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 LIMITED 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 Limited 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 RE'783 patent").

2. This action arises out of Sun's filing of Abbreviated New Drug Application ("ANDA") No. 214351, seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's 5 mg and 10 mg Xeljanz® (tofacitinib) tablets prior to the expiration of the RE'783 patent. Sun's proposed tofacitinib products are referred to hereinafter as "Sun Generic Tofacitinib 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 66 Hudson Boulevard, New York, NY 10001.

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 Limited 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 Limited 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 Limited.

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 Limited is the ultimate parent company of Sun Pharmaceutical Industries, Inc.

12. On information and belief, Sun Pharmaceutical Industries Limited, 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 Tofacitinib Tablets.

14. On information and belief, if ANDA No. 214351 is approved, Sun Generic Tofacitinib 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. 214351 and its intent to commercialize and sell Sun Generic Tofacitinib Tablets prior to the expiration of the RE'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 Limited under Federal Rule of Civil Procedure 4(k)(2). Sun Pharmaceutical Industries Limited has contacts with the United States by virtue, *inter alia*, of its filing ANDA No. 214351 with the FDA.

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

BACKGROUND

Xeljanz

18. The active ingredient in Pfizer's Xeljanz product is tofacitinib citrate. Xeljanz contains tofacitinib citrate in an amount equivalent to either 5 mg or 10 mg of tofacitinib base in tablets 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).

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 one or more Tumor Necrosis Factor ("TNF") blockers, for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to TNF blockers, 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

21. PF PRISM C.V. holds approved New Drug Application ("NDA") No. 203214 for EQ 5 mg and EQ 10 mg base tofacitinib citrate tablets, which Pfizer sells under the registered name Xeljanz. The Xeljanz 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 RE'783 patent is listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for the Xeljanz NDA.

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

24. The Orange Book lists one additional patent for Xeljanz, U.S. Patent No. 6,965,027, that has since expired and is not at issue.

The RE'783 Patent

25. On September 28, 2010, the United States Patent and Trademark Office ("USPTO") issued the RE'783 patent, titled "Pyrrolo[2,3- d]pyrimidine Compounds." The RE'783 patent is a reissue of U.S. Patent No. 6,627,754, which issued on September 30, 2003. The RE'783 patent is duly and legally assigned to Pfizer Inc. A copy of the RE'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 RE'783 patent to December 8, 2025.

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

28. C.P. Pharmaceuticals International C.V. conveyed rights under the RE'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 RE'783 patent to PBG Puerto Rico LLC.

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

Sun's ANDA

31. By letter dated May 18, 2023 (the "Sun Notice Letter") and received by Pfizer on/around May 22, 2023, Sun notified Pfizer that it had filed ANDA No. 214351 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Sun Generic Tofacitinib Tablets—generic copies of Xeljanz (tofacitinib citrate EQ 5 mg and EQ 10 mg base tablets)—prior to the expiration of the RE'783 patent.

32. The Sun Notice Letter describes the Sun Generic Tofacitinib Tablets as "[t]ofacitinib immediate-release tablets, for oral use," containing the equivalent of 5 mg or 10 mg of tofacitinib in the form of tofacitinib citrate.

33. The Sun Notice Letter states that Sun has filed ANDA No. 214351 "seeking to engage in the commercial manufacture, use, importation, offer for sale or sale" of Sun Generic Tofacitinib Tablets prior to the expiration of the RE'783 patent.

34. The Sun Notice Letter asserts that ANDA No. 214351 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j) alleging that the RE'783 patent is "invalid, unenforceable, and/or will not be infringed by" Sun Generic Tofacitinib Tablets.

35. Attached to the Sun Notice Letter was Sun's Detailed Statement asserting the purported factual and legal bases for Sun's contention that the claims of the RE'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 Tofacitinib Tablets.

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

37. On information and belief, Sun Pharmaceutical Industries Limited 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. 214351.

38. On information and belief, upon approval of ANDA No. 214351, Sun will sell and distribute Sun Generic Tofacitinib Tablets in the United States.

COUNT I
(Infringement of the RE'783 Patent by Sun Generic Tofacitinib Tablets)

39. The allegations of paragraphs 1-38 above are repeated and re-alleged as if set forth fully herein.

40. Pursuant to 35 U.S.C. § 271(e)(2)(A), Sun's filing of ANDA No. 214351 seeking approval to market and sell Sun Generic Tofacitinib Tablets before the expiration of the RE'783 patent was an act of infringement of at least claim 4 of the RE'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. 214351 be a date which is not earlier than the expiration date of the RE'783 patent.

41. Sun had knowledge of the RE'783 patent when it submitted ANDA No. 214351 to the FDA.

42. On information and belief, upon FDA approval of ANDA No 214351, Sun intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Sun Generic Tofacitinib Tablets in the United States and will thereby directly infringe at least claim 4 of the RE'783 patent under 35 U.S.C. § 271(a).

43. The foregoing actions by Sun constitute and/or would constitute infringement of at least claim 4 of the RE'783 patent.

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

45. Pfizer will be substantially and irreparably harmed if Sun is not enjoined from infringing the RE'783 patent. Pfizer has no adequate remedy at law.

COUNT II
(Sun Pharmaceutical Industries, Inc.'s Inducing of Infringement by Sun Pharmaceutical Industries Limited)

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

47. On information and belief, Sun Pharmaceutical Industries, Inc. actively and knowingly caused to be submitted and/or assisted with, participated in, contributed to, and/or directed the submission by Sun Pharmaceutical Industries Limited of ANDA No. 214351 to the FDA, knowing of the RE'783 patent.

48. The filing of ANDA No. 214351 by Sun Pharmaceutical Industries Limited constituted direct infringement under 35 U.S.C. § 271(e). On information and belief, under

35 U.S.C. §§ 271(b) and 271(e)(2)(A), Sun Pharmaceutical Industries, Inc. induced the infringement of the RE'783 patent by actively and knowingly causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 214351 to the FDA knowing that the submission of ANDA No. 214351 would constitute direct infringement of the RE'783 patent.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Sun Pharmaceutical Industries Limited's submission of ANDA No. 214351 was an act of infringement and that Sun's making, using, offering to sell, selling, or importing Sun Generic Tofacitinib Tablets in the United States prior to the expiration of the RE'783 patent will directly infringe that patent;

B. A judgment that Sun Pharmaceutical Industries, Inc. induced infringement of the RE'783 patent by its knowing and purposeful activities causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 214351, knowing that its submission would constitute direct infringement;

C. 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 Tofacitinib Tablets into the United States be no earlier than the date on which the RE'783 patent expires, or the later expiration of any exclusivity to which Pfizer is or becomes entitled;

D. 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 Tofacitinib Tablets into the United States, and from inducing or

contributing to any of the foregoing, prior to the expiration of the RE'783 patent, or the later expiration of any 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/ Megan E. Dellinger

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