IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., C.P. PHARMACEUTICALS INTERNATIONAL C.V., PF PRISM C.V., PBG PUERTO RICO LLC and PF PRISM IMB B.V.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SUN PHARMACEUTICAL INDUSTRIES LTD. and SUN PHARMACEUTICAL INDUSTRIES, INC.,	)	
Defendants.	)	

COMPLAINT

Pfizer Inc., C.P. Pharmaceuticals International C.V., PF PRISM C.V., PBG Puerto Rico LLC, and PF PRISM IMB B.V. (collectively "Plaintiffs" or "Pfizer"), for their Complaint against Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc. ("Defendants" or "Sun"), allege as follows:

NATURE OF THE ACTION

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

2. This action arises out of Sun's filing of Abbreviated New Drug Application ("ANDA") No. 209790, seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's Xeljanz® XR, 11 mg and 22 mg dosage strengths, (tofacitinib citrate extended-release tablets) prior to the expiration of the '783 patent. Sun's proposed extended-release tofacitinib citrate products are referred to hereinafter as respectively,

"Sun Generic 11 mg XR Tablets" and "Sun Generic 22 mg XR Tablets," and collectively, "Sun Generic XR Tablets."

THE PARTIES

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

4. Plaintiff C.P. Pharmaceuticals International C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands. Pfizer Inc. is the ultimate parent company of C.P. Pharmaceuticals International C.V.

5. 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, having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, 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.

6. Plaintiff PBG Puerto Rico LLC is a limited liability company organized and existing under the laws of Puerto Rico and having its business address at Professional Offices Park V, 996 San Roberto Street, 4th Floor, San Juan, Puerto Rico 00926. Pfizer Inc. is the ultimate parent company of PBG Puerto Rico LLC.

7. Plaintiff PF PRISM IMB B.V. is a private limited liability company (*besloten vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD,

Capelle aan den IJssel, the Netherlands. Pfizer Inc. is the ultimate parent company of PF PRISM IMB B.V.

8. On information and belief, defendant Sun Pharmaceutical Industries Ltd. is a company organized and existing under the laws of India, having its principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, India.

9. On information and belief, defendant Sun Pharmaceutical Industries, Inc. is a company organized and existing under the laws of the State of Delaware, having its principal place of business at 2 Independence Way, Princeton, New Jersey 08540. On information and belief, Sun Pharmaceutical Industries Ltd. is the ultimate parent company of Sun Pharmaceutical Industries, Inc. On information and belief, Sun Pharmaceutical Industries, Inc. is the U.S. agent for Sun Pharmaceutical Industries Ltd.

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. This Court has personal jurisdiction over Defendants by virtue of the fact, *inter alia*, that Sun Pharmaceutical Industries, Inc. is a Delaware corporation, and Sun Pharmaceutical Industries Ltd. is the ultimate parent company of Sun Pharmaceutical Industries, Inc.

12. On information and belief, Sun Pharmaceutical Industries Ltd., directly or through its subsidiary Sun Pharmaceutical Industries, Inc., manufactures, markets, imports and sells generic drugs for distribution in Delaware and throughout the United States.

13. On information and belief, Defendants are agents of each other and/or work in concert with each other on the development, obtaining of regulatory approval, manufacture,

marketing, sale, and/or distribution of generic drugs, including the proposed Sun Generic XR Tablets.

14. On information and belief, if ANDA No. 209790 is approved, Sun Generic XR Tablets will, among other things, be marketed and distributed by Sun in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and/or used by patients in Delaware.

15. Sun's infringing activities with respect to its filing of ANDA No. 209790 and its intent to commercialize and sell Sun Generic XR Tablets prior to the expiration of the '783 patent have led and/or will lead to foreseeable harm and injury to Plaintiffs, including Pfizer Inc., which is incorporated in Delaware.

