

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC.,)	
)	
Plaintiff,)	
)	
v.)	
)	
TEVA PHARMACEUTICALS USA, INC.,)	C.A. No. _____
)	
Defendants.)	

COMPLAINT

Pfizer Inc. (“Plaintiff” or “Pfizer”), for its Complaint against Teva Pharmaceuticals USA, Inc. (“Teva”), alleges as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Teva for infringement of United States Patent No. 9,937,181 (the “’181 patent”).
2. This action arises out of Teva’s filing of ANDA No. 209813 seeking approval by the FDA to sell generic copies of Xeljanz XR[®] (tofacitinib extended release tablets, 11 mg) prior to the expiration of the ’181 patent.

THE PARTIES

3. Pfizer 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. 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

5. 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).

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

7. In addition, Teva has committed a tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiff, including in Delaware. In particular, this suit arises out of Teva's filing of ANDA No. 209813 seeking FDA approval to sell tofacitinib extended release tablets, 11 mg ("Teva Generic XR Tablets") prior to the expiration of the '181 patent, throughout the United States, including in Delaware.

8. On information and belief, Teva works on the development, obtaining of regulatory approval, marketing, sale, and/or distribution of generic drugs, including Teva Generic 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.

9. On information and belief, if ANDA No. 209813 is approved, Teva Generic 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.

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

11. On information and belief, Teva maintains substantial, systematic and continuous contacts throughout the United States, including in Delaware. Teva's website states that "[o]ne in every six prescriptions dispensed in the US is a Teva Product. Approximately 22 prescriptions in the US are filled by Teva products *every second*." (Teva Company page, <https://www.tevausea.com/Company.aspx> (last visited Nov. 2, 2018)). Upon information and belief, Teva has distribution and customer service teams at multiple locations across the United States.

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

BACKGROUND

Xeljanz XR

13. Pfizer holds approved NDA No. 208246 for EQ 11 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 11 mg of tofacitinib base in an extended release tablet formulated for once-daily administration.

14. 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.

15. 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)- β -oxo-1-piperidinepropanenitrile, 2-hydroxy-1,2,3-propanetricarboxylate (1:1).

Orange Book Listing for Xeljanz XR

16. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the '181 patent is listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for the Xeljanz XR NDA.

17. The Orange Book lists the expiration date for the '181 patent as March 14, 2034.

18. The Orange Book also lists four 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); and 7,301,023 (expiring May 23, 2022).

The '181 Patent

19. On April 10, 2018, the USPTO issued the '181 patent, titled "Tofacitinib Oral Sustained Release Dosage Forms." The '181 patent is duly and legally assigned to Pfizer. A copy of the '181 patent is attached hereto as Exhibit A.

Teva's ANDA

20. By letter dated October 30, 2018 (the "Teva Notice Letter") and received by Pfizer on October 31, 2018, Teva notified Pfizer that it had submitted ANDA No. 209813 to the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act ("FDCA") to market and sell Teva Generic XR Tablets – generic copies of Xeljanz XR (tofacitinib citrate EQ 11 mg base extended release tablets) – prior to the expiration of the '181 patent.

21. The Teva Notice Letter asserts that 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 '181 patent is "invalid, unenforceable, and/or will not be infringed by" by Teva Generic XR Tablets.

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

23. The Teva Notice Letter states that ANDA No. 209813 requests “approval to engage in the commercial manufacture, use or sale of” Teva Generic XR Tablets prior to the expiration of the ’181 patent.

24. 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. 9,937,181 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 [’181 patent] are invalid, unenforceable and/or will not be infringed” by the commercial manufacture, use, or sale of Teva Generic XR Tablets.

25. Teva’s Detailed Statement does not set forth a noninfringement argument with respect to any claim of the ’181 patent.

26. On information and belief, upon approval of ANDA No. 209813, Teva will distribute Teva Generic XR Tablets in the United States.

CLAIM FOR RELIEF
(Infringement of the ’181 Patent by Teva Generic XR Tablets)

27. The allegations of paragraphs 1-26 above are repeated and re-alleged as if set forth fully herein.

28. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva’s submission of ANDA No. 209813 to the FDA seeking approval to market Teva Generic XR Tablets was an act of infringement of at least claim 1 of the ’181 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 ’181 patent.

29. Teva had knowledge of the '181 patent when it submitted ANDA No. 209813 to the FDA.

30. On information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Teva Generic XR Tablets and will thereby infringe at least claim 1 of the '181 patent.

31. The foregoing actions by Teva constitute and/or would constitute infringement of at least claim 1 of the '181 patent.

32. Pfizer will be substantially and irreparably harmed if Teva is not enjoined from infringing the '181 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 ANDA No. 209813 was an act of infringement and that Teva's making, using, offering to sell, selling, or importing Teva Generic XR Tablets prior to the expiration of the '181 patent will infringe the '181 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 XR Tablets be no earlier than the date on which the '181 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 XR Tablets, and from inducing or contributing to any of the

foregoing, prior to the expiration of the '181 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

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