IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PF PRISM C.V., C.P. PHARMACEUTICALS INTERNATIONAL C.V., PFIZER PHARMACEUTICALS LLC, and PFIZER PFE IRELAND PHARMACEUTICALS HOLDING 1 B.V.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 17-158 (LPS) CONSOLIDATED
ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD.,	)	
Defendants.	)	

AMENDED COMPLAINT

Pfizer Inc., PF PRISM C.V., C.P. Pharmaceuticals International C.V., Pfizer Pharmaceuticals LLC, and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. (collectively "Plaintiffs" or "Pfizer"), for their Amended Complaint against Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively "Zydus"), allege as follows:

NATURE OF THE ACTION

1. 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").

2. 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.

THE PARTIES

3. 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.

4. 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. Pfizer Inc. is the ultimate parent company of PF PRISM C.V.

5. 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. Pfizer Inc. is the ultimate parent company of C.P. Pharmaceuticals International C.V.

6. Plaintiff Pfizer Pharmaceuticals LLC is a limited liability company organized and existing under the laws of Delaware and having its principal place of business at Bo. Carmelitas, Road 689, Km. 1.9, Vega Baja, Puerto Rico. Pfizer Inc. is the ultimate parent company of Pfizer Pharmaceuticals LLC.

7. Plaintiff Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. is a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) 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. Pfizer Inc. is the ultimate parent company of Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

8. 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.

9. 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.

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

12. This Court has personal jurisdiction over Zydus.

13. This Court has personal jurisdiction over Zydus by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including in Delaware. In particular, this suit arises out of Zydus Pharmaceuticals (USA) Inc.'s filing of ANDA No. 209829 seeking FDA approval to sell 5 mg tofacitinib tablets ("Zydus Generic Tablets") prior to the expiration of the '027, '023, and RE'783 patents, throughout the United States, including in Delaware.

14. On information and belief, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. are agents of each other and/or work in concert with each other on the development, obtaining of regulatory approval, marketing, sale, and/or distribution of generic

drugs, including Zydus Generic Tablets, throughout the United States, including in or into Delaware. 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.

15. On information and belief, if ANDA No. 209829 is approved, Zydus 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.

16. Zydus' infringing activities with respect to its filing of ANDA No. 209829 and its intent to commercialize and sell Zydus Generic Tablets has led and/or will lead to foreseeable harm and injury to Plaintiffs, including Pfizer Inc., which is incorporated in Delaware.

17. On information and belief, Zydus maintains substantial, systematic, and continuous and systemic contacts throughout the United States, including with Delaware. Zydus' website states that it is "one of the top 10 U.S. generic companies in total prescriptions dispensed" and has been recognized as "one of the fastest growing pharmaceutical companies in the U.S." (http://www.zydususa.com/company-overview/ (last accessed June 14, 2018)). Zydus' website lists over 94 generic pharmaceutical products. (http://www.zydususa.com/products/ (last accessed June 14, 2018)).

18. Zydus Pharmaceuticals (USA) Inc. has previously availed itself of the United States District Court for the District of Delaware by consenting to the court's jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., Genzyme Corp. et al. v. Zydus Pharm. (USA) Inc.*, No. 1:16-cv-00540 (D. Del.) (D.I. 10); *Upsher-Smith Labs. Inc. v. Zydus Pharm. (USA) Inc. et al.*, No. 1:16-cv-00248 (D. Del.) (D.I. 15); *UCB Inc. et*

al. v. Zydus Pharm. (USA) Inc. et al., No. 1:13-cv-01220-LPS (D. Del.) (D.I. 12); *UCB Inc. et al. v. Accord Healthcare Inc. et al.*, No. 1:13-cv-01206-LPS (D. Del.) (D.I. 99); *Pfizer Inc. et al. v. Zydus Pharm. (USA) Inc. et al.*, No. 1:12-cv-00818-SLR (D. Del.) (D.I. 9); *Pfizer Inc. et al. v. Zydus Pharm. (USA) Inc. et al.*, No. 1:12-cv-00808-SLR (D. Del.) (D.I. 65).

