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

PFIZER INC. and PFIZER LIMITED, Plaintiffs, v. APPCO PHARMA LTD. and APPCO PHARMA LLC, Defendants.	Civil Action No. _____

COMPLAINT

Pfizer Inc. and Pfizer Limited (collectively, "Plaintiffs" or "Pfizer"), by their attorneys, for their Complaint against APPCO Pharma Ltd. and APPCO Pharma LLC (collectively, "Defendants" or "APPCO"), allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against APPCO for patent infringement of United States Patent No. 6,469,012 (the "'012 patent").

2. This action arises out of APPCO Pharma Ltd.'s filing of Abbreviated New Drug Application ("ANDA") No. 207178 seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's revolutionary oral treatment for erectile dysfunction, Viagra®, prior to the expiration of the '012 patent.

THE PARTIES

3. Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware, having 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 corporation organized under the laws of England and has its principal place of business at Ramsgate Road, Sandwich, Kent, England.

5. Pfizer has all right, title, and interest in the '012 patent and the right to sue for infringement thereof.

6. On information and belief, defendant APPCO Pharma Ltd. is a corporation organized and existing under the laws of a foreign country.

7. On information and belief, defendant APPCO Pharma LLC is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 120 Belmont Drive, Somerset, New Jersey 08873.

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. This Court has personal jurisdiction over APPCO.

10. This Court has personal jurisdiction over APPCO Pharma LLC. Upon information and belief, APPCO Pharma LLC is a New Jersey company with a registered agent in the State of New Jersey.

11. This Court has personal jurisdiction over APPCO Pharma Ltd. 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 the State of New Jersey. In particular, this action arises out of APPCO Pharma Ltd.'s filing of ANDA No. 207178 seeking approval by the FDA to sell, prior to the expiration of the '012 patent, 25 mg, 50 mg, and 100 mg

tablets of sildenafil citrate for treatment of erectile dysfunction (the "APPCO Generic Tablets"), throughout the United States, including in the State of New Jersey.

12. Upon information and belief, APPCO Pharma Ltd. and APPCO Pharma LLC are agents of each other and/or work in concert with each other on the development, obtaining of regulatory approval, marketing, manufacturing, sale, and/or distribution of generic drugs, including APPCO Generic Tablets, throughout the United States, including in or into the State of New Jersey.

13. Upon information and belief, if ANDA No. 207178 is approved, APPCO Generic Tablets will be, among other things, marketed and distributed in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and/or used by patients in the State of New Jersey.

14. Upon information and belief, APPCO is in the business of developing and manufacturing generic pharmaceutical products.

15. Upon information and belief, APPCO Pharma LLC is a corporation organized under the laws of the State of New Jersey and has its principal place of business in New Jersey.

16. Upon information and belief, APPCO Pharma LLC is registered to conduct business in the State of New Jersey (Business ID Number: 0600414990) and has the following registered agent in the State of New Jersey: Nagaraju Kanchanapalli, 30 Tudor Drive, Somerset, New Jersey 08873.

17. By letter dated January 3, 2018 (the "APPCO Notice Letter"), APPCO Pharma Ltd. notified Pfizer that it had filed ANDA No. 207178 seeking approval by the FDA to sell, prior to the expiration of the '012 patent, 25 mg, 50 mg, and 100 mg tablets of sildenafil citrate

for treatment of erectile dysfunction throughout the United States, including in the State of New Jersey.

18. Upon information and belief, APPCO Pharma LLC has received tentative approval from the FDA to market the APPCO Generic Tablets prior to the expiration of the '012 patent.

19. Upon information and belief, APPCO directly, or indirectly through its subsidiaries and/or distributors, markets, distributes, and sells its generic pharmaceutical products within and throughout the United States, including in the State of New Jersey.

20. Upon information and belief, APPCO purposefully avails itself of the privilege of doing business in the State of New Jersey by continuously and systematically placing goods in the stream of commerce for distribution throughout the State of New Jersey, and/or by selling directly or through its agents, pharmaceutical products in the State of New Jersey.

21. Upon information and belief, if its ANDA is approved by the FDA, APPCO intends to directly, or indirectly through its subsidiaries and/or distributors, market, distribute, and sell generic copies of Pfizer's revolutionary oral treatment for erectile dysfunction, Viagra®, within and throughout the United States, including in the State of New Jersey. Thus, APPCO's ANDA filing was directed at selling its generic copies and challenging Pfizer's exclusive patent rights nationwide, including in New Jersey.

22. In the alternative, this Court has jurisdiction over APPCO Pharma Ltd. under Federal Rule of Civil Procedure 4(k)(2). APPCO Pharma Ltd. has contacts with the United States by, *inter alia*, having filed its ANDA with the FDA.

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

24. Venue is proper in this judicial district because defendant APPCO Pharma LLC is a corporation organized and existing under the laws of the State of New Jersey and because defendant APPCO Pharma Ltd. is a corporation organized and existing under the laws of a foreign country.

