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.	)	
BIOCON LIMITED, BIOCON PHARMA LIMITED and BIOCON PHARMA, 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 Biocon Limited, Biocon Pharma Limited, and Biocon Pharma, Inc. ("Defendants" or "Biocon"), allege as follows:

NATURE OF THE ACTION

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

2. This action arises out of Biocon Pharma, Inc.'s filing of Abbreviated New Drug Application ("ANDA") No. 219442, seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's Xeljanz® XR, 11 mg and 22 mg dosage strengths (tofacitinib citrate extended-release tablets), prior to the expiration of the RE'783 patent. Biocon's proposed extended-release tofacitinib citrate products are referred to herein as "Biocon 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 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. On information and belief, defendant Biocon Limited is a company organized and existing under the laws of India, having its corporate office at 20th KM, Hosur Road, Electronic City, Bangalore 560100, Karnataka, India.

9. On information and belief, defendant Biocon Pharma Limited is a company organized and existing under the laws of India, having its corporate office at 20th KM, Hosur Road, Electronic City, Bangalore 560100, Karnataka, India. On information and belief, Biocon Pharma Limited is a wholly owned subsidiary of Biocon Limited.

10. On information and belief, defendant Biocon Pharma, Inc. is a company organized and existing under the laws of the state of Delaware, having its principal place of business at 485 US Highway 1 South, Building B Suite 305, Iselin, NJ 08830. On information and belief, Biocon Pharma, Inc. is a wholly owned subsidiary of Biocon Pharma Limited. On information and belief, Biocon Limited is the ultimate parent company of Biocon Pharma, Inc. On information and belief, Biocon Pharma, Inc. is the U.S. agent for Biocon Limited and/or Biocon Pharma Limited.

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 by virtue of the fact, *inter alia*, that Biocon Pharma, Inc. is a Delaware corporation; Biocon Pharma, Inc. is a wholly owned subsidiary of Biocon Pharma Limited; and Biocon Limited is the ultimate parent company of Biocon Pharma, Inc.

13. On information and belief, Biocon Limited, directly or through its subsidiaries Biocon Pharma Limited and Biocon Pharma, 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 Biocon Generic XR Tablets.

15. On information and belief, if ANDA No. 219442 is approved, Biocon Generic XR Tablets will, among other things, be marketed and distributed by Biocon in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and/or used by patients in Delaware.

16. Biocon's infringing activities with respect to its filing of ANDA No. 219442 and its intent to commercialize and sell Biocon Generic XR 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.

17. In the alternative, this Court has personal jurisdiction over Biocon Limited and Biocon Pharma Limited under Federal Rule of Civil Procedure 4(k)(2).

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

BACKGROUND

Xeljanz XR

19. The active ingredient in Pfizer's Xeljanz XR product is tofacitinib citrate. Xeljanz XR contains tofacitinib citrate in an amount equivalent to 11 mg or 22 mg of tofacitinib base in extended-release tablets formulated for once-daily administration.

20. 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).

21. 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 XR

22. Pfizer Inc. holds approved New Drug Application ("NDA") No. 208246 for EQ 11 mg and 22 mg base tofacitinib citrate extended-release tablets, which it sells under the registered name Xeljanz XR. The Xeljanz XR tablets are approved for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis.

23. 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 XR NDA.

24. The Orange Book lists the expiration date for the RE'783 patent as December 8, 2025.

25. The Orange Book lists three additional patents for Xeljanz XR that are not at issue: U.S. Patent No. 9,937,181, U.S. Patent No. 10,639,309, and U.S. Patent No. 11,253,523 (all expiring March 14, 2034).

The RE'783 Patent

26. 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.

27. 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.

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

29. 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.

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

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

Biocon's ANDA

32. By letter dated May 13, 2024 (the "Biocon Notice Letter") and received by Pfizer on or around May 14, 2024, Biocon notified Pfizer that it had submitted ANDA No. 219442 to the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Biocon Generic XR Tablets—generic copies of Xeljanz XR (tofacitinib citrate EQ 11 mg and 22 mg base extended-release tablets)—prior to the expiration of the RE'783 patent.

33. The Biocon Notice Letter describes the Biocon Generic XR Tablets as "tofacitinib citrate extended-release oral tablets, 11 mg and 22 mg strengths."