19. 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®

20. 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.

21. The active ingredient in Xeljanz® is tofacitinib citrate. Xeljanz® contains tofacitinib citrate in an amount equivalent to 5 mg of tofacitinib base in a tablet formulated for twice-daily administration.

22. 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®

23. PF PRISM C.V. holds approved New Drug Application ("NDA") No. 203214 for EQ 5 mg base tofacitinib citrate tablets, which Pfizer sells under the registered name Xeljanz®.

24. 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.

25. 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, 2020. 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.

26. The Orange Book also lists three 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).

The ’027 Patent

27. 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.

28. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the ’027 patent.

29. 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 Coöperatief U.A.

30. Pursuant to a Deed of Conversion and Amendment to Articles of Association dated December 30, 2017, Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A. changed its name to Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

The ’023 Patent

31. 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.

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

33. 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 Coöperatief U.A.

34. Pursuant to a Deed of Conversion and Amendment to Articles of Association dated December 30, 2017, Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A. changed its name to Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

The RE’783 Patent

35. 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.

36. 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.

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

38. 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 Coöperatief U.A.

39. Pursuant to a Deed of Conversion and Amendment to Articles of Association dated December 30, 2017, Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A. changed its name to Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

Zydus' ANDA

40. By letter dated January 19, 2017 (the "Zydus Notice Letter") and received by Pfizer on January 20, 2017, Zydus notified Pfizer that it had filed ANDA No. 209829 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act ("FDCA") to market and sell Zydus Generic Tablets prior to the expiration of the '027, '023, and RE'783 patents.

41. The Zydus Notice Letter asserts that ANDA No. 209829 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(1) and (j)(2)(A) alleging that "no valid claim of the RE'783 patent, the '027 patent and the '023 patent will be infringed by" Zydus Generic Tablets.

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

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

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

45. Attached to the Zydus Notice Letter was Zydus' Detailed Statement ("Zydus' Detailed Statement") asserting the purported factual and legal bases for Zydus' 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 Generic Tablets.

46. Zydus’ 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’ 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.

47. 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.

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

COUNT I
(Infringement of the ’027 Patent by Zydus Generic 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. 209829 seeking approval to market Zydus Generic Tablets is an act of infringement of one or more claims 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.

51. Zydus had knowledge of the ’027 patent when it submitted ANDA No. 209829 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 Generic 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 II
(Infringement of the ’023 Patent by Zydus Generic Tablets)

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

56. 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 Generic Tablets is an act of infringement of one or more claims 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.

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

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

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

60. 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 Generic Tablets)

61. The allegations of paragraphs 1-60 above are repeated and re-alleged as if set forth fully herein.

62. 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 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.

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

64. On information and belief, upon FDA approval Zydus intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Zydus Generic Tablets and will thereby infringe at least claim 1 of the RE’783 patent.

65. The foregoing actions by Zydus constitute and/or would constitute infringement of at least claim 1 of the RE’783 patent.

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

67. The allegations of paragraphs 1-66 above are repeated and re-alleged as if set forth fully herein.

68. 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. 209829 to the FDA, knowing of the '027, '023, and RE'783 patents.

69. The filing of ANDA No. 209829 by Zydus Pharmaceuticals (USA) Inc. constituted direct infringement under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Cadila Healthcare Ltd. induced the infringement of the '027, '023, and RE'783 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. 209829 to the FDA knowing that the submission of ANDA No. 209829 would constitute direct infringement of the '027, '023, and RE'783 patents.

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' making, using, offering to sell, selling or importing Zydus Generic Tablets prior to the expiration of the '027, '023, and RE'783 patents will infringe each of those patents;

B. A judgment that defendant 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. 209829, knowing that its submission would constitute direct infringement, induced infringement of the ’027, ’023, and RE’783 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 the Zydus 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;

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 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;

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.

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/s/ Maryellen Noreika

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