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.	)	
ANNORA PHARMA PRIVATE LIMITED and HETERO 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 Annora Pharma Private Limited and Hetero USA, Inc. (collectively "Defendants" or "Annora") allege as follows:

NATURE OF THE ACTION

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

2. This action arises out of Annora Pharma Private Limited's filing of Abbreviated New Drug Application ("ANDA") No. 218123 seeking approval by the United States Food and Drug Administration ("FDA") to sell a generic copy of Pfizer's Xeljanz® (tofacitinib) oral solution (1 mg/mL) prior to the expiration of the RE'783 patent. Annora's ANDA product is referred to hereinafter as "Annora Tofacitinib Oral Solution."

THE PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws 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 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*) organized 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 Annora Pharma Private Limited is a corporation organized and existing under the laws of India, having its principal place of business

at Sy. No. 261, Annaram Village, Gummadidala Mandal, Sangareddy District, Telengana State, 502313, India.

9. On information and belief, defendant Hetero USA, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854. On information and belief, Hetero USA, Inc. is the U.S. agent for Annora Pharma Private Limited.

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 Hetero USA, Inc. is a Delaware corporation.

13. 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 Annora Tofacitinib Oral Solution.

14. On information and belief, if ANDA No. 218123 is approved, Annora Tofacitinib Oral Solution will be, among other things, marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and/or used by patients in Delaware.

15. Annora's infringing activities with respect to its filing of ANDA No. 218123 and its intent to commercialize and sell Annora Tofacitinib Oral Solution have led and/or will lead to foreseeable harm and injury to Plaintiffs, including Pfizer Inc., which is incorporated in Delaware.

16. In the alternative, this Court has jurisdiction over Annora Private Pharma Limited under Federal Rule of Civil Procedure 4(k)(2). Annora Private Pharma Limited has contacts with the United States by, *inter alia*, having filed ANDA No. 218123 with the FDA.

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

BACKGROUND

Xeljanz

18. The active ingredient in Pfizer's Xeljanz product is tofacitinib citrate. Xeljanz contains tofacitinib citrate in an amount equivalent to 1 mg/mL of tofacitinib base in oral solution formulated for twice-daily administration.

19. 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).

20. Tofacitinib 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 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 moderately to severely active ulcerative colitis 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 TNF blockers, and for the treatment of active polyarticular course of juvenile idiopathic arthritis in patients 2 years of age and older who have had an inadequate response or intolerance to TNF blockers.

Orange Book Listing for Xeljanz

21. Pfizer Inc. holds approved New Drug Application ("NDA") No. 213082 for EQ 1 mg/mL base tofacitinib oral solution, which Pfizer sells under the registered name Xeljanz.

22. 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 oral solution NDA.

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

The RE'783 Patent

24. 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 A.

25. 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.

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

27. 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.

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

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

Annora's ANDA

30. By letter dated April 27, 2023 (the "Annora Notice Letter"), and received by Pfizer on or around April 28, 2023, Annora notified Pfizer that it had filed ANDA No. 218123 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Annora Tofacitinib Oral Solution—a generic copy of Xeljanz (tofacitinib citrate EQ 1 mg/mL base oral solution)—prior to the expiration of the RE'783 patent. The Annora Notice Letter describes the Annora Tofacitinib Oral Solution as "Tofacitinib Citrate Solution; Oral, Eq. 1mg/mL Base."

31. The Annora Notice Letter states that ANDA No. 218123 seeks "to obtain approval to engage in the commercial manufacture, use, or sale of" Annora Tofacitinib Oral Solution prior to the expiration of the RE'783 patent.

32. The Annora Notice Letter asserts that ANDA No. 218123 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the RE'783 patent "is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of" Annora Tofacitinib Oral Solution.

33. Attached to the Annora Notice Letter was Annora's Detailed Statement for ANDA No. 218123 ("Annora's Detailed Statement"), asserting the purported factual and legal bases for Annora's contention that the RE'783 patent is invalid and/or will not be infringed by the commercial manufacture, use, or sale of Annora Tofacitinib Oral Solution.

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

35. On information and belief, Annora Pharma Private Limited and Hetero USA, Inc. collaborated and acted in concert in the decision to prepare and file and in the preparation and filing of ANDA No. 218123.

36. On information and belief, upon approval of ANDA No. 218123, Annora will sell and distribute Annora Tofacitinib Oral Solution throughout the United States.

COUNT I
(Infringement of the RE'783 Patent by Annora Tofacitinib Oral Solution)

37. The allegations of paragraphs 1-36 above are repeated and re-alleged as if set forth fully herein.

38. Pursuant to 35 U.S.C. § 271(e)(2)(A), Annora's filing of ANDA No. 218123 seeking approval to market Annora Tofacitinib Oral Solution 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. 218123 be a date which is not earlier than the expiration date of the RE'783 patent.

39. Annora had knowledge of the RE'783 patent when it submitted ANDA No. 218123 to the FDA.

40. On information and belief, upon FDA approval, Annora intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Annora Tofacitinib Oral Solution and will thereby infringe at least claim 4 of the RE'783 patent.

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

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

COUNT II
(Hetero USA, Inc.'s Inducing of Infringement by Annora Pharma Private Limited)

43. The allegations of paragraphs 1-42 above are repeated and re-alleged as if set forth fully herein.

44. On information and belief, Hetero USA, Inc. actively and knowingly caused to be submitted and/or assisted with, participated in, contributed to, and/or directed the submission by Annora Pharma Private Limited of ANDA No. 218123 to the FDA, knowing of the RE'783 patent.

45. The filing of ANDA No. 218123 by Annora Pharma Private Limited 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), Hetero USA, Inc. 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. 218123 to the FDA knowing that the submission of ANDA No. 218123 would constitute direct infringement of the RE'783 patent.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Annora Pharma Private Limited's submission of ANDA No. 218123 was an act of infringement and that Annora's making, using, offering to sell, selling, or importing Annora Tofacitinib Oral Solution prior to the expiration of the RE'783 patent will infringe that patent;

B. A judgment that defendant Hetero 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. 218123, knowing that its submission would constitute direct infringement, induced infringement of the RE'783 patent;

C. A judgment that the effective date of any FDA approval for Annora to make, use, offer for sale, sell, market, distribute, or import Annora Tofacitinib Oral Solution 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 Annora, 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 Annora Tofacitinib Oral Solution, 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

/s/ Megan E. Dellinger

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