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. _____
SINOTHERAPEUTICS INC.,	)	
Defendant	)	

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 Sinotherapeutics Inc. ("Defendant" or "Sinotherapeutics"), allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Sinotherapeutics for infringement of United States Patents Nos. 10,639,309 ("the '309 patent") and 11,253,523 ("the '523 patent") (collectively, the "Patents-in-Suit").

2. This action arises out of Sinotherapeutics' filing of a supplement to Abbreviated New Drug Application ("ANDA") No. 216001, seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's 22 mg Xeljanz® XR (tofacitinib citrate extended-release tablets) prior to the expiration of the Patents-in-Suit. Sinotherapeutics' proposed 22 mg extended-release tofacitinib citrate product is referred to hereinafter as "Sinotherapeutics Generic 22 mg 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 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 Sinotherapeutics Inc. is a company organized and existing under the laws of China, having its principal place of business at 99 Haike Road, Bldg. 3, First Floor, Pudong New District, Shanghai 201210, China.

JURISDICTION AND VENUE

9. 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.

10. This Court has personal jurisdiction over Sinotherapeutics by virtue of the fact that, *inter alia*, Sinotherapeutics has committed a tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Pfizer throughout the United States, including in the State of Delaware. In particular, this suit arises out of Sinotherapeutics' filing of a supplement to ANDA No. 216001 seeking FDA approval to sell Sinotherapeutics Generic 22 mg XR Tablets prior to the expiration of the Patents-in-Suit throughout the United States, including in the State of Delaware.

11. On information and belief, if ANDA No. 216001 is approved, Sinotherapeutics Generic 22 mg XR Tablets will, among other things, be marketed and distributed by Sinotherapeutics in the State of Delaware, prescribed by physicians practicing in the State of Delaware, dispensed by pharmacies located within the State of Delaware, and/or used by patients in the State of Delaware.

12. Sinotherapeutics' infringing activities with respect to its filing of the supplement to ANDA No. 216001 and its intent to commercialize and sell Sinotherapeutics Generic 22 mg XR Tablets prior to the expiration of the Patents-in-Suit have led and/or will lead to foreseeable harm and injury to Pfizer, which is incorporated in Delaware.

13. In the alternative, this Court has personal jurisdiction over Sinotherapeutics under Federal Rule of Civil Procedure 4(k)(2). Sinotherapeutics has contacts with the United States by virtue, *inter alia*, of its filing ANDA No. 216001 and the supplement thereto with the FDA.

14. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391. As a foreign corporation, Sinotherapeutics may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c)(3).

BACKGROUND

Xeljanz XR

15. 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.

16. 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).

17. 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

18. 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. As stated in Pfizer's FDA approved label for Xeljanz ("Xeljanz Label"), Xeljanz XR is approved for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis.

19. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the Patents-in-Suit are listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for the Xeljanz XR NDA.

20. The Orange Book lists the expiration date for the Patents-in-Suit as March 14, 2034.

21. The Orange Book lists two additional patents for the 22 mg strength of Xeljanz XR that are not at issue: U.S. Patent No. 6,965,027 (expiring March 25, 2023) and U.S. Patent No. RE41,783 (expiring December 8, 2025).

The '309 Patent

22. On May 5, 2020, the United States Patent and Trademark Office ("USPTO") issued the '309 patent, titled "Tofacitinib Oral Sustained Release Dosage Forms." The '309 patent is duly and legally assigned to Pfizer Inc. A copy of the '309 patent is attached hereto as Exhibit A.

23. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the '309 patent.

24. C.P. Pharmaceuticals International C.V. conveyed rights under the '309 patent to Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

25. Pfizer Pharmaceuticals LLC has conveyed its rights to the '309 patent to PBG Puerto Rico LLC.

26. Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. has conveyed its rights to the '309 patent to PF PRISM IMB B.V.

The '523 Patent

27. On February 22, 2022, the USPTO issued the '523 patent, titled "Tofacitinib Oral Sustained Release Dosage Forms." The '523 patent is duly and legally assigned to Pfizer Inc. A copy of the '523 patent is attached hereto as Exhibit B.

28. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the '523 patent.

29. C.P. Pharmaceuticals International C.V. conveyed rights under the '523 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 '523 patent to PBG Puerto Rico LLC.

31. Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. has conveyed its rights to the '523 patent to PF PRISM IMB B.V.

Sinotherapeutics' ANDA

32. By letter dated September 26, 2022 (the "Sinotherapeutics Supplemental Notice Letter"), and received by Pfizer on or around September 29, 2022, Sinotherapeutics notified Pfizer that it had submitted a supplement to ANDA No. 216001 to the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Sinotherapeutics Generic 22 mg XR Tablets – generic copies of Xeljanz XR (tofacitinib citrate EQ 22 mg base extended-release tablets) – prior to the expiration of the Patents-in-Suit.

33. The Sinotherapeutics Supplemental Notice Letter describes the Sinotherapeutics Generic 22 mg XR Tablets as "Extended-Release tablet[s]" containing 22 mg of tofacitinib citrate.

34. The Sinotherapeutics Notice Letter states that Sinotherapeutics has filed the supplement to ANDA No. 216001 to obtain "approval to engage in commercial manufacture, use, or sale" of Sinotherapeutics Generic 22 mg XR Tablets prior to the expiration of the Patents-in-Suit.

35. The Sinotherapeutics Notice Letter asserts that ANDA No. 216001 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A) alleging that the Patents-in-Suit "are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of" Sinotherapeutics Generic 22 mg XR Tablets.

36. Attached to the Sinotherapeutics Notice Letter was Sinotherapeutics' "Confidential Detailed Factual and Legal Bases for [Sinotherapeutics'] Paragraph IV Certification that U.S. Patent Nos.: 11,253,523 (expiration 3/14/2034) and 10,639,309 (expiration 3/14/2034) Are Invalid, Unenforceable and/or Will Not Be Infringed" ("Sinotherapeutics' Detailed Statement") asserting the purported factual and legal bases for Sinotherapeutics' contention that the claims of the Patents-in-Suit will not be infringed, literally or under the doctrine of equivalents, by the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Sinotherapeutics Generic 22 mg XR Tablets.

37. Sinotherapeutics' Detailed Statement does not set forth an invalidity argument with respect to any claim of the Patents-in-Suit.

38. On information and belief, upon approval of ANDA No. 216001, Sinotherapeutics will sell and distribute Sinotherapeutics Generic 22 mg XR Tablets in the United States.

COUNT I
(Infringement of the '309 Patent by Sinotherapeutics Generic 22 mg XR Tablets)

39. The allegations of paragraphs 1-38 above are repeated and re-alleged as if set forth fully herein.

40. Pursuant to 35 U.S.C. § 271(e)(2)(A), Sinotherapeutics' filing of a supplement to ANDA No. 216001 seeking approval to market and sell Sinotherapeutics Generic 22 mg XR Tablets before the expiration of the '309 patent was an act of infringement, either literally or through the doctrine of equivalents, of at least claim 1 of the '309 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. 216001 be a date which is not earlier than the expiration date of the '309 patent.

41. Sinotherapeutics had knowledge of the '309 patent when it submitted the supplement to ANDA No. 216001 to the FDA.

42. On information and belief, upon FDA approval of ANDA No 216001, Sinotherapeutics intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Sinotherapeutics Generic 22 mg XR Tablets in the United States and will thereby directly infringe, either literally or through the doctrine of equivalents, at least claim 1 of the '309 patent under 35 U.S.C. § 271(a).

43. The foregoing actions by Sinotherapeutics constitute and/or would constitute infringement of at least claim 1 of the '309 patent.

44. An actual controversy exists relating to Sinotherapeutics' threatened direct infringement of the '309 patent.

45. Pfizer will be substantially and irreparably harmed if Sinotherapeutics is not enjoined from infringing the '309 patent. Pfizer has no adequate remedy at law.

COUNT II

(Infringement of the '523 Patent by Sinotherapeutics Generic 22 mg XR Tablets)

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

47. Pursuant to 35 U.S.C. § 271(e)(2)(A), Sinotherapeutics' filing of a supplement to ANDA No. 216001 seeking approval to market and sell Sinotherapeutics Generic 22 mg XR Tablets before the expiration of the '523 patent was an act of infringement, either literally or through the doctrine of equivalents, of at least claim 50 of the '523 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. 216001 be a date which is not earlier than the expiration date of the '523 patent.

