states that tofacitinib citrate has the following chemical name: (3R,4R)-4-methyl-3-(methyl-7H-pyrrolo [2,3-d] pyrimidin-4-ylamino)-ß-oxo-1-piperidinepropanenitrile, 2-hydroxy-1,2,3-propanetricarboxylate (1:1).

Orange Book Listing for Xeljanz®

25. PF PRISM C.V. holds approved New Drug Application ("NDA") No. 203214 for EQ 5 mg base tofacitinib citrate tablets, which Pfizer sells under the registered name Xeljanz®.

26. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the '027 and '023 patents are listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for the Xeljanz® NDA.

27. The Orange Book lists the expiration date for the '027 patent as March 25, 2023 and the '023 patent as May 23, 2022.

28. The Orange Book also lists four additional patents for Xeljanz® that are not at issue: U.S. Patent Nos. 6,956,041 (expiring December 8, 2020); 7,091,208 (expiring December 8, 2020); 7,265,221 (expiring December 8, 2020); RE41,783 (expiring December 8, 2020). On December 14, 2016, the United States Patent and Trademark Office ("USPTO") issued a Notice of Final Determination extending the expiration date of the RE'783 patent to December 8, 2025.

The '027 Patent

29. On November 15, 2005, the USPTO issued the '027 patent, titled "Crystalline 3-{4-methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-amino]-piperidin-1-yl}-3-oxo-propionitrile citrate." The '027 patent is duly and legally assigned to Pfizer Inc. A copy of the '027 patent is attached hereto as Exhibit A.

30. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the '027 patent.

The ’023 Patent

31. On November 27, 2007, the USPTO issued the ’023 patent, titled “Chiral Salt Resolution.” The ’023 patent is duly and legally assigned to Pfizer Inc. A copy of the ’023 patent is attached hereto as Exhibit B.

32. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the ’023 patent.

Prinston’s ANDA

33. By letter dated January 16, 2017 (the “Prinston Notice Letter”) and received by Pfizer on January 17, 2017, Prinston notified Pfizer that it had filed ANDA No. 209923 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act (“FDCA”) to market and sell Prinston Generic Tablets prior to the expiration of the ’027 and ’023 patents.

34. The Prinston Notice Letter asserts that ANDA No. 209923 contains a “Paragraph IV” certification under 21 U.S.C. §§ 355(j)(1) and (j)(2)(A) alleging that each of the ’027 and ’023 Patents “are invalid or unenforceable” and “will not be infringed by the commercial manufacture, use, importation, offer for sale or sale of” Prinston Generic Tablets.

35. The Prinston Notice Letter indicates that Prinston Generic Tablets will contain tofacitinib citrate as the active ingredient.

36. The Prinston Notice Letter states that ANDA No. 209923 seeks “to obtain approval to engage in the commercial manufacture, use or sale of” Prinston Generic Tablets prior to the expiration of the ’027 and ’023 patents.

37. Attached to the Prinston Notice Letter was Prinston’s Detailed Statement (“Prinston’s Detailed Statement”) asserting the purported factual and legal bases for Prinston’s contention that the ’027 and ’023 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Prinston Generic Tablets.

38. Prinston's Detailed Statement alleges that all claims of the '027 and '023 patents are invalid. Other than with respect to claim 5 of the '027 patent, Prinston's Detailed Statement does not contain a noninfringement argument with respect to any claim of the '027 and '023 patents, other than that all claims are invalid.

39. On information and belief, Zhejiang Huahai Pharmaceutical Co., Ltd. and Prinston Pharmaceutical Inc. collaborated and acted in concert in the decision to prepare and file and in the preparation and filing of ANDA No. 209923.

40. On information and belief, upon approval of ANDA No. 209923, Prinston will distribute Prinston Generic Tablets throughout the United States.

