**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF VIRGINIA**

PFIZER INC., PFIZER LIMITED, and PFIZER IRELAND PHARMACEUTICALS,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,

Defendants.

Civil Action No. 2:10 CV 128 RBS/FBS

## COMPLAINT

Pfizer Inc., Pfizer Limited, and Pfizer Ireland Pharmaceuticals (collectively "Pfizer"), by their attorneys, for their complaint against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries Ltd. (collectively "Teva"), allege as follows:

## NATURE OF THE ACTION

1. This is an action by Pfizer against Teva for patent infringement of United States Patent No. 6,469,012 (the "'012 patent"). This action arises out of Teva's filing of an Abbreviated New Drug Application ("ANDA") seeking approval by the United States Food and Drug Administration ("FDA") to sell a generic copy of Pfizer's revolutionary oral treatment for erectile dysfunction, Viagra®, prior to the expiration of the '012 patent owned by Pfizer.

## THE PARTIES

2. Pfizer Inc. is a corporation organized under the laws of the State of Delaware and has its principal place of business located at 235 East 42nd Street, New York, New York. Pfizer invests extensively in designing, developing, and evaluating new and innovative pharmaceutical products and sells pharmaceutical products to the public throughout the United States.

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

4. Pfizer Ireland Pharmaceuticals is a partnership existing pursuant to the laws of Ireland and has its registered office at Pottery Road, Dun Laoghaire, County Dublin, Republic of Ireland.

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, Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized under the laws of the State of Delaware and has its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania.

7. On information and belief, Teva Pharmaceutical Industries Ltd. ("Teva Industries") is a corporation organized under the laws of Israel and has its principal place of business at 5 Basel Street, Petah Tikva, Israel.

8. On information and belief, Teva USA is a wholly-owned subsidiary of Teva Industries.

## JURISDICTION AND VENUE

9. 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.

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

11. Teva USA is subject to personal jurisdiction in the Eastern District of Virginia due, among other things, to Teva USA's systematic, purposeful, and continuous contacts in this district and Teva USA's registration to do business in this district.

12. Teva Industries is subject to personal jurisdiction in the Eastern District of Virginia because, among other things, Teva Industries directly and/or through its wholly-owned subsidiaries markets and sells generic drugs throughout the United States and within this district and, therefore, purposefully avails itself of the privilege of conducting activities within this district.

## BACKGROUND

### The '012 Patent

13. 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, has 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 not asserting claim 24 of the '012 patent in this case. A copy of the '012 patent is attached hereto as Exhibit A.

14. Pfizer Limited is the owner of a beneficial interest in the '012 patent.

15. Pfizer Ireland Pharmaceuticals is an exclusive licensee under the '012 patent.

### Orange Book Listing for Viagra®

16. Pfizer holds an approved New Drug Application 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") for treatment of erectile dysfunction.

17. The Orange Book lists the '012 patent's expiration date as October 22, 2019.

18. The Orange Book also lists United States Patent No. 5,250,534 (the "'534 patent") with respect to Viagra®, and lists the '534 patent's expiration date as March 27, 2012.

**Teva's ANDA**

19. By letter dated December 17, 2004 (the "Notice Letter"), Teva USA notified Pfizer Inc. and Pfizer Ireland that it had filed ANDA No. 77-342 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act ("FDCA") 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 (the "ANDA Products").

20. The Notice Letter states that ANDA No. 77-342 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the '012 patent is invalid and/or will not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Products.

21. On information and belief, Teva USA and Teva Industries collaborated and acted in concert in the decision to file and the filing of ANDA No. 77-342.

22. On information and belief, in April 2007, the FDA granted tentative approval of ANDA No. 77-342.

23. On information and belief, Teva intends to market, immediately upon expiration of the '534 patent on March 27, 2012, Teva's ANDA Products for treatment of erectile dysfunction, and Teva intends for doctors to prescribe, and patients to use, Teva's ANDA Products in accordance with and as directed by Teva's proposed labeling for the ANDA Products.

**COUNT I**
**(Patent Infringement)**

24. The allegations of paragraphs 1 through 23 above are repeated and re-alleged as if set forth fully herein.

25. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva's filing of ANDA No. 77-342 seeking approval to market Teva's ANDA Products is an act of infringement of one or more claims of the '012 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. 77-342 be a date which is not earlier than the expiration date of the '012 patent.

26. Teva had knowledge of the '012 patent when it submitted ANDA No. 77-342 to the FDA.

27. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the ANDA Products with the proposed labeling immediately upon expiration of the '534 patent on March 27, 2012. The use of Teva's ANDA Products in accordance with and as directed by Teva's proposed labeling would infringe one or more claims of the '012 patent.

28. Upon information and belief, Teva intends to actively induce infringement of one or more claims of the '012 patent immediately upon expiration of the '534 patent on March 27, 2012.

29. Upon information and belief, Teva knows that the ANDA Products and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '012 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

30. Upon information and belief, Teva intends to contribute to the infringement of one or more claims of the '012 patent immediately upon expiration of the '534 patent on March 27, 2012.

31. The foregoing actions by Teva constitute and/or would constitute infringement of one or more claims of the '012 patent, active inducement of infringement of one or more claims of the '012 patent, and/or contribution to the infringement by others of one or more claims of the '012 patent.

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

**COUNT II**
**(Declaratory Judgment of Infringement)**

33. Pfizer repeats and re-alleges paragraphs 1 through 32 above as if fully set forth herein.

34. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties.

35. Upon information and belief, Teva has taken active steps relating to importing, using, selling, or offering for sale in the United States, including in the Eastern District of Virginia, the ANDA Products with the proposed labeling immediately upon expiration of the '534 patent on March 27, 2012. Teva's active steps include, among other things, filing ANDA No. 77-342, challenging the validity of the '012 patent by its Paragraph IV certification and Notice Letter to Pfizer, obtaining tentative approval with respect to ANDA No. 77-342, and notifying the public of that tentative approval. As a result, Teva is committed to selling the ANDA Products for treatment of erectile dysfunction immediately upon expiration of the '534 patent on March 27, 2012.

36. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the ANDA Products with the proposed labeling immediately upon expiration of the '534 patent on March 27, 2012. The use of the ANDA Products in accordance with and as directed by the proposed labeling would infringe one or more claims of the '012 patent.

37. Upon information and belief, Teva intends to actively induce infringement of one or more claims of the '012 patent immediately upon expiration of the '534 patent on March 27, 2012.

38. Upon information and belief, Teva knows that the ANDA Products and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '012 patent, and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

39. Upon information and belief, Teva intends to contribute to the infringement of one or more claims of the '012 patent immediately upon expiration of the '534 patent on March 27, 2012.

40. The foregoing actions by Teva constitute and/or would constitute infringement of one or more claims of the '012 patent, active inducement of infringement of one or more claims of the '012 patent, and/or contribution to the infringement by others of one or more claims of the '012 patent.

41. Pfizer will be substantially and irreparably harmed if Teva 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 Teva's submission of ANDA No. 77-342 was an act of infringement and that Teva's making, using, offering to sell, selling or importing the ANDA Products 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 Teva to make, use offer for sale, sell, market, distribute, or import the ANDA Products be no earlier than the expiration of the '012 patent;

C. A permanent injunction enjoining Teva, 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 ANDA Products, and from inducing or contributing to any of the foregoing, prior to the expiration of the '012 patent;

D. A declaratory judgment that Teva's making, using, offering to sell, selling or importing the ANDA Products prior to the expiration of the '012 patent will infringe, actively induce infringement, and/or contribute to the infringement of the '012 patent;

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;

G. Such further and additional relief as this Court deems just and proper.

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