

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.)

ALKEM LABORATORIES LIMITED,)

Defendant.)

C.A. No. _____

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 Alkem Laboratories Limited (“Defendant” or “Alkem”), allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Alkem for infringement of United States Patent No. RE41,783 (“the RE’783 patent”).

2. This action arises out of Alkem’s filing of Abbreviated New Drug Application (“ANDA”) No. 220395, 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 (tofacitinib citrate extended-release tablets), prior to the expiration of the RE’783 patent. Alkem’s proposed tofacitinib products are referred to hereinafter as “Alkem Generic Tofacitinib 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 Alkem Laboratories Limited is a corporation organized and existing under the laws of India, having its principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, Maharashtra 400 013, 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 Alkem by virtue of the fact, *inter alia*, that Alkem 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 the State of Delaware. In particular, this suit arises out of Alkem's filing of ANDA No. 220395 seeking FDA approval to sell Alkem Generic Tofacitinib 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. 220395 is approved, Alkem Generic Tofacitinib XR Tablets will, among other things, be marketed and distributed by Alkem in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and/or used by patients in Delaware.

12. Alkem's infringing activities with respect to its filing of ANDA No. 220395 and its intent to commercialize and sell Alkem Generic Tofacitinib 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 Alkem under Federal Rule of Civil Procedure 4(k)(2). Alkem has contacts with the United States by virtue, *inter alia*, of its filing ANDA No. 220395 with the FDA.

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

BACKGROUND

Xeljanz

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 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).

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

18. Pfizer Inc. holds approved New Drug Application ("NDA") No. 208246 for EQ 11 mg and EQ 22 mg base tofacitinib citrate extended-release tablets, which it sells under the registered name Xeljanz XR. The 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 NDA.

20. The Orange Book lists the expiration date for the RE'783 patent as December 8, 2025, and states that NDA No. 208246 has exclusivity until June 8, 2026, because the FDA has granted Xeljanz pediatric exclusivity pursuant to § 505A of the Federal Food Drug & Cosmetic Act.

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

Alkem's ANDA

28. By letter dated March 21, 2025 (the "Alkem Notice Letter") and received by Pfizer on/around March 25, 20205, Alkem notified Pfizer that it had filed ANDA No. 220395 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Alkem Generic Tofacitinib XR Tablets—generic copies of Xeljanz XR (tofacitinib citrate EQ 11 mg and 22 mg base tablets)—prior to the expiration of the RE'783 patent.

29. The Alkem Notice Letter describes the Alkem Generic Tofacitinib XR Tablets as "Tofacitinib Citrate Tablets, Extended Release Eq 11 mg base and 22 mg base."

30. The Alkem Notice Letter states that Alkem has filed ANDA No. 220395 seeking to "engage in the commercial manufacture, use or sale" of Alkem Generic Tofacitinib XR Tablets prior to the expiration of the RE'783 patent.

31. The Alkem Notice Letter asserts that ANDA No. 220395 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 Alkem Generic Tofacitinib XR Tablets.

32. Attached to the Alkem Notice Letter was Alkem's detailed statement asserting the purported factual and legal bases for Alkem'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 Alkem Generic Tofacitinib XR Tablets.

33. Alkem's detailed statement alleges that all claims of the RE'783 patent are invalid. Alkem'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. 220395, Alkem will sell and distribute Alkem Generic Tofacitinib XR Tablets in the United States.

CLAIM FOR RELIEF

COUNT I

(Infringement of the RE'783 Patent by Alkem Generic Tofacitinib 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), Alkem's filing of ANDA No. 220395 seeking approval to market and sell Alkem Generic Tofacitinib 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. 220395 be a date which is not earlier than the expiration date of the RE'783 patent.

37. Alkem had knowledge of the RE'783 patent when it submitted ANDA No. 220395 to the FDA.

38. On information and belief, upon FDA approval of ANDA No 220395, Alkem intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Alkem Generic Tofacitinib 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 Alkem constitute and/or would constitute infringement of at least claim 4 of the RE'783 patent.

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

41. Pfizer will be substantially and irreparably harmed if Alkem 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 Alkem's submission of ANDA No. 220395 was an act of infringement and that Alkem's making, using, offering to sell, selling, or importing Alkem Generic Tofacitinib 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 Alkem to make, use, offer for sale, sell, market, distribute, or import Alkem Generic Tofacitinib 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 Alkem, 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 Alkem Generic Tofacitinib XR 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;
- 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

OF COUNSEL:

/s/ Megan E. Dellinger

Aaron Stiefel
Daniel P. DiNapoli
Michael Sapiro
ARNOLD & PORTER KAYE SCHOLER LLP
250 West 55th Street
New York, NY 10019-9710
(212) 836-8000

Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
mdellinger@morrisnichols.com

Attorneys for Plaintiffs

Soumitra Deka
DLA PIPER LLP (US)
555 Mission Street, Suite 2400
San Francisco, CA 94105-2933
(415) 836-2500

May 7, 2025