IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PF PRISM C.V., C.P. PHARMACEUTICALS INTERNATIONAL C.V., PFIZER PHARMACEUTICALS LLC, and PFIZER PFE IRELAND PHARMACEUTICALS HOLDING 1 COÖPERATIEF U.A.,	)	
	)	C.A. No. _____
Plaintiffs,	)	
v.	)	
PRINSTON PHARMACEUTICAL INC.,	)	
Defendant.	)	

COMPLAINT

Pfizer Inc., PF PRISM C.V., C.P. Pharmaceuticals International C.V., Pfizer Pharmaceuticals LLC, and Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A. (collectively "Plaintiffs" or "Pfizer"), for their Complaint against Defendant Prinston Pharmaceutical Inc. ("Prinston") , allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Prinston for infringement of United States Reissue Patent No. RE41,783 (the "'783 patent").

2. This action arises out of Prinston'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 '783 patent.

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. Pfizer Pharmaceuticals LLC is a limited liability company organized and existing under the laws of Delaware and having its principal place of business at Bo. Carmelitas, Road 689, Km. 1.9, Vega Baja, Puerto Rico. Pfizer Inc. is the ultimate parent company of Pfizer Pharmaceuticals LLC.

7. Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A. is a cooperative with no liability for its members (*coöperatie met uitsluiting van aansprakelijkheid voor haar leden*) under Dutch law, having its registered seat in Rotterdam, the Netherlands, having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands, and registered with the Dutch Trade Register under number 60558814. Pfizer Inc. is the ultimate parent company of Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A.

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

JURISDICTION AND VENUE

9. 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.

10. Venue is proper in this judicial district pursuant to the provision of 28 U.S.C. § 1400(b).

11. Prinston has not contested venue in a pending action brought against it in this Court by plaintiffs Pfizer Inc., PF PRISM C.V., and C.P. Pharmaceuticals International C.V., Civil Action No. 1:17-cv-00213-LPS, arising out of Prinston's filing of the same ANDA that gives rise to this action.

12. This Court has personal jurisdiction over Prinston by virtue of the fact that Prinston is incorporated in Delaware. In addition, Prinston 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's filing of ANDA No. 209923 seeking FDA approval to sell 5 mg tofacitinib tablets ("Prinston Generic Tablets") prior to the expiration of the '783 patent, throughout the United States, including in Delaware.

13. 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.

14. 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.

15. 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).

16. Prinston has not contested personal jurisdiction in a pending action brought against it in this Court by plaintiffs Pfizer Inc., PF PRISM C.V., and C.P. Pharmaceuticals International C.V., Civil Action No. 1:17-cv-00213-LPS, arising out of Prinston's filing of the same ANDA that gives rise to this action.

BACKGROUND

Xeljanz®

17. 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.

18. 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.

19. 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®

20. 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®.

21. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the '783 patent is listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for the Xeljanz® NDA.

22. The Orange Book lists the expiration date for the '783 patent as December 8, 2025.

23. The Orange Book also lists five additional patents for Xeljanz® that are not a subject of this Complaint : U.S. Patent Nos. 6,956,041 (expiring December 8, 2020); 6,965,027 (expiring March 25, 2023); 7,091,208 (expiring December 8, 2020); 7,265,221 (expiring December 8, 2020); and 7,301,023 (expiring May 23, 2022). Prinston's prior paragraph IV notice, dated January 16, 2017, addressed U.S. Patent Nos. 6,965,027 and 7,301,023, and those patents are at issue in Civil Action No. 1:17-cv-00213-LPS.

The '783 Patent

24. On September 28, 2010, the USPTO issued the '783 patent, titled "Pyrrolo[2,3d]pyrimidine Compounds." The '783 patent is a reissue of U.S. Patent No. 6,627,754, which issued on September 30, 2003. The '783 patent is duly and legally assigned to Pfizer Inc. A copy of the '783 patent is attached hereto as Exhibit A.

Prinston's ANDA

25. By letter dated February 22, 2018 (the "Prinston Notice Letter") and received by Pfizer on February 26, 2018, Prinston notified Pfizer that it had filed ANDA No. 209923 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Prinston Generic Tablets prior to the expiration of the '783 patent.

26. 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 the claims of the '783 patent "are invalid or unenforceable" and "will not be infringed by the commercial manufacture, use, importation, offer for sale or sale of" Prinston Generic Tablets.

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

28. 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 '783 patent.

29. 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 '783 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Prinston Generic Tablets.

30. Prinston's Detailed Statement alleges that all claims of the '783 patent is invalid.

31. Prinston's Detailed Statement does not contain a noninfringement argument with respect to claims 1, 2, and 4 of the '783 patent, other than that the claims are invalid.

32. 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 '783 Patent by Prinston Generic Tablets)

33. The allegations of paragraphs 1-32 above are repeated and re-alleged as if set forth fully herein.

34. 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 at least claim 1 of the ’783 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 ’783 patent.

35. Prinston had knowledge of the ’783 patent when it submitted ANDA No. 209923 to the FDA.

36. 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 ’783 patent.

37. The foregoing actions by Prinston constitute and/or would constitute infringement of at least claim 1 of the ’783 patent.

38. Pfizer will be substantially and irreparably harmed if Prinston is not enjoined from infringing the ’783 patent. Pfizer has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Prinston’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 ’783 will infringe the ’783 patent;

B. 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 ’783 patent expires, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

C. 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'783 patent, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

D. 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;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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