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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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.,	)	**COMPLAINT**
Defendants.	)	

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:

THE PARTIES

1. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017.

2. 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 235 East 42nd Street, New York, New York 10017, and Pfizer Inc. is the ultimate parent company of C.P. Pharmaceuticals International C.V.

3. 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, and registered at the Trade Register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456, and Pfizer Inc. is the ultimate parent company of PF PRISM C.V.

4. 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, and Pfizer Inc. is the ultimate parent company of PBG Puerto Rico LLC.

5. Plaintiff PRISM IMB B.V. is a private limited liability company (*besloten vennootschap*) under Dutch law, 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 with the Dutch Trade Register under number 60558814, and Pfizer Inc. is the ultimate parent company of PF Prism IMB B.V.

6. 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 Tower, Satellite Cross Roads, Sarkhej-Gandhinagar Highway, Ahmedabad, India, 380 015.

7. 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. 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.

NATURE OF THE ACTION

8. This is an action by Pfizer against Zydus for infringement of United States Patent No. 6,965,027 ("the '027 patent"), United States Patent No. 7,301,023 ("the '023 patent"), and United States Reissue Patent No. RE41,783 ("the RE'783 patent").

9. This action arises out of Zydus Pharmaceuticals (USA) Inc.'s filing of Abbreviated New Drug Application ("ANDA") No. 209829 seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's Xeljanz® prior to the expiration of the '027, '023, and RE'783 patents.

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 by virtue of the facts, *inter alia*, that Zydus Pharmaceuticals (USA) Inc. is a New Jersey corporation and Cadila Healthcare Ltd. is the ultimate parent company of Zydus Pharmaceuticals (USA) Inc.

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

13. 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 Zydus Pharmaceuticals (USA) Inc.'s ANDA with the FDA.

BACKGROUND

Xeljanz

14. 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 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 had an inadequate response or who are intolerant to TNF blockers.

15. The active ingredient in Xeljanz is tofacitinib citrate. Xeljanz contains tofacitinib citrate in an amount equivalent to 10 mg of tofacitinib base in a tablet formulated for twice-daily administration.

16. 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).

Orange Book Listing for Xeljanz

17. PF PRISM C.V. holds approved New Drug Application ("NDA") No. 203214 for 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, the '027, '023, and RE'783 patents are 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 '027 patent as March 25, 2023, the '023 patent as May 23, 2022, and the RE'783 patent as December 8, 2025. The '023 patent is subject to a terminal disclaimer relative to the RE'783 patent and therefore expires on December 8, 2020.

20. The Orange Book also lists four additional patents for Xeljanz that are not at issue: U.S. Patent Nos. 6,956,041 (expiring December 8, 2020); 7,091,208 (expiring December 8, 2020); 7,265,221 (expiring December 8, 2020); and 7,842,699 (expiring December 8, 2020).

The '027 Patent

21. 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 A.

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

23. 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.

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

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

The ’023 Patent

26. On November 27, 2007, the USPTO issued the ’023 patent, titled “Chiral Salt Resolution.” The ’023 patent is duly and legally assigned to Pfizer Inc. A copy of the ’023 patent is attached hereto as Exhibit B.

27. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the ’023 patent.

28. C.P. Pharmaceuticals International C.V. conveyed rights under the ’023 patent to Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

29. Pfizer Pharmaceuticals LLC has conveyed its rights to the ’023 patent to PBG Puerto Rico LLC.

30. Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. has conveyed its rights to the ’023 patent to PF PRISM IMB B.V.

The RE’783 Patent

31. 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 C.

32. 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.

33. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the RE’783 patent.

34. 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.

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

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

Zydus's ANDA

37. By letter dated January 31, 2020 (the "Zydus Notice Letter") and received by Pfizer on February 3, 2020, Zydus notified Pfizer that it had amended ANDA No. 209829 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act ("FDCA") to market and sell Zydus 10 mg Generic Tablets -- generic copies of Xeljanz (tofacitinib citrate EQ 10 mg tablets) -- prior to the expiration of the '027, '023, and RE'783 patents.

38. The Zydus Notice Letter asserts that ANDA No. 209829 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(B)(iv) alleging that "no valid claim of [the RE'783 patent, the '027 patent, and the '023 patent] will be infringed by the manufacture, use, or sales of" Zydus 10 mg Generic Tablets.