COUNT I
(Infringement of the '027 Patent by Prinston Generic Tablets)

41. The allegations of paragraphs 1-40 above are repeated and re-alleged as if set forth fully herein.

42. Pursuant to 35 U.S.C. § 271(e)(2)(A), Prinston Pharmaceutical Inc.'s filing of ANDA No. 209923 seeking approval to market Prinston Generic Tablets is an act of infringement of one or more claims of the '027 patent entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 209923 be a date which is not earlier than the expiration date of the '027 patent.

43. Prinston had knowledge of the '027 patent when it submitted ANDA No. 209923 to the FDA.

44. On information and belief, upon FDA approval, Prinston intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Prinston Generic Tablets and will thereby infringe at least claim 1 of the '027 patent.

45. The foregoing actions by Prinston constitute and/or would constitute infringement of at least claim 1 of the ’027 patent.

46. Pfizer will be substantially and irreparably harmed if Prinston is not enjoined from infringing the ’027 patent. Pfizer has no adequate remedy at law.

COUNT II
(Infringement of the ’023 Patent by Prinston Generic Tablets)

47. The allegations of paragraphs 1-46 above are repeated and re-alleged as if set forth fully herein.

48. Pursuant to 35 U.S.C. § 271(e)(2)(A), Prinston Pharmaceutical Inc.’s filing of ANDA No. 209923 seeking approval to market Prinston Generic Tablets is an act of infringement of claim 1 of the ’023 patent entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 209923 be a date which is not earlier than the expiration date of the ’023 patent.

49. Prinston had knowledge of the ’023 patent when it submitted ANDA No. 209923 to the FDA.

50. On information and belief, upon FDA approval, Prinston intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Prinston Generic Tablets and will thereby infringe claim 1 of the ’023 patent.

51. The foregoing actions by Prinston constitute and/or would constitute infringement of claim 1 of the ’023 patent.

52. Pfizer will be substantially and irreparably harmed if Prinston is not enjoined from infringing the ’023 patent. Pfizer has no adequate remedy at law.

COUNT III
(Zhejiang Huahai Pharmaceutical Co., Ltd.'s Inducing of Infringement by Prinston Pharmaceutical Inc.)

53. The allegations of paragraphs 1-52 above are repeated and re-alleged as if set forth fully herein.

54. On information and belief, Zhejiang Huahai Pharmaceutical Co., Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission by Prinston Pharmaceutical Inc. of ANDA No. 209923 to the FDA, knowing of the '027 and '023 patents.

55. The filing of ANDA No. 209923 by Prinston Pharmaceutical Inc. constituted direct infringement under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Zhejiang Huahai Pharmaceutical Co., Ltd. induced the infringement of the '027 and '023 patents by actively and knowingly causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 209923 to the FDA knowing that the submission of ANDA No. 209923 would constitute direct infringement of the '027 and '023 patents.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Prinston Pharmaceutical Inc.'s submission of ANDA No. 209923 was an act of infringement and that Prinston's making, using, offering to sell, selling or importing Prinston Generic Tablets prior to the expiration of the '027 and '023 patents will infringe each of those patents;

B. A judgment that defendant Zhejiang Huahai Pharmaceutical Co., Ltd.'s knowing and purposeful activities causing to be submitted, and/or assisting with, participating in,

contributing to, and/or directing the filing of ANDA No. 209923, knowing that its submission would constitute direct infringement, induced infringement of the '027 and '023 patents;

C. A judgment that the effective date of any FDA approval for Prinston to make, use offer for sale, sell, market, distribute, or import the Prinston Generic Tablets be no earlier than the dates on which the '027 and '023 patents expire, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

D. A permanent injunction enjoining Prinston, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making using, selling, offering for sale, marketing, distributing, or importing Prinston Generic Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the'027 and '023 patents, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

E. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Pfizer to an award of its reasonable attorneys' fees for bringing and prosecuting this action;

F. An award of Pfizer's costs and expenses in this action; and

G. Such further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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