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. _____
ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD.,	)	
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 Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively "Defendants" or "Zydus"), allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Zydus for infringement of United States Patent No. RE41,783 ("the RE'783 patent") and United States Patent No. 6,965,027 ("the '027 patent").

2. This action arises out of Zydus's filing of Abbreviated New Drug Application ("ANDA") No. 214264 as amended, seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's 22 mg Xeljanz® XR (tofacitinib extended-release tablets) prior to the expiration of, *inter alia*, the RE'783 and'027 patents. Zydus's proposed 22 mg tofacitinib product is referred to hereinafter as "Zydus 22 mg 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 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 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 PRISM IMB B.V. is a private limited liability company (*besloten vennootschap*) 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 Zydus Pharmaceuticals (USA) Inc. is a company organized and existing under the laws of New Jersey, having its principal place of business at 73 Route 31 N., Pennington, NJ 08534.

9. On information and belief, defendant Cadila Healthcare Ltd. is a company organized and existing under the laws of India, having its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Kohraj (Gandhinigar), Nr. Vaishnodevi Circle, Sarkhej-Gandhinagar Highway, Ahmedabad, Gujurat, India 382481.

10. On information and belief, Cadila Healthcare Ltd. is the ultimate parent company of Zydus Pharmaceuticals (USA) Inc. On information and belief, Zydus Pharmaceuticals (USA) Inc. is the U.S. agent for Cadila Healthcare Ltd.

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, and venue is proper in this action.

13. Zydus Pharmaceuticals (USA) Inc. is a wholly-owned subsidiary of Cadila Healthcare Ltd. (https://zyduscadila.com/public/pdf/financial/annual/Annual-Report-2019-2020.pdf, at 56, last accessed on Feb. 3, 2021). On information and belief, Cadila Healthcare Ltd., directly or through its subsidiary Zydus Pharmaceuticals (USA) 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 Zydus 22 mg Generic XR Tablets.

15. In the alternative, this Court has jurisdiction over Cadila Healthcare Ltd. under Federal Rule of Civil Procedure 4(k)(2). Cadila Healthcare Ltd. has contacts with the United States by, *inter alia*, having caused the filing of ANDA No. 214264 as amended with the FDA.

BACKGROUND

Xeljanz XR

16. 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.

17. 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).

18. 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

19. 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. The 22 mg Xeljanz XR tablets are approved for the treatment of ulcerative colitis.

20. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the RE'783 and '027 patents are listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for the Xeljanz XR NDA.

21. The Orange Book lists the expiration date for the RE'783 patent as December 8, 2025, and the expiration date for the '027 patent as March 25, 2023.

22. The Orange Book lists one additional patent for the 22 mg strength of Xeljanz XR that is not at issue: U.S. Patent No. 10,639,309, expiring March 14, 2034.

The RE'783 Patent

23. 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.

24. 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.

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

26. 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.

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

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

The '027 Patent

29. On November 15, 2005, the USPTO issued the '027 patent, titled "Crystalline 3-{4-methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-amino]-piperidin-1-yl}-3-oxo-propionitrile citrate." The '027 patent is duly and legally assigned to Pfizer Inc. A copy of the '027 patent is attached hereto as Exhibit B.

30. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the '027 patent.

31. C.P. Pharmaceuticals International C.V. conveyed rights under the '027 patent to Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

32. Pfizer Pharmaceuticals LLC has conveyed its rights to the '027 patent to PBG Puerto Rico LLC.

33. Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. has conveyed its rights to the '027 patent to PF PRISM IMB B.V.

Zydus's ANDA

34. By letter dated January 7, 2021 (the "Zydus Notice Letter"), and received by Pfizer on January 8, 2021, Zydus notified Pfizer that it had submitted an amendment to ANDA No. 214264 to the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Zydus 22 mg Generic XR Tablets – generic copies of Xeljanz XR (tofacitinib citrate EQ 22 mg base extended-release tablets) – prior to the expiration of, *inter alia*, the RE'783 and '027

patents. The Zydus Notice Letter describes the Zydus 22 mg Generic XR Tablets as "tofacitinib extended-release tablets, 22 mg."

35. On information and belief, Zydus 22 mg Generic XR Tablets will contain tofacitinib citrate as the active ingredient.

36. On information and belief, Cadila Healthcare Ltd. holds DMF No. 030531 for tofacitinib citrate.

37. The Zydus Notice Letter states that Zydus has amended ANDA No. 214264 "to obtain approval to engage in the commercial manufacture, use or sale of" Zydus 22 mg Generic XR Tablets prior to the expiration of, *inter alia*, the RE'783 and '027 patents.