39. On information and belief Zydus 10 mg Generic Tablets will contain tofacitinib citrate as the active ingredient.

40. On information and belief Cadila Healthcare Ltd. holds DMF No. 30531 for tofacitinib citrate.

41. The Zydus Notice Letter states that ANDA No. 209829 seeks "to obtain approval to engage in the commercial manufacture, use or sale of" Zydus 10 mg Generic Tablets prior to the expiration of the '027, '023, and RE'783 patents.

42. Attached to the Zydus Notice Letter was Zydus's Detailed Factual and Legal Basis in Support of its Paragraph IV Certification for Tofacitinib Tablets, 10mg ("Zydus's Detailed Statement") asserting the purported factual and legal bases for Zydus's contention that the '027, '023, and RE'783 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Zydus 10 mg Generic Tablets.

43. Zydus's Detailed Statement alleges that all claims of the '027, '023, and RE'783 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 the '027, '023, and RE'783 patents, other than that all claims are invalid.

44. On information and belief, Cadila Healthcare Ltd. and Zydus Pharmaceuticals (USA) Inc. collaborated and acted in concert in the decision to prepare and file and in the preparation and filing of ANDA No. 209829.

45. On information and belief, upon approval of ANDA No. 209829, Zydus will distribute Zydus 10 mg Generic Tablets throughout the United States.

COUNT I
(Infringement of the '027 Patent by Zydus 10 mg Generic 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), Zydus Pharmaceuticals (USA) Inc.'s filing of ANDA No. 209829 seeking approval to market Zydus 10 mg Generic Tablets 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. 209829 be a date which is not earlier than the expiration date of the '027 patent.

48. Zydus had knowledge of the '027 patent when it submitted ANDA No. 209829 to the FDA.

49. On information and belief, upon FDA approval, Zydus intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Zydus 10 mg Generic Tablets and will thereby infringe at least claim 1 of the '027 patent.

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

51. 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 II
(Infringement of the '023 Patent by Zydus 10 mg Generic Tablets)

52. The allegations of paragraphs 1-51 above are repeated and re-alleged as if set forth fully herein.

53. Pursuant to 35 U.S.C. § 271(e)(2)(A), Zydus Pharmaceuticals (USA) Inc.'s filing of ANDA No. 209829 seeking approval to market Zydus 10 mg Generic Tablets is an act of infringement of claim 1 of the '023 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. 209829 be a date which is not earlier than the expiration date of the '023 patent.

54. Zydus had knowledge of the '023 patent when it submitted ANDA No. 209829 to the FDA.

55. On information and belief, upon FDA approval, Zydus intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Zydus 10 mg Generic Tablets and will thereby infringe claim 1 of the '023 patent.

56. The foregoing actions by Zydus constitute and/or would constitute infringement of claim 1 of the ’023 patent.

57. Pfizer will be substantially and irreparably harmed if Zydus is not enjoined from infringing the ’023 patent. Pfizer has no adequate remedy at law.

COUNT III
(Infringement of the RE’783 Patent by Zydus 10 mg Generic Tablets)

58. The allegations of paragraphs 1-57 above are repeated and re-alleged as if set forth fully herein.

59. Pursuant to 35 U.S.C. § 271(e)(2)(A), Zydus Pharmaceuticals (USA) Inc.’s filing of ANDA No. 209829 seeking approval to market Zydus 10 mg Generic Tablets is an act of infringement of one or more claims 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. 209829 be a date which is not earlier than the expiration date of the RE’783 patent.

60. Zydus had knowledge of the RE’783 patent when it submitted ANDA No. 209829 to the FDA.

61. On information and belief, upon FDA approval, Zydus intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Zydus 10 mg Generic Tablets and will thereby infringe at least claims 3 and 4 of the RE’783 patent.

62. The foregoing actions by Zydus constitute and/or would constitute infringement of at least claims 3 and 4 of the RE’783 patent.

63. 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.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Zydus Pharmaceuticals (USA) Inc.'s submission of ANDA No. 209829 was an act of infringement and that Zydus's making, using, offering to sell, selling, or importing Zydus 10 mg Generic Tablets prior to the expiration of the '027, '023, and RE'783 patents will infringe each of those patents;

B. A judgment that the effective date of any FDA approval for Zydus to make, use, offer for sale, sell, market, distribute, or import the Zydus 10 mg Generic Tablets be no earlier than the dates on which the '027, '023, and RE'783 patents expire, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

C. 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 10 mg Generic Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the '027, '023, and RE'783 patents, or any later expiration of 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.

Dated: February 28, 2020

Respectfully submitted,

By: /s/ John M. Fietkiewicz
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**Pro hac vice* application to be filed