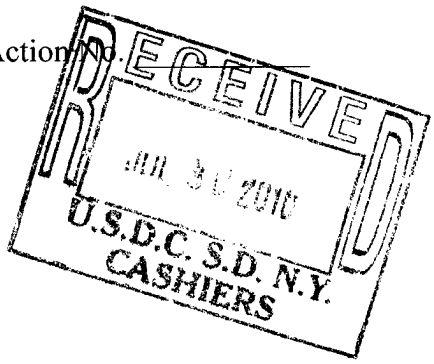
UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PFIZER INC. and PFIZER IRELAND PHARMACEUTICALS, Plaintiffs, v. TEVA PHARMACEUTICALS USA INC., Defendants.	10 CIV 5794 Civil Action No.



COMPLAINT

Plaintiffs Pfizer Inc. and Pfizer Ireland Pharmaceuticals (collectively, "Pfizer"), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendant Teva Pharmaceuticals USA Inc. ("Teva") of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Pfizer's RELPAX® eletriptan hydrobromide tablets for oral administration ("RELPAX®") prior to the expiration of U.S. Patent No. 6,110,940 ("the '940 patent") attached hereto as Exhibit 1.

2. RELPAX® tablets are indicated for the acute treatment of migraine with or without aura in adults. The active ingredient in RELPAX® is eletriptan

hydrobromide. Each RELPAX® tablet contains 24.2 mg or 48.5 mg of eletriptan hydrobromide, equivalent to 20 mg or 40 mg of eletriptan, respectively.

3. By letter dated June 17, 2010 (the "Notice Letter"), Teva notified Pfizer that Teva had submitted to the FDA an ANDA, No. 202040, for eletriptan hydrobromide tablets 20 mg, 40 mg ("Teva's ANDA Product"). Teva's ANDA Product is a drug product that is a generic version of RELPAX®.

PARTIES

4. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the assignee of the '940 patent.

5. Plaintiff Pfizer Ireland Pharmaceuticals is a partnership, organized and existing under the laws of the Republic of Ireland, with registered offices at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland. Pfizer Ireland Pharmaceuticals is a wholly owned, indirect subsidiary of Pfizer Inc.

6. Upon information and belief, defendant Teva is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

JURISDICTION AND VENUE

7. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 1391, and 1400(b).

8. Teva is subject to personal jurisdiction in New York because, among other things: Upon information and belief, Teva is in the business of manufacturing, distributing, and selling drug products throughout the United States,

including in New York; it derives substantial revenue from services or things used or consumed in the state of New York; it transacts business with companies located and/or headquartered in New York; and, upon receiving FDA approval, it intends to offer to sell and sell Teva's ANDA Product in the United States, including in New York, which will cause injury to Pfizer Inc., a corporation headquartered in New York. As a part of its business, upon information and belief, Teva regularly files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. Upon information and belief, as a part of these ANDAs, Teva regularly files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of U.S. patents that cover them. Upon information and belief, Teva's ordinary business operations include litigating in the courts of the United States, including the U.S. District Court for the Southern District of New York, the infringement, validity, and/or enforceability of United States patents that cover or are alleged to cover generic drug products that are the subject of ANDAs filed by Teva. Upon information and belief, Teva is registered with the New York Department of State, Division of Corporations, to conduct business in the State of New York, and has a registered agent in the State of New York. Upon information and belief, Teva has a physical presence in the State of New York, including a place of business in Pomona, New York.

BACKGROUND

9. The '940 patent has been listed in connection with RELPAX® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly (and hereinafter) known as the "Orange Book."

10. The purpose of Teva's submission of ANDA No. 202040 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product prior to the expiration of the '940 patent.

11. In the Notice Letter, Teva also notified Pfizer that, as part of its ANDA No. 202040, Teva had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '940 patent. Upon information and belief, Teva submitted ANDA No. 202040 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '940 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Teva's ANDA Product.