BACKGROUND

The '012 Patent

25. On October 22, 2002, the United States Patent and Trademark Office ("USPTO") issued the '012 patent, titled "Pyrazolopyrimidinones for the Treatment of Impotence," based on an application filed by Dr. Peter Ellis and Dr. Nicholas Kenneth Terrett. Drs. Ellis and Terrett duly and legally assigned the '012 patent to Pfizer Inc. The USPTO, during the course of reexamination proceedings, confirmed the patentability of claims 1–23, 25, and 26 of the '012 patent over numerous prior art references. The USPTO found claim 24 not patentable. Pfizer is only asserting claims 25 and 26 of the '012 patent (the "Asserted Claims") in this case. In *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 803 F. Supp. 2d 409 (E.D. Va. 2011), the Eastern District of Virginia found claims 25 and 26 of the '012 patent valid, enforceable, and infringed. A copy of the '012 patent is attached hereto as Exhibit A.

26. Pfizer Limited has the right to grant licenses and enforce the '012 patent.

Orange Book Listing for Viagra

27. Pfizer holds approved New Drug Application No. 020895 for treating erectile dysfunction with sildenafil citrate which Pfizer sells under the registered name Viagra®. Treatment of erectile dysfunction with Viagra® is covered by the '012 patent. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the '012 patent is listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") as covering Viagra®.

28. The Orange Book lists the '012 patent's expiration date as October 22, 2019. The Orange Book further reflects that Viagra® has been granted pediatric exclusivity through April 22, 2020.

APPCO's ANDA

29. APPCO Pharma Ltd., via the APPCO Notice Letter, notified Pfizer that it had filed ANDA No. 207178 with the FDA, seeking approval under the Federal Food, Drug, and Cosmetic Act to market and sell, prior to the expiration of the '012 patent, 25 mg, 50 mg, and 100 mg tablets of sildenafil citrate, generic copies of Viagra, for treatment of erectile dysfunction.

30. The APPCO Notice Letter asserts that ANDA No. 207178 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '012 patent "is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of" APPCO's Generic Tablets.

31. Attached to the APPCO Notice Letter was APPCO's "Confidential Detailed Factual and Legal Bases for APPCO's Paragraph IV Certification that U.S. Patent No.: 6,469,012 Is Invalid, Unenforceable and/or Will Not Be Infringed" ("APPCO's Detailed Statement") asserting the purported factual and legal bases for APPCO's contention that the '012 patent is invalid and/or each valid claim of the '012 patent will not be infringed by the commercial manufacture, use, or sale of the APPCO Generic Tablets.

32. APPCO's Detailed Statement does not contain a noninfringement argument with respect to the Asserted Claims of the '012 patent.

33. On information and belief, upon approval of ANDA No. 207178, APPCO will distribute the APPCO Generic Tablets throughout the United States, including throughout New Jersey.

COUNT I
(Patent Infringement by Defendants)

34. The allegations of paragraphs 1-33 above are repeated and re-alleged as if set forth fully herein.

35. Pursuant to 35 U.S.C. § 271(e)(2)(A), APPCO Pharma Ltd.'s filing of ANDA No. 207178 seeking approval to market APPCO's Generic Tablets is an act of infringement of each of the Asserted Claims, 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 of ANDA No. 207178 be a date which is not earlier than the expiration date of the '012 patent.

36. APPCO Pharma Ltd. had knowledge of the '012 patent when it submitted ANDA No. 207178 to the FDA.

37. Upon information and belief, APPCO Pharma Ltd.'s actions relating to ANDA No. 207178 were done with the cooperation, participation, assistance, and for the benefit of, both APPCO Pharma LLC and APPCO Pharma Ltd.

38. On information and belief, upon FDA approval, APPCO intends to engage in the manufacture, use, offer for sale, sale, and/or importation of APPCO Generic Tablets with APPCO's proposed labeling. The use of APPCO Generic Tablets in accordance with and as directed by APPCO's proposed labeling would infringe each of the Asserted Claims.

39. Upon information and belief, APPCO intends to actively induce infringement of each of the Asserted Claims.

40. Upon information and belief, APPCO knows that APPCO Generic Tablets and the proposed labeling are especially made or adapted for use in infringing each of the Asserted Claims and that the APPCO Generic Tablets and the proposed labeling are not suitable for any substantial noninfringing use.

41. Upon information and belief, APPCO intends to contribute to the infringement of each of the Asserted Claims.

42. The foregoing actions by APPCO constitute and/or would constitute infringement of each of the Asserted Claims, active inducement of infringement of each of the Asserted Claims, and/or contribution to the infringement by others of each of the Asserted Claims.

43. Pfizer will be substantially and irreparably harmed if APPCO is not enjoined from infringing the '012 patent. Pfizer has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that APPCO Pharma Ltd.'s submission of ANDA No. 207178 was an act of infringement and that APPCO's making, using, offering to sell, selling or importing APPCO Generic Tablets prior to the expiration of the '012 patent will infringe, actively induce infringement and/or contribute to the infringement of the '012 patent;

B. A judgment that the effective date of any FDA approval for APPCO to make, use, offer for sale, sell, market, distribute, or import the APPCO Generic Tablets be no earlier than the expiration of the '012 patent, or any later expiration of exclusivity to which Pfizer is entitled;

C. A permanent injunction enjoining APPCO, 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 the APPCO Generic Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the '012 patent;

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 16, 2018

By: s/ David E. De Lorenzi

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