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.	)	
MICRO LABS, LTD. and MICRO LABS USA INC.,	)	
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 Micro Labs, Ltd. and Micro Labs USA Inc. (collectively "Defendants" or "Micro Labs") allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Micro Labs 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 Micro Labs, Ltd.'s filing of Abbreviated New Drug Application ("ANDA") No. 209738 as amended, seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's 10 mg Xeljanz® (tofacitinib) tablets prior to the expiration of the RE'783 and '027 patents. Micro Labs' proposed 10 mg tofacitinib product is referred to hereinafter as "Micro Labs 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 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 PF 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 Micro Labs, Ltd. is a company organized and existing under the laws of India, having its principal place of business at 31 Race Course Road, Bangalore, India 560 001.

9. On information and belief, defendant Micro Labs USA Inc. is a company organized and existing under the laws of New Jersey, having its principal place of business at 106 Allen Road, Suite 102, Basking Ridge, NJ 07920.

10. On information and belief, Micro Labs, Ltd. is the ultimate parent company of Micro Labs USA Inc. On information and belief, Micro Labs USA Inc. is the U.S. agent for Micro Labs, 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 in that counsel for Micro Labs has represented to Pfizer that for the purposes of this litigation Micro Labs will not object to personal jurisdiction or venue in this judicial district.

BACKGROUND

Xeljanz

13. The active ingredient in Pfizer's Xeljanz product is tofacitinib citrate. Pfizer markets Xeljanz tablets that contain tofacitinib citrate in an amount equivalent to 10 mg of tofacitinib base.

14. 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).

15. 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 ulcerative colitis who have had an inadequate response or who are intolerant to TNF blockers.

Orange Book Listing for Xeljanz

16. PF PRISM C.V. holds approved New Drug Application ("NDA") No. 203214 for, *inter alia*, EQ 10 mg base tofacitinib citrate tablets, which Pfizer sells under the registered name Xeljanz. The 10 mg Xeljanz tablets are approved for the treatment of ulcerative colitis.

17. 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 NDA.

18. 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.

The RE'783 Patent

19. 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.

20. 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.

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

22. 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.

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

24. 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

25. 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.

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

27. 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.

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

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

Micro Labs' ANDA

30. By letter dated February 1, 2021 (the "Micro Labs Notice Letter"), and received by Pfizer on February 2, 2021, Micro Labs notified Pfizer that it had submitted to the FDA an amendment to ANDA No. 209738, seeking approval under the Federal Food, Drug and Cosmetic

Act to market and sell Micro Labs 10 mg Generic Tablets -- generic copies of Xeljanz (tofacitinib citrate EQ 10 mg tablets) -- prior to the expiration of the RE'783 and '027 patents.

31. On information and belief, Micro Labs 10 mg Generic Tablets will contain tofacitinib citrate as the active ingredient.

32. On information and belief, Micro Labs, Ltd. holds DMF No. 30621 for tofacitinib citrate.

33. The Micro Labs Notice Letter states that Micro Labs has amended ANDA No. 209738 "to obtain approval to engage in the commercial manufacture, use or sale of" Micro Labs 10 mg Generic Tablets prior to the expiration of the RE'783 and '027 patents.

34. The Micro Labs Notice Letter asserts that ANDA No. 209738 as amended contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A) alleging that the RE'783 and '027 patents "are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of" Micro Labs 10 mg Generic Tablets.

35. Attached to the Micro Labs Notice Letter was Micro Labs' Detailed Statement for ANDA 209738 ("Micro Labs' Detailed Statement") asserting the purported factual and legal bases for Micro Labs' contention that the RE'783 and '027 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Micro Labs 10 mg Generic Tablets.

36. Micro Labs' Detailed Statement alleges that all claims of the RE'783 and '027 patents are invalid. Micro Labs' Detailed Statement does not contain a noninfringement argument with respect to either the RE'783 patent or the '027 patent.

37. On information and belief, Micro Labs, Ltd. and Micro Labs USA Inc. collaborated and acted in concert in the decision to prepare and file and in the preparation and filing of ANDA No. 209738 as amended.

38. On information and belief, upon approval of ANDA No. 209738 as amended, Micro Labs will sell and distribute Micro Labs 10 mg Generic Tablets throughout the United States.

COUNT I
(Infringement of the RE'783 Patent by Micro Labs 10 mg Generic Tablets)

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

40. Pursuant to 35 U.S.C. § 271(e)(2)(A), Micro Labs, Ltd.'s filing of ANDA No. 209738 as amended, seeking approval to market Micro Labs 10 mg Generic 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. 209738 as amended be a date which is not earlier than the expiration date of the RE'783 patent.

41. Micro Labs had knowledge of the RE'783 patent when it submitted ANDA No. 209738 as amended to the FDA.

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

43. The foregoing actions by Micro Labs 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 Micro Labs is not enjoined from infringing the RE'783 patent. Pfizer has no adequate remedy at law.

COUNT II
(Infringement of the '027 Patent by Micro Labs 10 mg Generic Tablets)

45. The allegations of paragraphs 1-44 above are repeated and re-alleged as if set forth fully herein.

46. Pursuant to 35 U.S.C. § 271(e)(2)(A), Micro Labs, Ltd.'s filing of ANDA No. 209738 as amended, seeking approval to market Micro Labs 10 mg Generic 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. 209738 as amended be a date which is not earlier than the expiration date of the '027 patent.

47. Micro Labs had knowledge of the '027 patent when it submitted ANDA No. 209738 as amended to the FDA.

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

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

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

COUNT III
(Micro Labs USA Inc.'s Inducing of Infringement by Micro Labs, Ltd.)

51. The allegations of paragraphs 1-50 above are repeated and re-alleged as if set forth fully herein.

52. On information and belief, Micro Labs USA Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission by Micro Labs, Ltd. of ANDA No. 209738 as amended to the FDA, knowing of the RE'783 and '027 patents.

53. The filing by Micro Labs, Ltd. of ANDA No. 209738 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), Micro Labs USA Inc. 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. 209738 as amended to the FDA, knowing that the submission of ANDA No. 209738 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 Micro Labs, Ltd.'s submission of ANDA No. 209738 as amended, was an act of infringement and that Micro Labs' making, using, offering to sell, selling, or importing Micro Labs 10 mg Generic Tablets prior to the expiration of the RE'783 and '027 patents will infringe each of those patents;

B. A judgment that Micro Labs USA Inc.'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. 209738 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 Micro Labs to make, use, offer for sale, sell, market, distribute, or import Micro Labs 10 mg Generic 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 Micro Labs, 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 Micro Labs 10 mg Generic 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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