16. In the alternative, this Court has personal jurisdiction over Sun Pharmaceutical Industries Ltd. under Federal Rule of Civil Procedure 4(k)(2). Sun Pharmaceutical Industries Ltd. has contacts with the United States by virtue, *inter alia*, of its filing ANDA No. 209790 with the FDA.

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

BACKGROUND

Xeljanz XR

18. The active ingredient in Pfizer's Xeljanz XR product is tofacitinib citrate. Xeljanz XR contains tofacitinib citrate in an amount equivalent to either 11 mg or 22 mg of tofacitinib base in extended-release tablets formulated for once-daily administration.

19. The FDA-approved Prescribing Information for Xeljanz XR 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).

20. Tofacitinib citrate is an inhibitor of Janus kinases ("JAKs") and is indicated, *inter alia*, for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate, for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs ("DMARDs"), and for the treatment of adult patients with moderately to severely active ulcerative colitis who have an inadequate response or who are intolerant to TNF blockers.

Orange Book Listing for Xeljanz XR

21. Pfizer Inc. holds approved New Drug Application ("NDA") No. 208246 for EQ 11 mg and 22 mg base tofacitinib citrate extended-release tablets, which it sells under the registered name Xeljanz XR. The Xeljanz XR tablets are approved for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis.

22. 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 XR NDA.

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

24. The Orange Book lists four additional patents for Xeljanz XR that are not at issue: U.S. Patent No. 6,965,027 (expiring March 25, 2023), U.S. Patent No. 9,937,181 (expiring March 14, 2034), U.S. Patent No. 11,253,523 (expiring March 14, 2034), and U.S. Patent No. 10,639,309 (expiring March 14, 2034).

The '783 Patent

25. On September 28, 2010, the United States Patent and Trademark Office ("USPTO") issued the '783 patent, titled "Pyrrolo[2,3- d]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.

26. On December 14, 2016, the USPTO issued a Notice of Final Determination extending the expiration date of the '783 patent to December 8, 2025.

27. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the '783 patent.

28. C.P. Pharmaceuticals International C.V. conveyed rights under the '783 patent to Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

29. Pfizer Pharmaceuticals LLC has conveyed its rights to the '783 patent to PBG Puerto Rico LLC.

30. Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. has conveyed its rights to the '783 patent to PF PRISM IMB B.V.

Sun's ANDA

31. By letter dated May 31, 2022 (the "Sun 11 mg Notice Letter"), Sun notified Pfizer that it had submitted an amendment to ANDA No. 209790 to the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Sun Generic 11 mg XR Tablets—generic copies of Xeljanz XR (tofacitinib citrate EQ 11 mg base extended-release tablets)—prior to the expiration of the '783 patent.

32. The Sun 11 mg Notice Letter describes the Sun Generic 11 mg XR Tablets as "[t]ofacitinib extended-release tablets, for oral use," containing 11 mg of tofacitinib citrate.

33. The Sun 11 mg Notice Letter states that Sun has filed ANDA No. 209790 "seeking to engage in the commercial manufacture, use, importation, offer for sale or sale" of Sun Generic 11 mg XR Tablets prior to the expiration of the '783 patent.

34. The Sun 11 mg Notice Letter asserts that ANDA No. 209790 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j) alleging that the '783 patent is "invalid, unenforceable, and/or will not be infringed by" Sun Generic 11 mg XR Tablets.

35. Attached to the Sun 11 mg Notice Letter was Sun's Detailed Statement ("Sun's 11 mg Detailed Statement") asserting the purported factual and legal bases for Sun's contention that the claims of the '783 patent are invalid and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Sun Generic 11 mg XR Tablets.

36. Sun's 11 mg Detailed Statement alleges that all claims of the '783 patent are invalid. Sun's 11 mg Detailed Statement alleges that Sun Generic 11 mg XR Tablets will not infringe, either directly or under the doctrine of equivalents, claims 1-3 of the '783 patent. Sun's 11 mg Detailed Statement does not contain a noninfringement argument with respect to claim 4 of the '783 patent.

