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. _____
AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC.,	)	
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 Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively "Defendants" or "Aurobindo") allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Aurobindo for infringement of United States Patent No. 6,965,027 ("the '027 patent") and United States Reissue Patent No. RE41,783 ("the RE'783 patent").

2. This action arises out of Aurobindo Pharma Ltd.'s filing of Abbreviated New Drug Application ("ANDA") No. 215356 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 '027 and RE'783 patents. Aurobindo's ANDA products are referred to hereinafter individually as "Aurobindo 5 mg Generic Tablets" and "Aurobindo 10 mg Generic Tablets" and collectively as "Aurobindo 5 mg and 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 a place of business 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 PF PRISM IMB B.V. is a private limited liability company (*besloten vennootschap*) under the law 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 Aurobindo Pharma Ltd. is a company organized and existing under the laws of India, having its principal place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad-500038, Telangana, India.

9. On information and belief, defendant Aurobindo Pharma USA, Inc. is a company organized and existing under the laws of Delaware, having its principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ 08520. On information and belief, Aurobindo Pharma Ltd. is the ultimate parent company of Aurobindo Pharma USA, Inc. On information and belief, Aurobindo Pharma USA, Inc. is the U.S. agent for Aurobindo Pharma Ltd.

JURISDICTION AND VENUE

10. 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.

11. This Court has personal jurisdiction over Defendants.

12. This Court has personal jurisdiction over Defendants by virtue of the fact, *inter alia*, that Aurobindo Pharma USA, Inc. is a Delaware corporation and Aurobindo Pharma Ltd. is the ultimate parent company of Aurobindo Pharma USA, Inc.

13. Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary of Aurobindo Pharma Ltd. (https://www.aurobindo.com/wp-content/uploads/2020/08/Aurobindo-Pharma-Limited-Annual-Report-2019-20.pdf, at 95, last accessed on Jan. 5, 2021). On information and belief, Aurobindo Pharma Ltd., directly or through its subsidiary Aurobindo Pharma 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 Aurobindo 5 mg and 10 mg Generic Tablets.

15. On information and belief, if ANDA No. 215356 is approved, Aurobindo 5 mg and 10 mg Generic Tablets will, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and/or used by patients in Delaware.

16. Aurobindo's infringing activities with respect to its filing of ANDA No. 215356 and its intent to commercialize and sell Aurobindo 5 mg and 10 mg Generic Tablets have led and/or will lead to foreseeable harm and injury to Plaintiffs, including Pfizer Inc., which is incorporated in Delaware.

17. On information and belief, Defendants maintain substantial, systematic, and continuous contacts with Delaware. Aurobindo Pharma USA, Inc.'s website states that the company has earned its "reputation by building an extremely robust company, ensuring AuroControl through vertical integration [and] multiple manufacturing units in . . . the U.S. " (https://www.aurobindousa.com/company/investors/, last accessed on Jan. 5, 2021). Aurobindo Pharma Ltd.'s 2019-2020 annual report states that the company has so far "[f]iled 586 ANDAs with USFDA and received approval for 425 ANDAs, including 28 tentative approvals," and refers to Aurobindo's "core geographies such as USA." (https://www.aurobindo.com/wp-content/uploads/2020/08/Aurobindo-Pharma-Limited-Annual-Report-2019-20.pdf, at 6, 11, last accessed on Jan. 5, 2021). As of March 31, 2020, Aurobindo claims to be "the second largest generics company in the US in terms of prescriptions (Rx) dispensed as per IQVIA data." (*Id.* at 67).

18. In the alternative, this Court has jurisdiction over Aurobindo Pharma Ltd. under Federal Rule of Civil Procedure 4(k)(2). Aurobindo Pharma Ltd. has contacts with the United States by, *inter alia*, having filed ANDA No. 215356 with the FDA.

19. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

Xeljanz

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

21. 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).

22. Tofacitinib citrate is an inhibitor of Janus kinases ("JAKs") and is indicated 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), 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, and for the treatment of active polyarticular course of juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older.

Orange Book Listing for Xeljanz

23. PF PRISM C.V. holds approved New Drug Application ("NDA") No. 203214 for EQ 5 and EQ 10 mg base tofacitinib citrate tablets, which Pfizer sells under the registered name Xeljanz.

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