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.	)	
ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD.,	)	
Defendants.	)	

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 Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively "Defendants" or "Zydus"), allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Zydus 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 Zydus's filing of Abbreviated New Drug Application ("ANDA") No. 214264 as amended, seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's 22 mg Xeljanz® XR (tofacitinib extended-release tablets) prior to the expiration of, *inter alia*, the RE'783 and'027 patents. Zydus's proposed 22 mg tofacitinib product is referred to hereinafter as "Zydus 22 mg 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 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, 4th Floor, San Juan, Puerto Rico 00926. Pfizer Inc. is the ultimate parent company of PBG Puerto Rico LLC.

7. Plaintiff 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 Zydus Pharmaceuticals (USA) Inc. is a company organized and existing under the laws of New Jersey, having its principal place of business at 73 Route 31 N., Pennington, NJ 08534.

9. On information and belief, defendant Cadila Healthcare Ltd. is a company organized and existing under the laws of India, having its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Kohraj (Gandhinigar), Nr. Vaishnodevi Circle, Sarkhej-Gandhinagar Highway, Ahmedabad, Gujurat, India 382481.

10. On information and belief, Cadila Healthcare Ltd. is the ultimate parent company of Zydus Pharmaceuticals (USA) Inc. On information and belief, Zydus Pharmaceuticals (USA) Inc. is the U.S. agent for Cadila Healthcare 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.

13. Zydus Pharmaceuticals (USA) Inc. is a wholly-owned subsidiary of Cadila Healthcare Ltd. (https://zyduscadila.com/public/pdf/financial/annual/Annual-Report-2019-2020.pdf, at 56, last accessed on Feb. 3, 2021). On information and belief, Cadila Healthcare Ltd., directly or through its subsidiary Zydus Pharmaceuticals (USA) Inc., manufactures, markets, imports, and sells generic drugs for distribution in Delaware and throughout the United States.

14. On information and belief, Defendants are agents of each other and/or work in concert with each other on the development, obtaining of regulatory approval, manufacture,

marketing, sale, and/or distribution of generic drugs, including the proposed Zydus 22 mg Generic XR Tablets.

15. In the alternative, this Court has jurisdiction over Cadila Healthcare Ltd. under Federal Rule of Civil Procedure 4(k)(2). Cadila Healthcare Ltd. has contacts with the United States by, *inter alia*, having caused the filing of ANDA No. 214264 as amended with the FDA.

BACKGROUND

Xeljanz XR

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

17. 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).

18. 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 methotrexate, for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs ("DMARDs"), 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

19. Pfizer Inc. holds approved New Drug Application ("NDA") No. 208246 for, *inter alia*, EQ 22 mg base tofacitinib citrate extended-release tablets, which it sells under the registered

name Xeljanz XR. The 22 mg Xeljanz XR tablets are approved for the treatment of ulcerative colitis.

20. 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 XR NDA.

21. 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.

22. The Orange Book lists one additional patent for the 22 mg strength of Xeljanz XR that is not at issue: U.S. Patent No. 10,639,309, expiring March 14, 2034.

The RE'783 Patent

23. 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.

24. 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.

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

26. 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.

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