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,	)	
	)	C.A. No. _____
v.	)	
AJANTA PHARMA LIMITED,	)	
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 Ajanta Pharma Limited ("Defendant" or "Ajanta"), allege as follows:

NATURE OF THE ACTION

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

2. This action arises out of Ajanta's filing of Abbreviated New Drug Application ("ANDA") No. 219542, 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 RE'783 patent. Ajanta's proposed extended-release tofacitinib citrate products are referred to herein as "Ajanta 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 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 Ajanta Pharma Limited is a corporation organized and existing under the laws of India, having its principal place of business at Ajanta House, Charkop, Kandivali West, Mumbai, Maharashtra 400067, India.

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, 1338(a), 2201, and 2202.

10. This Court has personal jurisdiction over Ajanta by virtue of the fact, *inter alia*, that Ajanta has committed a tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Pfizer throughout the United States, including in Delaware. In particular, this suit arises out of Ajanta's filing of ANDA No. 219542 seeking FDA approval to sell Ajanta Generic XR Tablets prior to the expiration of the RE'783 patent throughout the United States, including in Delaware.

11. On information and belief, if ANDA No. 219542 is approved, Ajanta Generic XR Tablets will, among other things, be marketed and distributed by Ajanta in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and/or used by patients in Delaware.

12. Ajanta's infringing activities with respect to its filing of ANDA No. 219542 and its intent to commercialize and sell Ajanta Generic XR 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.

13. In the alternative, this Court has personal jurisdiction over Ajanta under Federal Rule of Civil Procedure 4(k)(2).

14. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391. As a foreign corporation, Ajanta may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c)(3).

BACKGROUND

Xeljanz XR

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

16. 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).

17. 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, for the treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more 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 XR

18. 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. Xeljanz XR tablets are approved for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis.

19. 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 XR NDA.

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

21. The Orange Book lists three additional patents for Xeljanz XR that are not at issue: U.S. Patent No. 9,937,181, U.S. Patent No. 10,639,309, and U.S. Patent No. 11,253,523 (all expiring March 14, 2034).

The RE'783 Patent

22. 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.

23. 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.

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

25. 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.

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

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

Ajanta's ANDA

28. By letter dated July 1, 2024 (the "Ajanta Notice Letter") and received by Pfizer on or around July 3, 2024, Ajanta notified Pfizer that it had submitted ANDA No. 219542 to the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Ajanta Generic XR Tablets—generic copies of Xeljanz XR (tofacitinib citrate EQ 11 mg and 22 mg base extended-release tablets)—prior to the expiration of the RE'783 patent.

29. The Ajanta Notice Letter describes the Ajanta Generic XR Tablets as "Tofacitinib Extended Release Tablets, Eq 11 mg Base; Eq 22 mg Base."

30. The Ajanta Notice Letter states that Ajanta has filed ANDA No. 219542 seeking approval to market Ajanta Generic XR Tablets prior to the expiration of the RE'783 patent.

31. The Ajanta Notice Letter asserts that ANDA No. 219542 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j) alleging that the RE'783 patent is "invalid, unenforceable, and/or not infringed" by Ajanta Generic XR Tablets.

32. Attached to the Ajanta Notice Letter was Ajanta's Detailed Statement of the Factual and Legal Bases in Support of Its Paragraph IV Certification that the Claimed Subject Matter of U.S. Patent Nos. RE41,783; 9,937,181; 10,639,309 and 11,253,523 Are Invalid, Unenforceable, and/or Not Infringed ("Ajanta's Detailed Statement") asserting, *inter alia*, the purported factual and legal bases for Ajanta's contention that the claims of the RE'783 patent are invalid, unenforceable, 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 Ajanta Generic XR Tablets.

33. Ajanta's Detailed Statement alleges that all claims of the RE'783 patent are invalid. Ajanta's Detailed Statement does not contain a noninfringement argument with respect to the RE'783 patent.

34. On information and belief, upon approval of ANDA No. 219542, Ajanta will sell and distribute Ajanta Generic XR Tablets in the United States.

COUNT I
(Infringement of the RE'783 Patent by Ajanta Generic 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), Ajanta's filing of ANDA No. 219542 seeking approval to market and sell Ajanta Generic XR 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. 219542 be a date that is not earlier than the expiration date of the RE'783 patent.

37. Ajanta had knowledge of the RE'783 patent when it submitted ANDA No. 219542 to the FDA.

38. On information and belief, upon FDA approval of ANDA No 219542, Ajanta intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Ajanta Generic XR 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).

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

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

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Ajanta's submission of ANDA No. 219542 was an act of infringement and that Ajanta's making, using, offering to sell, selling, or importing Ajanta Generic XR Tablets in the United States prior to the expiration of the RE'783 patent will directly infringe that patent;

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

C. A permanent injunction enjoining Ajanta, 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 into the United States Ajanta Generic XR Tablets, 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;

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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