IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER LIMITED, and PFIZER IRELAND PHARMACEUTICALS,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
PAR PHARMACEUTICAL, INC.,	)	
Defendant.	)	

COMPLAINT

Pfizer Inc., Pfizer Limited, and Pfizer Ireland Pharmaceuticals (collectively "Plaintiffs" or "Pfizer"), by their attorneys, for their complaint against Par Pharmaceutical, Inc. ("Defendant" or "Par"), allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Par for patent infringement of United States Patent No. 6,124,363 (the "'363 patent") arising from Par's filing of Abbreviated New Drug Application ("ANDA") No. 208519 with the United States Food and Drug Administration ("FDA") seeking approval to market generic versions of Pfizer's Tikosyn® (dofetilide) capsules prior to expiration of the '363 patent.

2. On information and belief, Par intends to market generic versions of Pfizer's Tikosyn® capsules prior to the expiration of the '363 patent. This will cause Pfizer to suffer irreparable harm.

THE PARTIES

Plaintiffs

3. Pfizer Inc. is a corporation organized under the laws of the State of Delaware and has its principal place of business at 235 East 42nd Street, New York, New York 10017. Pfizer

invests extensively in designing, developing, and evaluating new and innovative pharmaceutical products and sells pharmaceutical products to the public throughout the United States.

4. Pfizer Limited is a company organized under the laws of England and has its principal place of business at Ramsgate Road, Sandwich, Kent CT13 9NJ, England.

5. Pfizer Ireland Pharmaceuticals is a private unlimited liability company organized under the laws of Ireland and has its registered office at Operations Support Group, Ringaskiddy, Co. Cork, Ireland.

6. Pfizer has all right, title, and interest in the '363 patent and the right to sue for infringement thereof.

Defendant

7. On information and belief, Par Pharmaceutical, Inc. is a company organized and existing under the laws of New York, having its principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977.

JURISDICTION AND VENUE

8. 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.

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

10. This Court has personal jurisdiction over Par 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 Pfizer, including in the State of Delaware. In particular, this suit arises out of Par's filing of ANDA No. 208519 seeking FDA approval to sell generic copies of Pfizer's Tikosyn capsules, 0.125 mg, 0.25 mg, and 0.50 mg dofetilide capsules (collectively, "Par's

ANDA Products") prior to the expiration of the '363 patent throughout the United States, including in the State of Delaware.

11. On information and belief, if ANDA No. 208519 is approved, Par's ANDA Products will, among other things, be marketed and distributed by Par in the State of Delaware, prescribed by physicians practicing in the State of Delaware, dispensed by pharmacies located within the State of Delaware, and/or used by patients in the State of Delaware.

12. Par's infringing activities with respect to its filing of ANDA No. 208519 and its intent to commercialize and sell Par's ANDA Products has led and/or will lead to foreseeable harm and injury to Plaintiffs, including Pfizer Inc., which is incorporated in the State of Delaware.

13. On information and belief, Par maintains substantial, systematic, and continuous contacts throughout the United States, including with the State of Delaware. Par's website states that Par's "sales place it among the leading generic pharmaceutical companies in the United States." (https://www.parpharm.com/about/ (last visited Mar. 29, 2017)). Par "[c]onducts manufacturing in the United States and abroad and markets and/or license more than 200 prescriptions drug products families." (*Id.*). Par has "[s]trong distribution relationships in place at top U.S. retail chains, wholesalers, distributors, managed care organizations, mail order pharmacies and group purchasing organizations." (*Id.*).

14. On information and belief, Par is registered to conduct business in the State of Delaware (File No. 6125148) and has the following registered agent in the State of Delaware: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

15. On information and belief, Par Pharmaceutical, Inc. does business as Par Pharmaceutical. On information and belief, Par holds Delaware distributor/manufacturer CSR license no. DM-0011836 and Delaware pharmacy - wholesale license no. A4-0002347.

16. Par has previously availed itself of this Court by initiating litigation. *See Par Pharmaceutical, Inc. et al. v. TWi Pharmaceuticals, Inc. et al.*, 1:15-cv-00698-SLR (D. Del.) (D.I. 1). In addition, Par has previously availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction. *See Omeros Corporation v. Par Sterile Products, LLC et al.*, 1:15-cv-00773-RGA (D. Del.) (D.I. 8) (Par submitted counterclaims and did not contest personal jurisdiction); *Cosmo Technologies Limited et al v. Par Pharmaceutical, Inc.*, 1:15-cv-01049-LPS (D. Del.) (D.I. 10) (same).

BACKGROUND

The '363 Patent

17. On September 26, 2000, the United States Patent and Trademark Office ("USPTO") issued the '363 patent, titled "Dofetilide Polymorphs." A copy of the '363 patent is attached hereto as Exhibit A.

18. The '363 patent discloses and claims, *inter alia*, certain dofetilide polymorphs, processes for preparing certain dofetilide polymorphs, pharmaceutical compositions comprising certain dofetilide polymorphs, and methods of treating heart failure and cardiac arrhythmia by administering certain dofetilide polymorphs.

