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.	)	
SPECGX LLC,	)	
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 SpecGX LLC ("Defendant" or "SpecGX") allege as follows:

NATURE OF THE ACTION

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

2. This action arises out of SpecGX's filing of Abbreviated New Drug Application ("ANDA") No. 219395 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 RE'783 patent. SpecGX's ANDA products are referred to hereinafter individually as "SpecGX 5 mg Generic Tablets" and "SpecGX 10 mg Generic Tablets" and collectively as "SpecGX 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 66 Hudson Boulevard East, New York, New York 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 (beloten 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 PF PRISM IMB B.V.

8. On information and belief, SpecGX LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 385 Marshall Avenue, Webster Groves, Missouri 63119.

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 SpecGX by virtue of the fact, *inter alia*, that SpecGX is a company organized and existing under the laws of Delaware.

11. On information and belief, if ANDA No. 219395 is approved, SpecGX 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.

12. SpecGX's infringing activities with respect to its filing of ANDA No. 219395 and its intent to commercialize and sell SpecGX 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.

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

BACKGROUND

Xeljanz

14. 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.

15. 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).

16. 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 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 one or more 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, for the treatment of adult patients with moderately to severely active ulcerative colitis ("UC") 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 who have had an inadequate response or intolerance to one or more TNF blockers.

Orange Book Listing for Xeljanz

17. 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.

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

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

The RE'783 Patent

20. 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.

21. 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.

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

23. 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.

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

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

SpecGX's ANDA

26. By letter dated June 25, 2024 (the "SpecGX Notice Letter"), and received by Pfizer on June 26, 2024, SpecGX notified Pfizer that it had filed ANDA No. 219395 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell SpecGX 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 RE'783 patent. The SpecGX Notice Letter describes the SpecGX 5 mg and 10 mg Generic Tablets as "Tofacitinib Tablets, 5 mg and 10 mg."

27. On information and belief, SpecGX 5 mg and 10 mg Generic Tablets will contain tofacitinib, or a pharmaceutically acceptable salt thereof, as the active ingredient.

28. The SpecGX Notice Letter states that ANDA No. 219395 seeks "to obtain approval to engage in the commercial manufacture, use or sale of" SpecGX 5 mg and 10 mg Generic Tablets prior to the expiration of the RE'783 patent.

29. The SpecGX Notice Letter asserts that ANDA No. 219395 contains a "Paragraph IV" certification alleging that the RE'783 patent is "asserted to be invalid, unenforceable, and/or not infringed."

30. Attached to the SpecGX Notice Letter was SpecGX's Detailed Statement of the Factual and Legal Basis for SpecGX's ANDA Paragraph IV Certification of U.S. Pat. No. RE41,783 ("SpecGX's Detailed Statement") asserting the purported factual and legal bases for SpecGX's contention that the RE'783 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of SpecGX's 5 mg and 10 mg Generic Tablets.

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

32. On information and belief, upon approval of ANDA No. 219395, SpecGX will sell and distribute SpecGX 5 mg and 10 mg Generic Tablets throughout the United States.

COUNT I
(Infringement of the RE'783 Patent by SpecGX 5 mg Generic Tablets)

33. The allegations of paragraphs 1-32 are repeated and re-alleged as if set forth fully herein.

34. Pursuant to 35 U.S.C. § 271(e)(2)(A), SpecGX's filing of ANDA No. 219395 seeking approval to market and sell SpecGX 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. 219395 be a date which is not earlier than the expiration date of the RE'783 patent.

35. SpecGX had knowledge of the RE'783 patent when it submitted ANDA No. 219395 to the FDA.

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

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

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

COUNT II
(Infringement of the RE'783 Patent by SpecGX 10 mg Generic Tablets)

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

40. Pursuant to 35 U.S.C. § 271(e)(2)(A), SpecGX's filing of ANDA No. 219395 seeking approval to market and sell SpecGX 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. 219395 be a date which is not earlier than the expiration date of the RE'783 patent.

41. SpecGX had knowledge of the RE'783 patent when it submitted ANDA No. 219395 to the FDA.

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that SpecGX's submission of ANDA No. 219395 was an act of infringement and that SpecGX's making, using, offering to sell, selling or importing SpecGX 5 mg and 10 mg Generic Tablets prior to the expiration of the RE'783 patent will infringe the RE'783 patent;

B. A judgment that the effective date of any FDA approval for SpecGX to make, use, offer for sale, sell, market, distribute, or import SpecGX 5 mg and 10 mg Generic Tablets 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;

C. A permanent injunction enjoining SpecGX, 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 SpecGX 5 mg and 10 mg Generic Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the RE'783, 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 other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

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