12. In the Notice Letter, Teva asserted that Teva's ANDA Product does not infringe any claim of the '940 patent because "[t]here is no evidence of the α-polymorphic form of eletriptan hydrobromide in the eletriptan hydrobromide used to make the [Teva's ANDA Product] or in [Teva's ANDA Product] [it]sel[f]." Accordingly, Teva asserted, Teva's ANDA Product does not contain eletriptan hydrobromide in the α-polymorphic form.

13. In the Notice Letter, Teva included an Offer of Confidential Access to "relevant portions" of its ANDA, subject to certain specified conditions.

14. On June 29, 2010, Pfizer, through counsel, sent Mr. Philip Erickson, the contact person listed in Teva's Offer of Confidential Access, a letter requesting, in addition to the offered portions of Teva's ANDA, particular documents, data, and samples necessary to verify Teva's noninfringement claims and to determine whether Teva's ANDA Product infringes the '940 patent. Upon information and belief, through counsel, Teva responded that it was unwilling to share all of the documents Pfizer requested, and was also unwilling to share any samples.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 6,110,940

15. Pfizer incorporates each of the preceding paragraphs 1–14 as if fully set forth herein.

16. The '940 patent, entitled "Salts of an Anti-Migraine Indole Derivative" (Exhibit A hereto), was duly and legally issued on August 29, 2000, to Pfizer Inc., as assignee of Valerie Denise Harding, Ross James Macrae, and Ronald James Ogilvie, and is incorporated herein by reference.

17. Pfizer will be substantially and irreparably damaged by infringement of the '940 patent.

18. Teva has knowledge of the '940 patent.

19. Teva's submission of ANDA No. 202040 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product prior to the expiration of the '940 patent was an act of infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A).

20. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product would infringe one or more claims of the '940 patent.

21. Upon information and belief, Teva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 202040.

22. Upon information and belief, the use of Teva's ANDA Product in accordance with and as directed by Teva's proposed labeling for that product would infringe one or more claims of the '940 patent.

23. Upon information and belief, Teva plans and intends to, and will, actively induce infringement of the '940 patent when ANDA No. 202040 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

24. Upon information and belief, Teva knows that Teva's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '940 patent, and that Teva's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Teva plans and intends to, and will, contribute to infringement of the '940 patent immediately and imminently upon approval of ANDA No. 202040.

25. The foregoing actions by Teva constitute and/or will constitute infringement of the '940 patent, active inducement of infringement of the '940 patent, and contribution to the infringement by others of the '940 patent.

26. Upon information and belief, Teva acted without a reasonable basis for believing that it would not be liable for infringing the '940 patent, actively inducing infringement of the '940 patent, and contributing to the infringement by others of the '940 patent.

27. Unless Teva is enjoined from infringing the '940 patent, actively inducing infringement of the '940 patent, and contributing to the infringement by others of the '940 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

WHEREFORE, Pfizer requests the following relief:

(a) A judgment that Teva has infringed the '940 patent;

(b) A judgment ordering that the effective date of any FDA approval for Teva to make, use, offer for sale, sell, market, distribute, or import Teva's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '940 patent, be not earlier than the expiration date of the '940 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Teva, and all persons acting in concert with Teva, from making, using, selling, offering for sale, marketing, distributing, or importing Teva's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '940 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '940 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Teva's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '940 patent, prior to the expiration date of the '940 patent, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '940 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Pfizer's costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

ROPES & GRAY LLP

By: _____
Denise L. Loring
(denise.loring@ropesgray.com)
Michael P. Kahn
(michael.kahn@ropesgray.com)
1211 Avenue of the Americas
New York, NY 10036-8704
(212) 596-9000
(212) 596-9090 (facsimile)

Attorneys for Plaintiffs Pfizer Inc. and Pfizer Ireland Pharmaceuticals

OF COUNSEL:
Bruce R. Genderson
David I. Berl
David M. Krinsky
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000
(202) 434-5029 (Facsimile)

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