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. _____
SOMERSET THERAPEUTICS LLC,	)	
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 Somerset Therapeutics LLC ("Defendant" or "Somerset"), allege as follows:

NATURE OF THE ACTION

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

2. This action arises out of Somerset's filing of Abbreviated New Drug Application ("ANDA") No. 220137, seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's 5 mg and 10 mg Xeljanz® (tofacitinib) tablets prior to the expiration of the RE'783 patent. Somerset's proposed tofacitinib products are referred to hereinafter as "Somerset Generic Tofacitinib 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 Somerset Therapeutics LLC is a company organized and existing under the laws of the state of Delaware and having its principal place of business at 300 Franklin Square Drive, Somerset, NJ 08873.

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 Somerset by virtue of the fact, *inter alia*, that Somerset 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 Somerset's filing of ANDA No. 220137 seeking FDA approval to sell Somerset Generic Tofacitinib 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. 220137 is approved, Somerset Generic Tofacitinib Tablets will, among other things, be marketed and distributed by Somerset in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and/or used by patients in Delaware.

12. Somerset's infringing activities with respect to its filing of ANDA No. 220137 and its intent to commercialize and sell Somerset Generic Tofacitinib 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. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

Xeljanz

14. The active ingredient in Pfizer's Xeljanz product is tofacitinib citrate. Xeljanz contains tofacitinib citrate in an amount equivalent to either 5 mg or 10 mg of tofacitinib base in tablets formulated for twice-daily administration.

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

16. Tofacitinib citrate is an inhibitor of Janus kinases 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

17. PF PRISM C.V. holds approved New Drug Application ("NDA") No. 203214 for EQ 5 mg and 10 mg base tofacitinib citrate tablets, which Pfizer sells under the registered name Xeljanz. The Xeljanz tablets are approved for, *inter alia*, the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis.

18. 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.

19. The Orange Book lists the expiration date for the RE'783 patent as December 8, 2025, and states that NDA No. 203214 has exclusivity until June 8, 2026, because the FDA has granted Xeljanz pediatric exclusivity pursuant to § 505A of the Federal Food Drug & Cosmetic Act.

The RE'783 Patent

20. 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.

21. 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.

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

23. 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.

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

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

Somerset's ANDA

26. By letter dated April 3, 2025 (the "Somerset Notice Letter") and received by Pfizer on/around April 4, 2025, Somerset notified Pfizer that it had filed ANDA No. 220137 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Somerset Generic Tofacitinib Tablets—generic copies of Xeljanz (tofacitinib citrate EQ 5 mg and 10 mg base tablets)—prior to the expiration of the RE'783 patent.

27. The Somerset Notice Letter describes the Somerset Generic Tofacitinib Tablets as "tofacitinib tablets, 5 mg and 10 mg."

28. The Somerset Notice Letter states that Somerset has filed ANDA No. 220137 seeking to "engage in the commercial manufacture, use or sale" of Somerset Generic Tofacitinib Tablets prior to the expiration of the RE'783 patent.

29. The Somerset Notice Letter asserts that ANDA No. 220137 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j) alleging that the RE'783 patent is "invalid, unenforceable, or will not be not infringed" by Somerset Generic Tofacitinib Tablets.

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

31. Somerset's detailed statement alleges that all claims of the RE'783 patent are invalid. Somerset's detailed statement does not contain a noninfringement argument with respect to the RE'783 patent.

32. On information and belief, upon approval of ANDA No. 220137, Somerset will sell and distribute Somerset Generic Tofacitinib Tablets in the United States.

CLAIM FOR RELIEF

COUNT I

(Infringement of the RE'783 Patent by Somerset Generic Tofacitinib Tablets)

33. The allegations of paragraphs 1-32 above are repeated and re-alleged as if set forth fully herein.

34. Pursuant to 35 U.S.C. § 271(e)(2)(A), Somerset's filing of ANDA No. 220137 seeking approval to market and sell Somerset Generic Tofacitinib 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. 220137 be a date which is not earlier than the expiration date of the RE'783 patent.

35. Somerset had knowledge of the RE'783 patent when it submitted ANDA No. 220137 to the FDA.

36. On information and belief, upon FDA approval of ANDA No 220137, Somerset intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Somerset Generic Tofacitinib 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).

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

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

39. Pfizer will be substantially and irreparably harmed if Somerset 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 Somerset's submission of ANDA No. 220137 was an act of infringement and that Somerset's making, using, offering to sell, selling, or importing Somerset Generic Tofacitinib 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 Somerset to make, use, offer for sale, sell, market, distribute, or import Somerset Generic Tofacitinib 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 Somerset, 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 Somerset Generic Tofacitinib 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

/s/ Megan E. Dellinger

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