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. _____
SLAYBACK PHARMA 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 "Pfizer" or "Plaintiffs") for their Complaint against Slayback Pharma LLC ("Slayback" or "Defendant") allege as follows:

NATURE OF THE ACTION

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

2. This action arises out of Slayback's filing of Abbreviated New Drug Application ("ANDA") No. 216878, seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's Xeljanz® Oral Solution (tofacitinib), 1 mg/mL, prior to the expiration of the RE'783 patent. Slayback's ANDA product is referred to hereinafter as "Slayback Generic Oral Solution."

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 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 Slayback Pharma LLC is a company organized and existing under the laws of the State of Delaware, having its principal place of business at 301 Carnegie Center, Suite 303, Princeton, NJ 08540.

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 and 1338(a).

10. This Court has personal jurisdiction over Slayback by virtue of the fact, *inter alia*, that Slayback is a limited liability company organized and existing under the laws of the State of Delaware.

11. In addition, Slayback has committed a tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs throughout the United States, including in the State of Delaware. In particular, this suit arises out of Slayback's filing of ANDA No. 216878, seeking FDA approval to sell Slayback Generic Oral Solution prior to the expiration of the RE'783 patent throughout the United States, including in the State of Delaware.

12. On information and belief, Slayback works on the development, obtaining of regulatory approval, marketing, sale, and/or distribution of generic drugs, including Slayback Generic Oral Solution, throughout the United States, including in or into Delaware. On information and belief, Slayback manufactures, markets, imports, and sells generic drugs for distribution in Delaware and throughout the United States.

13. On information and belief, if ANDA No. 216878 is approved, Slayback Generic Oral Solution will, among other things, be marketed and distributed by Slayback in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and/or used by patients in Delaware.

14. Slayback's infringing activities with respect to its filing of ANDA No. 216878 and its intent to commercialize and sell Slayback Generic Oral Solution have led and/or will lead to foreseeable harm and injury to Plaintiffs, including Pfizer Inc., which is incorporated in Delaware.

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

BACKGROUND

Xeljanz Oral Solution

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

17. 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).

18. 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 who are intolerant 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 who are intolerant to TNF blockers; for the treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or who are intolerant to TNF blockers; 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 in patients 2 years of age and older who have had an inadequate response or who are intolerant to TNF blockers.

Orange Book Listing for Xeljanz

19. PF PRISM C.V. holds approved New Drug Application ("NDA") No. 213082 for EQ 1 mg/mL base tofacitinib citrate oral solution, which Pfizer sells under the registered name Xeljanz.

20. 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 NDA.

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

The RE'783 Patent

22. 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.

23. 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.

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

25. 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.

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

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

Slayback's ANDA

28. By Letter "re: Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act for U.S. Patent No. RE 41,783 (NDA No. 213082)," dated January 13, 2022 (the "Slayback Notice Letter"), and received by Pfizer on January 14, 2022, Slayback notified Pfizer that it had filed ANDA No. 216878 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Slayback Generic Oral Solution—a generic version of Xeljanz Oral Solution (tofacitinib citrate EQ 1 mg/mL oral solution)—prior to the expiration of the RE'783 patent. The Slayback Notice Letter describes Slayback Generic Oral Solution as "tofacitinib oral solution, 1 mg/ml" and the active ingredient in Slayback Generic Oral Solution as "tofacitinib citrate."

29. The Slayback Notice Letter states that ANDA No. 216878 seeks "to obtain approval to engage in the commercial manufacture, use or sale of" Slayback Generic Oral Solution prior to the expiration of the RE'783 patent.

30. The Slayback Notice Letter asserts that ANDA No. 216878 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the RE'783 patent "will not be infringed by the commercial manufacture, use, importation, offer for sale or sale of [Slayback Generic Oral Solution], and/or that the claims of [the RE'783 patent] are invalid or unenforceable."

31. Attached to the Slayback Notice Letter was Slayback's "Detailed Factual and Legal Basis for Slayback's Certification that U.S. Patent No. RE41,783 Is Invalid, Unenforceable, and/or Will Not Be Infringed by the Manufacture, Use or Sale of Slayback's Proposed ANDA Product As Defined by ANDA No. 216878" ("Slayback's Detailed Statement"). Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), Slayback's Detailed Statement asserts the

purported factual and legal bases for Slayback's contention that the RE'783 patent is invalid and/or will not be infringed by the commercial manufacture, use, or sale of Slayback Generic Oral Solution.

32. Slayback's Detailed Statement alleges that Slayback Generic Oral Solution will not infringe claim 3 of the RE'783 patent, but does not contain a noninfringement argument as to claims 1, 2 or 4 of the RE'783 patent. Slayback's Detailed Statement further alleges that all claims of the RE'783 patent are invalid.

33. On information and belief, upon approval of ANDA No. 216878, Slayback will sell and distribute Slayback Generic Oral Solution throughout the United States.

COUNT I
(Infringement of the RE'783 Patent by Slayback Generic Oral Solution)

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

35. Pursuant to 35 U.S.C. § 271(e)(2)(A), Slayback's filing of ANDA No. 216878 seeking approval to market Slayback Generic 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. 216878 be a date which is not earlier than the expiration date of the RE'783 patent.

36. Slayback had knowledge of the RE'783 patent when it submitted ANDA No. 216878 to the FDA.

37. Slayback Oral Solution infringes at least claim 4 of the RE'783 patent.

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

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

40. Pfizer will be substantially and irreparably harmed if Slayback 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 Slayback's submission of ANDA No. 216878 was an act of infringement and that Slayback's making, using, offering to sell, selling, or importing Slayback Generic Oral Solution 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 Slayback to make, use, offer for sale, sell, market, distribute, or import Slayback Generic 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;

C. A permanent injunction enjoining Slayback, 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 Slayback Generic 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;

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

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