

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. )

MICRO LABS, LTD. and )  
MICRO LABS USA INC., )

Defendants. )

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 Micro Labs, Ltd. and Micro Labs USA Inc. (collectively “Defendants” or “Micro Labs”) allege as follows:

**NATURE OF THE ACTION**

1. This is an action by Pfizer against Micro Labs for infringement of United States Patent No. RE41,783 (“the RE’783 patent”) and United States Patent No. 6,965,027 (“the ’027 patent”).

2. This action arises out of Micro Labs, Ltd.’s filing of Abbreviated New Drug Application (“ANDA”) No. 209738 as amended, 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 and ’027 patents. Micro Labs’ proposed 10 mg tofacitinib product is referred to hereinafter as “Micro Labs 10 mg Generic Tablets.”

### THE PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017.

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 principal place of business at Professional Offices Park V, 996 San Roberto Street, 4<sup>th</sup> 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*) 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 Micro Labs, Ltd. is a company organized and existing under the laws of India, having its principal place of business at 31 Race Course Road, Bangalore, India 560 001.

9. On information and belief, defendant Micro Labs USA Inc. is a company organized and existing under the laws of New Jersey, having its principal place of business at 106 Allen Road, Suite 102, Basking Ridge, NJ 07920.

10. On information and belief, Micro Labs, Ltd. is the ultimate parent company of Micro Labs USA Inc. On information and belief, Micro Labs USA Inc. is the U.S. agent for Micro Labs, Ltd.

### **JURISDICTION AND VENUE**

11. 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.

12. This Court has personal jurisdiction over Defendants and venue is proper in this action in that counsel for Micro Labs has represented to Pfizer that for the purposes of this litigation Micro Labs will not object to personal jurisdiction or venue in this judicial district.

### **BACKGROUND**

#### **Xeljanz**

13. The active ingredient in Pfizer's Xeljanz product is tofacitinib citrate. Pfizer markets Xeljanz tablets that contain tofacitinib citrate in an amount equivalent to 10 mg of tofacitinib base.

14. 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)- $\beta$ -oxo-1-piperidinepropanenitrile, 2-hydroxy-1,2,3-propanetricarboxylate (1:1).

15. 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 ulcerative colitis who have had an inadequate response or who are intolerant to TNF blockers.

**Orange Book Listing for Xeljanz**

16. 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 10 mg Xeljanz tablets are approved for the treatment of ulcerative colitis.

17. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the RE’783 and ’027 patents are listed in the FDA publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) for the Xeljanz NDA.

18. The Orange Book lists the expiration date for the RE’783 patent as December 8, 2025, and the expiration date for the ’027 patent as March 25, 2023.

**The RE’783 Patent**

19. 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.

20. 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.

21. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the RE’783 patent.

22. 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.

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

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

### **The '027 Patent**

25. On November 15, 2005, the USPTO issued the '027 patent, titled "Crystalline 3-{4-methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-amino]-piperidin-1-yl}-3-oxo-propionitrile Citrate." The '027 patent is duly and legally assigned to Pfizer Inc. A copy of the '027 patent is attached hereto as Exhibit B.

26. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the '027 patent.

27. C.P. Pharmaceuticals International C.V. conveyed rights under the '027 patent to Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

28. Pfizer Pharmaceuticals LLC has conveyed its rights to the '027 patent to PBG Puerto Rico LLC.

29. Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. has conveyed its rights to the '027 patent to PF PRISM IMB B.V.

### **Micro Labs' ANDA**

30. By letter dated February 1, 2021 (the "Micro Labs Notice Letter"), and received by Pfizer on February 2, 2021, Micro Labs notified Pfizer that it had submitted to the FDA an amendment to ANDA No. 209738, seeking approval under the Federal Food, Drug and Cosmetic

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