Orange Book Listing for Tikosyn

19. Pfizer holds an approved New Drug Application ("NDA"), No. 20-931, for dofetilide capsules, 0.125 mg, 0.25 mg, and 0.5mg dosage strengths, under the registered name Tikosyn®. As stated in the FDA approved label for Tikosyn ("Pfizer's Tikosyn Label"), Tikosyn is indicated for "the maintenance of normal sinus rhythm (delay in time to recurrence of atrial

fibrillation/atrial flutter [AF/AFl]) in patients with atrial fibrillation/atrial flutter of greater than one week duration who have been converted to normal sinus rhythm" and "for the conversion of atrial fibrillation and atrial flutter to normal sinus rhythm."

20. The FDA lists the '363 patent in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") in connection with NDA No. 20-931 and Tikosyn (dofetilide) capsules.

21. The Orange Book states that the '363 patent's expiration date is October 9, 2018.

Par's ANDA

22. By letter dated February 13, 2017 and received by Pfizer on February 14, 2017 ("ANDA Notice Letter"), Par notified Pfizer that it had filed ANDA No. 208519 with the FDA seeking approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to market and sell Par's ANDA Products, prior to the expiration of the '363 patent.

23. The ANDA Notice Letter states that ANDA No. 208519 contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV" certification) alleging that the'363 patent "is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of [Par's ANDA Products]." The ANDA Notice Letter states that Par's "ANDA indicates that Par intends to market [Par's ANDA Products] before the expiration of the '363 patent."

24. On information and belief, on approval of ANDA No. 208519, Par intends to distribute Par's ANDA Products throughout the United States, including in Delaware. On information and belief, Par also intends for doctors to prescribe, and for patients to use, Par's ANDA Products in accordance with and as directed by Par's proposed labeling for Par's ANDA Products, which copies some or all of the indications in the label for Pfizer's Tikosyn capsules.

COUNT I
(Infringement of the '363 Patent by Par)

25. The allegations of paragraphs 1 through 24 above are repeated and re-alleged as if set forth fully herein.

26. Pursuant to 35 U.S.C. § 271(e)(2)(A), Par's filing of ANDA No. 208519 seeking approval to market Par's ANDA Products is an act of infringement of at least claim 1 of the '363 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. 208519 be a date which is not earlier than the expiration date of the '363 patent.

27. On information and belief, Par had knowledge of the '363 patent when it submitted ANDA No. 208519 to the FDA.

28. On information and belief, Par intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Par's ANDA Products prior to the expiration of the '363 patent. Par's ANDA Products will infringe at least claim 1 of the '363 patent.

29. On information and belief, the proposed labeling and/or package insert submitted with ANDA No. 208519 copies some or all of the indications in Pfizer's Tikosyn Label. On information and belief, Par intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Par's ANDA Products with the proposed labeling.

30. The use of Par's ANDA Products in accordance with and as directed by Par's proposed labeling will infringe at least claim 9 of the '363 patent.

31. On information and belief, Par intends to actively induce infringement of at least claim 9 of the '363 patent.

32. On information and belief, Par intends to contribute to the infringement of at least claim 9 of the '363 patent.

33. On information and belief, Par knows that Par's ANDA Products and the proposed labeling are especially made or adapted for use in infringing at least claim 9 of the '363 patent and that Par's ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

34. The foregoing actions by Par constitute and/or would constitute infringement of at least claim 1 of the '363 patent, active inducement of infringement of at least claim 9 of the '363 patent, and/or contribution to the infringement by others of at least claim 9 of the '363 patent.

35. Pfizer will be substantially and irreparably harmed if Par is not enjoined from infringing the '363 patent. Pfizer has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Par's submission and maintenance of ANDA No. 208519 was an act of infringement and that Par's making, using, offering to sell, selling, or importing Par's ANDA Products prior to the expiration of the '363 patent will infringe, actively induce infringement, and/or contribute to the infringement of the '363 patent;

B. A judgment that the effective date of any approval for Par to make, use, offer for sale, sell, market, distribute, or import Par's ANDA Products be no earlier than the expiration of the '363 patent, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

C. A permanent injunction against Par, its respective officers, agents, servants, and employees, and those persons in active concert or participation with any of them, making using, selling, offering for sale, marketing, distributing, or importing Par's ANDA Products, or any other infringement of the '363 patent, and enjoining Par from inducing or contributing to any of the foregoing, prior to the expiration of the '363 patent;

D. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Plaintiffs to an award of its reasonable attorneys' fees for bringing and prosecuting this action;

E. An award of Plaintiffs' 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/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiffs Pfizer Inc., Pfizer Limited, and Pfizer Ireland Pharmaceuticals

OF COUNSEL:

Daniel P. DiNapoli
Jeffrey Martin
ARNOLD & PORTER KAYE SCHOLER LLP
250 West 55th Street
New York, NY 10019-9710
(212) 836-8000

March 30, 2017