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.

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

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

The '027 Patent

26. 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 A.

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

28. 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.

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

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

The RE'783 Patent

31. On September 28, 2010, the 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 B.

32. On December 14, 2016, the United States Patent and Trademark Office ("USPTO") issued a Notice of Final Determination extending the expiration date of the RE'783 patent to December 8, 2025.

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

34. 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.

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

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

Aurobindo's ANDA

37. By letter dated November 25, 2020 (the "Aurobindo Notice Letter"), and received by Pfizer on November 30, 2020, Aurobindo notified Pfizer that it had filed ANDA No. 215356 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Aurobindo 5 mg and 10 mg Generic Tablets -- generic copies of Xeljanz (tofacitinib citrate EQ 5 mg and EQ 10 mg tablets) -- prior to the expiration of the '027 and RE'783 patents. The Aurobindo Notice Letter describes the Aurobindo 5 mg and 10 mg Generic Tablets as "tofacitinib citrate tablets in 5 mg and 10 mg strengths."

38. The Aurobindo Notice Letter states that ANDA No. 215356 seeks "to obtain approval to engage in the commercial manufacture, use or sale of" Aurobindo 5 mg and 10 mg Generic Tablets prior to the expiration of the '027 and RE'783 patents.

39. The Aurobindo Notice Letter asserts that ANDA No. 215356 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(B)(iv)(II) alleging that the '027 and RE'783 patents "are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of" Aurobindo 5 mg and 10 mg Generic Tablets.

40. Attached to the Aurobindo Notice Letter was Aurobindo's Detailed Factual and Legal Basis for Aurobindo's Paragraph IV Certification regarding U.S. Patent Nos. 6,965,027 and RE41,783 ("Aurobindo's Detailed Statement") asserting the purported factual and legal bases for Aurobindo's contention that the '027 and RE'783 patents are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Aurobindo 5 mg and 10 mg Generic Tablets.

41. Aurobindo's Detailed Statement alleges that all claims of the '027 and RE'783 patents are invalid. Aurobindo's Detailed Statement does not contain a noninfringement argument with respect to either the '027 patent or the RE'783 patent.

42. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. collaborated and acted in concert in the decision to prepare and file and in the preparation and filing of ANDA No. 215356.

43. On information and belief, upon approval of ANDA No. 215356, Aurobindo will sell and distribute Aurobindo 5 mg and 10 mg Generic Tablets throughout the United States.

COUNT I
(Infringement of the '027 Patent by Aurobindo 5 mg Generic Tablets)

44. The allegations of paragraphs 1-43 above are repeated and re-alleged as if set forth fully herein.

45. Pursuant to 35 U.S.C. § 271(e)(2)(A), Aurobindo's filing of ANDA No. 215356 seeking approval to market Aurobindo 5 mg Generic Tablets is an act of infringement of at least claim 1 of the '027 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. 215356 be a date which is not earlier than the expiration date of the '027 patent.

46. Aurobindo had knowledge of the '027 patent when it submitted ANDA No. 215356 to the FDA.

47. On information and belief, upon FDA approval, Aurobindo intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Aurobindo 5 mg Generic Tablets and will thereby infringe at least claim 1 of the '027 patent.

48. The foregoing actions by Aurobindo constitute and/or would constitute infringement of at least claim 1 of the '027 patent.

49. Pfizer will be substantially and irreparably harmed if Aurobindo is not enjoined from infringing the '027 patent. Pfizer has no adequate remedy at law.

COUNT II
(Infringement of the '027 Patent by Aurobindo 10 mg Generic Tablets)

50. The allegations of paragraphs 1-49 above are repeated and re-alleged as if set forth fully herein.

51. Pursuant to 35 U.S.C. § 271(e)(2)(A), Aurobindo's filing of ANDA No. 215356 seeking approval to market Aurobindo 10 mg Generic Tablets is an act of infringement of at least claim 1 of the '027 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. 215356 be a date which is not earlier than the expiration date of the '027 patent.

52. Aurobindo had knowledge of the '027 patent when it submitted ANDA No. 215356 to the FDA.

53. On information and belief, upon FDA approval, Aurobindo intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Aurobindo 10 mg Generic Tablets and will thereby infringe at least claim 1 of the '027 patent.

