IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| 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. _____ |
| BRECKENRIDGE PHARMACEUTICAL, 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 Breckenridge Pharmaceutical, Inc. ("Defendant" or "Breckenridge"), allege as follows:

**NATURE OF THE ACTION**

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

2. This action arises out of Breckenridge's filing of an amendment to Abbreviated New Drug Application ("ANDA") No. 209633, seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's 10 mg Xeljanz® (tofacitinib) tablets prior to the expiration of the RE'783 patent. Breckenridge's proposed tofacitinib product is referred to hereinafter as "Breckenridge Generic 10 mg 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. Breckenridge's notice letter to Pfizer, dated August 26, 2024 and referred to below, identified Breckenridge as a Florida corporation having its principal place of business at 200

Connell Drive, Suite 4200, Berkeley Heights, New Jersey 07922. The Delaware Division of Corporation's website identifies Breckenridge Pharmaceutical, Inc. as a Delaware corporation.

## 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 Breckenridge by virtue of Breckenridge's consent to jurisdiction for the purposes of this litigation.

11. In the alternative, this Court has personal jurisdiction over Breckenridge by virtue of the fact, *inter alia*, that Breckenridge 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 Breckenridge's filing of an amendment to ANDA No. 209633 seeking FDA approval to sell Breckenridge Generic 10 mg Tofacitinib Tablets prior to the expiration of the RE'783 patent throughout the United States, including in Delaware.

12. On information and belief, if ANDA No. 209633 is approved, Breckenridge Generic 10 mg Tofacitinib Tablets will, among other things, be marketed and distributed by Breckenridge in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and/or used by patients in Delaware.

13. Breckenridge's infringing activities with respect to its filing of the amendment to ANDA No. 209633 and its intent to commercialize and sell Breckenridge Generic 10 mg 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.

14. Breckenridge has consented to venue in this district for the purposes of this litigation.

## BACKGROUND

### Xeljanz

15. 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.

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)-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

18. PF PRISM C.V. holds approved New Drug Application ("NDA") No. 203214 for, *inter alia*, EQ 10 mg base tofacitinib citrate tablets, which Pfizer sells under the registered name Xeljanz. The Xeljanz 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.

**The RE'783 Patent**

21. 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.

22. 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.

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

24. 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.

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

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

**Breckenridge's ANDA**

27. By letter dated August 26, 2024 (the "Breckenridge Notice Letter") and received by Pfizer on/around August 27, 2024, Breckenridge notified Pfizer that it had filed an amendment to ANDA No. 209633 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Breckenridge Generic 10 mg Tofacitinib Tablets—generic copies of Xeljanz (tofacitinib citrate EQ 10 mg base tablets)—prior to the expiration of the RE'783 patent.

28. The Breckenridge Notice Letter describes the Breckenridge Generic 10 mg Tofacitinib Tablets as "tofacitinib citrate oral tablets," containing the equivalent of 10 mg of tofacitinib in the form of tofacitinib citrate.

29. The Breckenridge Notice Letter states that Breckenridge has filed the amendment to ANDA No. 209633 seeking to "engage in the commercial manufacture, use or sale" of Breckenridge Generic 10 mg Tofacitinib Tablets prior to the expiration of the RE'783 patent.

30. The Breckenridge Notice Letter asserts that the amendment to ANDA No. 209633 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j) alleging that the RE'783 patent is "invalid, unenforceable, and/or will not be infringed by" Breckenridge Generic 10 mg Tofacitinib Tablets.

31. Attached to the Breckenridge Notice Letter was Breckenridge's detailed statement asserting the purported factual and legal bases for Breckenridge'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 Breckenridge Generic 10 mg Tofacitinib Tablets.

32. On information and belief, upon approval of ANDA No. 209633, Breckenridge will sell and distribute Breckenridge Generic 10 mg Tofacitinib Tablets in the United States.

33. Pfizer previously sued Breckenridge in this Court based on Breckenridge's filing of ANDA 209633 seeking approval to sell generic copies of the 5 mg Xeljanz dosage strength. *See* Complaint, *Pfizer Inc. v. Breckenridge Pharmaceutical, Inc.*, C.A. No. 17-302 (D. Del. Mar. 21, 2017), D.I. 1. The parties voluntarily dismissed the case by joint stipulation pursuant to a settlement agreement. *See* Stipulation of Dismissal, C.A. No. 17-302, D.I. 32.

## CLAIMS FOR RELIEF

### COUNT I
### (Infringement of the RE'783 Patent by Breckenridge Generic 10 mg Tofacitinib Tablets)

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

35. Pursuant to 35 U.S.C. § 271(e)(2)(A), Breckenridge's filing of the amendment to ANDA No. 209633 seeking approval to market and sell Breckenridge Generic 10 mg 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. 209633 be a date which is not earlier than the expiration date of the RE'783 patent.

36. Breckenridge had knowledge of the RE'783 patent when it submitted the amendment to ANDA No. 209633 to the FDA.

37. On information and belief, upon FDA approval of ANDA No 209633, Breckenridge intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Breckenridge Generic 10 mg 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).

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

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

40. Pfizer will be substantially and irreparably harmed if Breckenridge 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 Breckenridge's submission of the amendment to ANDA No. 209633 was an act of infringement and that Breckenridge's making, using, offering to sell, selling, or importing Breckenridge Generic 10 mg 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 Breckenridge to make, use, offer for sale, sell, market, distribute, or import Breckenridge Generic 10 mg 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 Breckenridge, 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 Breckenridge Generic 10 mg 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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