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. SUN PHARMACEUTICAL INDUSTRIES LIMITED and SUN PHARMACEUTICAL INDUSTRIES, INC., Defendants.	)	C.A. No. _____

COMPLAINT

Pfizer Inc., PF PRISM C.V., and C.P. Pharmaceuticals International C.V. (collectively "Plaintiffs" or "Pfizer"), for their Complaint against Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. (collectively "Sun"), allege as follows:

NATURE OF THE ACTION

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

2. This action arises out of Sun Pharmaceutical Industries Limited's filing of ANDA No. 209790 seeking approval by the FDA to sell generic copies of Xeljanz XR® (11 mg tofacitinib extended release) prior to the expiration of the '027 patent.

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

7. On information and belief, defendant Sun Pharmaceutical Industries, Inc. is a company organized and existing under the laws of Michigan, having its principal place of business at 1 Commerce Drive, Cranbury, New Jersey 08512. On information and belief, Sun Pharmaceutical Industries, Inc. is a wholly-owned subsidiary of Sun Pharmaceutical Industries Limited. On information and belief, Sun Pharmaceutical Industries, Inc. is the U.S. agent for Sun Pharmaceutical Industries Limited.

JURISDICTION AND VENUE

8. 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.

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

10. This Court has personal jurisdiction over Sun.

11. This Court has personal jurisdiction over Sun 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 Sun Pharmaceutical Industries Limited's filing of ANDA No. 209790 seeking FDA approval to sell 11 mg tofacitinib extended release tablets ("Sun Generic XR Tablets") prior to the expiration of the '027 patent, throughout the United States, including in Delaware.

12. On information and belief, Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. 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 Sun Generic XR Tablets, throughout the United States, including in or into Delaware. 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, 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.

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

15. On information and belief, Sun maintains substantial, systematic and continuous contacts throughout the United States, including in Delaware. Sun's website states that "[i]n the

US market, which contributes a significant share of our revenues, we are the leader in the generic dermatology segment. We have strong capabilities in developing generic and complex products with a robust pipeline of 149 ANDAs, including high value First-to-File (FTF) opportunities." (http://www.sunpharma.com/business-development (last accessed Feb. 10, 2017)). Upon information and belief, Sun has distribution and customer service teams at multiple locations across the United States.

16. On information and belief, Sun Pharmaceutical Industries, Inc. was previously registered to conduct business in Delaware (File No. 5615437) and had the following registered agent in Delaware: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

17. On information and belief, Sun Pharmaceutical Industries, Inc. holds Delaware distributor/manufacturer CSR license nos. DM-0010549 and DM-0010171. Sun Pharmaceutical Industries, Inc. holds Delaware pharmacy - wholesale license nos. A4-0002148 and A4-0002107.

18. Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. have previously availed themselves of this Court by consenting to this Court's jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Galderma Labs., L.P. et al. v. Sun Pharm. Indus. Ltd. et al.*, No. 1:16-cv-01003-LPS (D. Del.) (D.I. 11) (Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. submitted counterclaims and did not contest personal jurisdiction); *Pfizer Inc. et al. v. Sun Pharma Global Inc. et al*., No. 1:09-cv-00313-GMS (D. Del.) (D.I. 13) (same).

19. In the alternative, this Court has 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, *inter alia*, having filed its ANDA with the FDA.

BACKGROUND

Xeljanz XR®

20. 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.

21. The active ingredient in Xeljanz XR® is tofacitinib citrate. Xeljanz XR® contains tofacitinib citrate in an amount equivalent to 11 mg of tofacitinib base in an extended release tablet formulated for once-daily administration.

22. 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).

Orange Book Listing for Xeljanz XR®

23. Pfizer Inc. holds approved NDA No. 208246 for EQ 11 mg base tofacitinib citrate extended release tablets, which Pfizer sells under the registered name Xeljanz XR®.

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

25. The Orange Book lists the expiration date for the '027 patent as March 25, 2023.

26. The Orange Book also lists five additional patents for Xeljanz XR® 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); 7,301,023 (expiring May 23, 2022); 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.

27. 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.

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

SUN'S ANDA

29. By letter dated January 5, 2017 (the "Sun XR Notice Letter") and received by Pfizer on January 6, 2017, Sun notified Pfizer that it had filed ANDA No. 209790 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act ("FDCA") to market and sell Sun Generic XR Tablets – generic copies of Xeljanz XR® (tofacitinib citrate EQ 11 mg base extended release tablets) – prior to the expiration of the '027 patent.

30. The Sun Notice Letter asserts that ANDA No. 209790 contains a "Paragraph IV" certification under 21 U.S.C. §§ 355(j)(1) and (2)(a) and that the '027 patent is "invalid, unenforceable and/or will not be infringed by" by Sun Generic XR Tablets.

31. The Sun Notice Letter indicates that the Sun Generic XR Tablets will contain tofacitinib citrate as the active ingredient.

32. On information and belief Sun Pharmaceutical Industries Limited holds DMF No. 30617 for tofacitinib citrate.

33. The Sun Notice Letter states that ANDA No. 209790 requests "approval to engage in the commercial manufacture, use or sale of" Sun Generic XR Tablets prior to the expiration of the '027 patent.

34. Attached to the Sun Notice Letter was Sun's Detailed Statement ("Sun's Detailed Statement") purportedly asserting "the factual and legal bases why, in Sun's opinion and to the best of Sun's knowledge, the '027 patent claims are invalid, unenforceable and/or will not be infringed" by the manufacture, use, offer for sale, and/or sale of Sun Generic XR Tablets.

35. Sun's Detailed Statement alleges that all claims of the '027 patent are invalid. Sun's Detailed Statement does not contain a noninfringement argument with respect to claims 1 and 6 the '027 patent, other than that all the claims are invalid.

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

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

37. The allegations of paragraphs 1-36 above are repeated and re-alleged as if set forth fully herein.

38. Pursuant to 35 U.S.C. § 271(e)(2)(A), Sun's filing of ANDA No. 209790 seeking approval to market Sun Generic XR 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. 209790 be a date which is not earlier than the expiration date of the '027 patent.

39. Sun had knowledge of the '027 patent when it submitted ANDA No. 209790 to the FDA.

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

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

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

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

43. The allegations of paragraphs 1-42 above are repeated and re-alleged as if set forth fully herein.

44. On information and belief, Sun Pharmaceutical Industries, Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission by Sun Pharmaceutical Industries Limited of ANDA No. 209790 to the FDA, knowing of the ’027 patent.

45. The filing of ANDA No. 209790 by Sun Pharmaceutical Industries Limited constituted direct infringement under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Sun Pharmaceutical Industries, Inc. induced the infringement of the ’027 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. 209790 to the FDA knowing that the submission of ANDA No. 209790 would constitute direct infringement of the ’027 patent.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Sun Pharmaceutical Industries Limited'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 prior to the expiration of the '027 patent will infringe the '027 patent;

B. A judgment that defendant Sun Pharmaceutical Industries, Inc.'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. 209790, knowing that its submission would constitute direct infringement, induced infringement of the '027 patent;

C. A judgment that the effective date of any FDA approval for Sun to make, use offer for sale, sell, market, distribute, or import the Sun Generic XR Tablets be no earlier than the dates on which the '027 patent expires, or any later expiration of 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 XR Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the'027 patent, 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.

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