54. The foregoing actions by Aurobindo constitute and/or would constitute infringement of at least claim 1 of the '027 patent.

55. Pfizer will be substantially and irreparably harmed if Aurobindo is not enjoined from infringing the '027 patent. Pfizer has no adequate remedy at law.

COUNT III
(Infringement of the RE'783 Patent by Aurobindo 5 mg Generic Tablets)

56. The allegations of paragraphs 1-55 above are repeated and re-alleged as if set forth fully herein.

57. Pursuant to 35 U.S.C. § 271(e)(2)(A), Aurobindo's filing of ANDA No. 215356 seeking approval to market Aurobindo 5 mg Generic Tablets is 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. 215356 be a date which is not earlier than the expiration date of the RE'783 patent.

58. Aurobindo had knowledge of the RE'783 patent when it submitted ANDA No. 215356 to the FDA.

59. On information and belief, upon FDA approval, Aurobindo intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Aurobindo 5 mg Generic Tablets and will thereby infringe at least claim 4 of the RE'783 patent.

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

61. Pfizer will be substantially and irreparably harmed if Aurobindo is not enjoined from infringing the RE'783 patent. Pfizer has no adequate remedy at law.

COUNT IV
(Infringement of the RE'783 Patent by Aurobindo 10 mg Generic Tablets)

62. The allegations of paragraphs 1-61 above are repeated and re-alleged as if set forth fully herein.

63. Pursuant to 35 U.S.C. § 271(e)(2)(A), Aurobindo's filing of ANDA No. 215356 seeking approval to market Aurobindo 10 mg Generic Tablets is 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. 215356 be a date which is not earlier than the expiration date of the RE'783 patent.

64. Aurobindo had knowledge of the RE'783 patent when it submitted ANDA No. 215356 to the FDA.

65. On information and belief, upon FDA approval, Aurobindo intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Aurobindo 10 mg Generic Tablets and will thereby infringe at least claim 4 of the RE'783 patent.

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

67. Pfizer will be substantially and irreparably harmed if Aurobindo is not enjoined from infringing the RE'783 patent. Pfizer has no adequate remedy at law.

COUNT V
(Aurobindo Pharma USA, Inc.'s Inducing of Infringement by Aurobindo Pharma Ltd.)

68. The allegations of paragraphs 1-67 above are repeated and re-alleged as if set forth fully herein.

69. On information and belief, Aurobindo Pharma USA, Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission by Aurobindo Pharma Ltd. of ANDA No. 215356 to the FDA, knowing of the '027 and RE'783 patents.

70. The filing of ANDA No. 215356 by Aurobindo Pharma Ltd. constituted direct infringement under 35 U.S.C. § 271(e). On information and belief, under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Aurobindo Pharma USA, Inc. induced the infringement of the '027 and RE'783 patents by actively and knowingly causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 215356 to the FDA knowing that the submission of ANDA No. 215356 would constitute direct infringement of the '027 and RE'783 patents.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Aurobindo Pharma Ltd.'s submission of ANDA No. 215356 was an act of infringement and that Aurobindo's making, using, offering to sell, selling, or importing Aurobindo 5 mg and 10 mg Generic Tablets prior to the expiration of the '027 and RE'783 patents will infringe each of those patents;

B. A judgment that defendant Aurobindo Pharma USA, Inc.'s knowing and purposeful activities causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 215356, knowing that its submission would constitute direct infringement, induced infringement of the '027 and RE'783 patents;

C. A judgment that the effective date of any FDA approval for Aurobindo to make, use, offer for sale, sell, market, distribute, or import Aurobindo 5 mg and 10 mg

Generic Tablets be no earlier than the dates on which the '027 and RE'783 patents expire, or the later expiration of any exclusivity to which Pfizer is or becomes entitled;

D. A permanent injunction enjoining Aurobindo, 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 Aurobindo 5 mg and 10 mg Generic Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the '027 and RE'783 patents, or the later expiration of any exclusivity to which Pfizer is or becomes entitled;

E. 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;

F. An award of Pfizer's costs and expenses in this action; and

G. 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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