37. By letter dated October 3, 2022 (the "Sun 22 mg Notice Letter"), Sun notified Pfizer that it had submitted an amendment to ANDA No. 209790 to the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Sun Generic 22 mg XR Tablets—generic copies of Xeljanz XR (tofacitinib citrate EQ 22 mg base extended-release tablets)—prior to the expiration of the '783 patent.

38. The Sun 22 mg Notice Letter describes the Sun Generic 22 mg XR Tablets as "[t]ofacitinib extended-release tablets, for oral use," containing 22 mg of tofacitinib citrate.

39. The Sun 22 mg Notice Letter states that Sun has filed ANDA No. 209790 "seeking to engage in the commercial manufacture, use, importation, offer for sale or sale" of Sun Generic 22 mg XR Tablets prior to the expiration of the '783 patent.

40. The Sun 22 mg Notice Letter asserts that ANDA No. 209790 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j) alleging that the '783 patent is "invalid, unenforceable, and/or will not be infringed by" Sun Generic 22 mg XR Tablets.

41. Attached to the Sun 22 mg Notice Letter was Sun's Detailed Statement ("Sun's 22 mg Detailed Statement") asserting the purported factual and legal bases for Sun's contention that the claims of the '783 patent are invalid and/or will not be infringed, either literally or under the doctrine of equivalents, by the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Sun Generic 22 mg XR Tablets.

42. Sun's 22 mg Detailed Statement alleges that all claims of the '783 patent are invalid. Sun's 22 mg Detailed Statement alleges that Sun Generic 22 mg XR Tablets will not infringe, either directly or under the doctrine of equivalents, claims 1-3 of the '783 patent. Sun's 22 mg Detailed Statement does not contain a noninfringement argument with respect to claim 4 of the '783 patent.

43. On information and belief, Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc. collaborated and acted in concert in the decision to prepare and file and in the preparation and filing of ANDA No. 209790.

44. On information and belief, upon approval of ANDA No. 209790, Sun will sell and distribute Sun Generic XR Tablets in the United States.

CLAIM FOR RELIEF

(Infringement of the '783 Patent by Sun Generic XR Tablets)

45. The allegations of paragraphs 1-44 above are repeated and re-alleged as if set forth fully herein.

46. Pursuant to 35 U.S.C. § 271(e)(2)(A), Sun's filing of ANDA No. 209790 seeking approval to market and sell Sun Generic XR Tablets before the expiration of the '783 patent was

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. 209790 be a date which is not earlier than the expiration date of the '783 patent.

47. Sun had knowledge of the '783 patent when it submitted ANDA No. 209790 to the FDA.

48. On information and belief, upon FDA approval of ANDA No 209790, Sun intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Sun Generic XR Tablets in the United States and will thereby directly infringe at least claim 1 of the '783 patent under 35 U.S.C. § 271(a).

49. The foregoing actions by Sun constitute and/or would constitute infringement of at least claim 1 of the '783 patent.

50. An actual controversy exists relating to Sun's threatened direct infringement of the '783 patent.

51. Pfizer will be substantially and irreparably harmed if Sun 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 Sun's submission of ANDA No. 209790 was an act of infringement and that Sun's making, using, offering to sell, selling, or importing Sun Generic XR Tablets in the United States prior to the expiration of the '783 patent will directly infringe that patent;

B. A judgment that the effective date of any FDA approval for Sun to make, use, offer for sale, sell, market, distribute, or import Sun Generic XR Tablets into the United

States be no earlier than the date on which the '783 patent expires, or the later expiration of any exclusivity to which Pfizer is or becomes entitled;

C. A permanent injunction enjoining Sun, 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 Sun Generic XR Tablets into the United States, and from inducing or contributing to any of the foregoing, prior to the expiration of the '783 patent, or the later expiration of any 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/ Megan E. Dellinger

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