38. The Zydus Notice Letter asserts that ANDA No. 214264 as amended contains a "Paragraph IV" certification under 21 U.S.C. §§ 355(j)(2)(A)(vii)(IV) alleging that "no valid and enforceable claim of [, *inter alia*, either the RE'783 patent or the '027 patent] will be infringed by the manufacture, use, sale, or offer to sell within, or importation into, the United States of" Zydus 22 mg Generic XR Tablets.

39. Attached to the Zydus Notice Letter was Zydus's Detailed Factual and Legal Bases in Support of Its Paragraph IV Certification for Tofacitinib Extended-Release Tablets, 22 MG ("Zydus's Detailed Statement") asserting the purported factual and legal bases for Zydus's contention that no valid and enforceable claim of, *inter alia*, either the RE'783 patent or the '027 patent will be infringed by the commercial manufacture, use, or sale of Zydus 22 mg Generic XR Tablets.

40. Zydus's Detailed Statement alleges, *inter alia,* that all claims of the RE'783 and '027 patents are invalid. Other than with respect to claim 5 of the '027 patent, Zydus's Detailed

Statement does not contain a noninfringement argument with respect to either the RE'783 patent or the '027 patent.

41. On information and belief, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. collaborated and acted in concert in the decision to prepare and file and in the preparation and filing of ANDA No. 214264 as amended.

42. On information and belief, upon approval of ANDA No. 214264 as amended, Zydus will sell and distribute Zydus 22 mg Generic XR Tablets in the United States.

COUNT I
(Infringement of the RE'783 Patent by Zydus 22 mg Generic XR Tablets)

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

44. Pursuant to 35 U.S.C. § 271(e)(2)(A), Zydus Pharmaceuticals (USA) Inc.'s filing of ANDA No. 214264 as amended, seeking approval to market Zydus 22 mg Generic XR Tablets before the expiration of the RE'783 patent 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. 214264 as amended be a date which is not earlier than the expiration date of the RE'783 patent.

45. Zydus had knowledge of the RE'783 patent when it submitted ANDA No. 214264 as amended to the FDA.

46. On information and belief, upon FDA approval, Zydus intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Zydus 22 mg Generic XR Tablets and will thereby infringe at least claim 4 of the RE'783 patent.

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

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

COUNT II
(Infringement of the '027 Patent by Zydus 22 mg Generic XR Tablets)

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

50. Pursuant to 35 U.S.C. § 271(e)(2)(A), Zydus Pharmaceuticals (USA) Inc.'s filing of ANDA No. 214264 as amended, seeking approval to market Zydus 22 mg Generic XR Tablets before the expiration of the '027 patent is an act of infringement of at least claim 1 of the '027 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. 214264 as amended be a date which is not earlier than the expiration date of the '027 patent.

51. Zydus had knowledge of the '027 patent when it submitted ANDA No. 214264 as amended to the FDA.

52. On information and belief, upon FDA approval, Zydus intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Zydus 22 mg Generic XR Tablets and will thereby infringe at least claim 1 of the '027 patent.

53. The foregoing actions by Zydus constitute and/or would constitute infringement of at least claim 1 of the '027 patent.

54. Pfizer will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '027 patent. Pfizer has no adequate remedy at law.

COUNT III
(Cadila Healthcare Ltd.'s Inducing of Infringement by Zydus Pharmaceuticals (USA) Inc.)

55. The allegations of paragraphs 1-54 above are repeated and re-alleged as if set forth fully herein.

56. On information and belief, Cadila Healthcare Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission by Zydus Pharmaceuticals (USA) Inc. of ANDA No. 214264 as amended to the FDA, knowing of the RE'783 and '027 patents.

57. The filing by Zydus Pharmaceuticals (USA) Inc. of ANDA No. 214264 as amended, constituted direct infringement under 35 U.S.C. § 271(e)(2)(A). On information and belief, under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Cadila Healthcare Ltd. induced the infringement of the RE'783 and '027 patents by actively and knowingly causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 214264 as amended, to the FDA knowing that the submission of ANDA No. 214264 as amended would constitute direct infringement of the RE'783 and '027 patents.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Zydus Pharmaceuticals (USA) Inc.'s submission of ANDA No. 214264 as amended, was an act of infringement and that Zydus's making, using, offering to sell, selling, or importing Zydus 22 mg Generic XR Tablets prior to the expiration of the RE'783 and '027 patents will infringe each of those patents;

B. A judgment that Cadila Healthcare Ltd.'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. 214264 as amended, knowing that its

submission would constitute direct infringement, induced infringement of the RE'783 and '027 patents;

C. A judgment that the effective date of any FDA approval for Zydus to make, use, offer for sale, sell, market, distribute, or import Zydus 22 mg Generic XR Tablets be no earlier than the dates on which the RE'783 and '027 patents expire, or the later expiration of any exclusivity to which Pfizer is or becomes entitled;

D. A permanent injunction enjoining Zydus, 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 Zydus 22 mg Generic XR Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the RE'783 and '027 patents, 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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