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. _____
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

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 Teva Pharmaceuticals USA, Inc. ("Teva"), allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Teva for infringement of United States Patent No. 10,639,309 (the "'309 patent").

2. This action arises out of Teva's filing of an amendment to Abbreviated New Drug Application ("ANDA") No. 209813, seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Xeljanz® XR (tofacitinib extended release tablets, 22 mg) prior to the expiration of the '309 patent. Teva's proposed 22 mg extended-release tofacitinib citrate product is referred to hereinafter as "Teva Generic 22 mg 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 Teva is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, PA 19454.

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 and 1338(a).

10. This Court has personal jurisdiction over Teva by virtue of the fact, *inter alia*, that Teva is a Delaware corporation.

11. In addition, Teva has committed a tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including in the State of Delaware. In particular, this suit arises out of Teva's filing of an amendment to ANDA No. 209813, seeking FDA approval to sell Teva Generic 22 mg XR Tablets prior to the expiration of the '309 patent, throughout the United States, including in the State of Delaware.

12. On information and belief, Teva works on the development, obtaining of regulatory approval, marketing, sale, and/or distribution of generic drugs, including Teva Generic 22 mg XR Tablets, throughout the United States, including in or into Delaware. On information and belief, Teva manufactures, markets, imports, and sells generic drugs for distribution in Delaware and throughout the United States.

13. On information and belief, if ANDA No. 209813 is approved, Teva Generic 22 mg XR Tablets will, among other things, be marketed and distributed by Teva in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and/or used by patients in Delaware.

14. Teva's infringing activities with respect to its filing of the amendment to ANDA No. 209813 and its intent to commercialize and sell Teva Generic 22 mg XR Tablets have led and/or will lead to foreseeable harm and injury to Pfizer, which is incorporated in Delaware.

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

BACKGROUND

Xeljanz XR 22 mg

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

17. 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).

18. 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 22 mg

19. Pfizer holds approved NDA No. 208246 for EQ 22 mg base tofacitinib citrate extended release tablets, which it sells under the registered name Xeljanz XR. The active

ingredient in Xeljanz XR is tofacitinib citrate. Xeljanz XR contains tofacitinib citrate in an amount equivalent to 22 mg of tofacitinib base in an extended release tablet formulated for once-daily administration.

20. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the '309 patent is listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for the Xeljanz XR 22 mg NDA.

21. The Orange Book lists the expiration date for the '309 patent as March 14, 2034.

22. The Orange Book also lists two additional patents for Xeljanz XR 22 mg that are not at issue: U.S. Patent Nos. 6,956,027 (expiring March 25, 2023) and RE41,783 (expiring December 8, 2025).

The '309 Patent

23. On May 5, 2020, the United States Patent and Trademark Office ("USPTO") issued the '309 patent, titled "Tofacitinib Oral Sustained Release Dosage Forms." The '309 patent is duly and legally assigned to Pfizer Inc. A copy of the '309 patent is attached hereto as Exhibit A.

24. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the '309 patent.

25. C.P. Pharmaceuticals International C.V. conveyed rights under the '309 patent to Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

26. Pfizer Pharmaceuticals LLC has conveyed its rights to the '309 patent to PBG Puerto Rico LLC.

27. Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. has conveyed its rights to the '309 patent to PF PRISM IMB B.V.

Teva's ANDA Amendment

28. By letter dated December 30, 2021 (the "Teva Notice Letter"), and received by Pfizer on January 3, 2022, Teva notified Pfizer that it had submitted an amendment to ANDA No. 209813 to the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act ("FDCA") to market and sell Teva Generic XR 22 mg Tablets—generic copies of Xeljanz XR 22 mg (tofacitinib citrate EQ 22 mg base extended release tablets)—prior to the expiration of the '309 patent.

29. The Teva Notice Letter asserts that the amendment to ANDA No. 209813 contains a "Paragraph IV" certification under 21 U.S.C. §§ 355(j)(2)(B)(ii)-(iv), 21 C.F.R. § 314.95 and/or § 314.95(d), and that the '309 patent is "invalid, unenforceable, and/or will not be infringed" by Teva Generic 22 mg XR Tablets.

30. The Teva Notice Letter indicates that Teva Generic 22 mg XR Tablets will contain tofacitinib citrate as the active ingredient.

31. The Teva Notice Letter states that the amendment to ANDA No. 209813 requests "approval to engage in the commercial manufacture, use or sale of" Teva Generic 22 mg XR Tablets prior to the expiration of the '309 patent.

32. Attached to the Teva Notice Letter was Teva's "Detailed Factual and Legal Bases for Teva Pharmaceutical USA's Paragraph IV Certification that the Claims of U.S. Patent No. 10,639,309 Are Invalid, Unenforceable and/or Not Infringed" ("Teva's Detailed Statement"). Teva's Detailed Statement purportedly asserts "the detailed factual and legal bases for the Paragraph IV certification of [Teva] that, in its opinion and to the best of its knowledge the claims of the ['309 patent] are invalid, unenforceable and/or will not be infringed" by the commercial manufacture, use, or sale of Teva Generic 22 mg XR Tablets.

33. Teva's Detailed Statement does not set forth a noninfringement argument with respect to any claim of the '309 patent.

34. On information and belief, upon approval of the amendment to ANDA No. 209813, Teva will distribute Teva Generic 22 mg XR Tablets in the United States.

CLAIM FOR RELIEF
(Infringement of the '309 Patent by Teva Generic 22 mg XR Tablets)

35. The allegations of paragraphs 1-34 above are repeated and re-alleged as if set forth fully herein.

36. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva's submission of the amendment to ANDA No. 209813 to the FDA seeking approval to market Teva Generic 22 mg XR Tablets was an act of infringement of at least claim 1 of the '309 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. 209813 be a date which is not earlier than the expiration date of the '309 patent.

37. Teva had knowledge of the '309 patent when it submitted the amendment to ANDA No. 209813 to the FDA.

38. Teva Generic 22 mg XR Tablets infringe at least claim 1 of the '309 patent.

39. On information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Teva Generic 22 mg XR Tablets and will thereby infringe at least claim 1 of the '309 patent.

40. The foregoing actions by Teva constitute and/or would constitute infringement of at least claim 1 of the '309 patent.

41. Pfizer will be substantially and irreparably harmed if Teva is not enjoined from infringing the '309 patent. Pfizer has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Teva's submission of amended ANDA No. 209813 was an act of infringement and that Teva's making, using, offering to sell, selling, or importing Teva Generic 22 mg XR Tablets prior to the expiration of the '309 patent will infringe the '309 patent;

B. A judgment that the effective date of any FDA approval for Teva to make, use, offer for sale, sell, market, distribute, or import the Teva Generic 22 mg XR Tablets be no earlier than the date on which the '309 patent expires, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

C. A permanent injunction enjoining Teva, 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 Teva Generic 22 mg XR Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the '309 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/ Megan E. Dellinger

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