48. Sinotherapeutics had knowledge of the '523 patent when it submitted ANDA No. 216001 to the FDA.

49. On information and belief, upon FDA approval of ANDA No 216001, Sinotherapeutics intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Sinotherapeutics Generic 22 mg XR Tablets in the United States.

50. On information and belief, the proposed labeling and/or package insert submitted with ANDA No. 216001 copies the indications for rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis in Pfizer's Xeljanz Label.

51. The use of Sinotherapeutics Generic 22 mg XR Tablets in accordance with and as directed by Sinotherapeutics' proposed labeling will directly infringe, either literally or through the doctrine of equivalents, at least claim 50 of the '523 patent.

52. On information and belief, Sinotherapeutics intends to actively induce infringement of at least claim 50 of the '523 patent. On information and belief, upon FDA approval, Sinotherapeutics will intentionally encourage acts of direct infringement with knowledge of the '523 patent and knowledge that its acts are encouraging infringement.

53. Unless enjoined by this Court, upon FDA approval, Sinotherapeutics will actively induce infringement of the '523 patent under 35 U.S.C. § 271(b).

54. On information and belief, Sinotherapeutics intends to contribute to the infringement of at least claim 50 of the '523 patent. On information and belief, upon FDA approval, Sinotherapeutics will offer to sell or sell the Sinotherapeutics Generic 22 mg XR Tablets within the United States, or will import the Sinotherapeutics Generic 22 mg XR Tablets into the United States, and will thereby contribute to the infringement of at least claim 50 of the '523 patent with knowledge of the '523 patent and knowledge that its acts will lead to infringement of the '523 patent.

55. On information and belief, Sinotherapeutics knows that Sinotherapeutics Generic 22 mg XR Tablets and the proposed labeling are especially made or adapted for use in infringing at least claim 50 of the '523 patent and that Sinotherapeutics Generic 22 mg XR Tablets and the proposed labeling are not suitable for any substantial noninfringing use.

56. Unless enjoined by this Court, upon FDA approval, Sinotherapeutics will contribute to the infringement of the '523 patent under 35 U.S.C. § 271(c).

57. The foregoing actions by Sinotherapeutics constitute and/or would constitute infringement of at least claim 50 of the '523 patent, active inducement of infringement of at least claim 50 of the '523 patent, and/or contribution to the infringement by others of at least claim 50 of the '523 patent.

58. An actual controversy exists relating to Sinotherapeutics' threatened infringement, active inducement of infringement, and/or contribution to the infringement by others of the '523 patent.

59. Pfizer will be substantially and irreparably harmed if Sinotherapeutics is not enjoined from infringing the '523 patent. Pfizer has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Sinotherapeutics' submission of the supplement to ANDA No. 216001 was an act of infringement and that Sinotherapeutics' making, using, offering to sell, selling, or importing Sinotherapeutics Generic 22 mg XR Tablets in the United States prior to the expiration of the '309 and '523 patents will directly infringe, actively induce infringement, and/or contribute to the infringement of each of those patents;

B. A judgment that the effective date of any FDA approval for Sinotherapeutics to make, use, offer for sale, sell, market, distribute, or import Sinotherapeutics Generic 22 mg XR Tablets into the United States be no earlier than the dates on which the '309 and '523 patents expire, or the later expiration of any exclusivity to which Pfizer is or becomes entitled;

C. A permanent injunction enjoining Sinotherapeutics, 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 Sinotherapeutics Generic 22 mg XR Tablets into the United States, and from inducing or contributing to any of the foregoing, prior to the expiration of the '309 and '523 patents, or the later expiration of any exclusivity to which Pfizer is or becomes entitled;

D. 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;

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

F. Such further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

Jack B. Blumenfeld (#1014)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
mdellinger@morrisnichols.com

Attorneys for Plaintiffs

OF COUNSEL:

Aaron Stiefel
Daniel P. DiNapoli
Michael Sapiro
ARNOLD & PORTER KAYE SCHOLER LLP
250 West 55th Street
New York, NY 10019-9710
(212) 836-8000

Soumitra Deka
DLA PIPER LLP (US)
555 Mission Street, Suite 2400
San Francisco, CA 94105-2933
(415) 836-2500

November 11, 2022