34. The Biocon Notice Letter states that Biocon has filed ANDA No. 219442 seeking approval to "engage in the commercial manufacture, use, or sale" of Biocon Generic XR Tablets prior to the expiration of the RE'783 patent.

35. The Biocon Notice Letter asserts that ANDA No. 219442 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2) alleging that the RE'783 patent is "invalid, unenforceable, and/or not infringed" by Biocon Generic XR Tablets.

36. Attached to the Biocon Notice Letter was Biocon's Detailed Factual and Legal Basis for Biocon's Paragraph IV Certification for Tofacitinib Citrate XR Tablets, 11 mg and 22 mg Strengths ("Biocon's Detailed Statement") asserting the purported factual and legal bases for Biocon's contention that the claims of the RE'783 patent are invalid, unenforceable, 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 Biocon Generic XR Tablets.

37. Biocon's Detailed Statement alleges that all claims of the RE'783 patent are invalid. Biocon's Detailed Statement does not contain a noninfringement argument with respect to the RE'783 patent.

38. On information and belief, Biocon Limited, Biocon Pharma Limited, and Biocon Pharma, Inc. collaborated and acted in concert in the decision to prepare and file and in the preparation and filing of ANDA No. 219442.

39. On information and belief, upon approval of ANDA No. 219442, Biocon will sell and distribute Biocon Generic XR Tablets in the United States.

COUNT I
(Infringement of the RE'783 Patent by Biocon Generic XR Tablets)

40. The allegations of paragraphs 1-39 above are repeated and re-alleged as if set forth fully herein.

41. Pursuant to 35 U.S.C. § 271(e)(2)(A), Biocon Pharma, Inc.'s filing of ANDA No. 219442 seeking approval to market and sell Biocon Generic XR 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. 219442 be a date that is not earlier than the expiration date of the RE'783 patent.

42. Biocon had knowledge of the RE'783 patent when it submitted ANDA No. 219442 to the FDA.

43. On information and belief, upon FDA approval of ANDA No 219442, Biocon intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Biocon Generic XR 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).

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

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

COUNT II
(Biocon Limited's Inducing of Infringement by Biocon Pharma, Inc.)

46. The allegations of paragraphs 1-45 above are repeated and re-alleged as if set forth fully herein.

47. On information and belief, Biocon Limited actively and knowingly caused to be submitted and/or assisted with, participated in, contributed to, and/or directed the submission by Biocon Pharma, Inc. of ANDA No. 219442 to the FDA, knowing of the RE'783 patent.

48. The filing of ANDA No. 219442 by Biocon Pharma, Inc. 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), Biocon Limited induced the infringement of the RE'783 patent by actively and knowingly causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 219442 to the FDA knowing that the submission of ANDA No. 219442 would constitute direct infringement of the RE'783 patent.

COUNT III

(Biocon Pharma Limited's Inducing of Infringement by Biocon Pharma, Inc.)

49. The allegations of paragraphs 1-48 above are repeated and re-alleged as if set forth fully herein.

50. On information and belief, Biocon Pharma Limited actively and knowingly caused to be submitted and/or assisted with, participated in, contributed to, and/or directed the submission by Biocon Pharma, Inc. of ANDA No. 219442 to the FDA, knowing of the RE'783 patent.

51. The filing of ANDA No. 219442 by Biocon Pharma, Inc. 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), Biocon Pharma Limited induced the infringement of the RE'783 patent by actively and knowingly causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 219442 to the FDA knowing that the submission of ANDA No. 219442 would constitute direct infringement of the RE'783 patent.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Biocon Pharma, Inc.'s submission of ANDA No. 219442 was an act of infringement and that Biocon's making, using, offering to sell, selling, or importing Biocon Generic XR Tablets in the United States prior to the expiration of the RE'783 patent will directly infringe that patent;

B. A judgment that Biocon Limited and Biocon Pharma Limited induced infringement of the RE'783 patent by their knowing and purposeful activities causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 219442, knowing that its submission would constitute direct infringement;

C. A judgment that the effective date of any FDA approval for Biocon to make, use, offer for sale, sell, market, distribute, or import Biocon Generic XR 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;

D. A permanent injunction enjoining Biocon, 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 Biocon Generic XR 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;

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

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