IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER SCHERING PHARMA AG, BAYER HEALTHCARE PHARMACEUTICALS INC., and SCHERING CORPORATION,	)	
Plaintiffs,	)	
v.	)	Civil Action No. _____
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer Schering Pharma AG, Bayer HealthCare Pharmaceuticals Inc., and Schering Corporation (collectively "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

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 filing by Defendant Teva Pharmaceuticals USA, Inc. of Abbreviated New Drug Application ("ANDA") No. 91-347 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of LEVITRA® prior to the expiration of U.S. Patent No. 6,362,178.

PARTIES

2. Plaintiff Bayer Schering Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with its principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

3. Plaintiff Bayer HealthCare Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

4. Plaintiff Schering Corporation is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

5. Upon information and belief, Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is a corporation organized and existing under the laws of Israel, with its principal place of business at 5 Basel Street, Petach Tikva 49131, Israel. Upon information and belief, Teva Ltd. is in the business of developing, manufacturing, marketing and selling generic drugs. Teva Ltd. maintains a website at URL www.tevapharm.com at which it holds itself out as an integrated worldwide pharmaceutical company. Upon information and belief, Teva Ltd. established Defendant Teva Pharmaceuticals USA, Inc. for the purpose of distributing, marketing, and selling its generic drugs throughout the United States.

6. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd. and is controlled and dominated by Teva Ltd. Upon information and belief, Teva USA manufactures, markets and sells numerous generic drugs for sale and use throughout the United States at the direction, under the control, and for the direct benefit of Teva Ltd.

7. Upon information and belief, Teva USA's preparation and submission of ANDA No. 91-347 was done at the direction, under the control, and for the direct benefit of Teva Ltd. Upon information and belief, Teva Ltd. directed Teva USA to submit ANDA No. 91-347.

8. Upon information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of ANDA No. 91-347, Teva Ltd. and Teva USA will act in concert to distribute and sell its generic product throughout the United States and within Delaware. Upon information and belief, following any FDA approval of ANDA No. 91-347, Teva knows and intends that its generic product will be distributed and sold in the United States and within Delaware.

9. Teva Ltd. and Teva USA are referred to hereafter collectively as "Teva."

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

11. Teva Ltd. is subject to personal jurisdiction in Delaware because, among other things, Teva Ltd., itself and through its wholly-owned subsidiary Teva USA, manufactures, markets and sells generic drugs throughout the United States and within the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. Teva Ltd. is subject to jurisdiction in Delaware on the basis of its inducement of Teva USA's acts of infringement in Delaware. In addition, Teva Ltd. is subject to personal jurisdiction in Delaware because it controls and dominates Teva USA, and therefore the activities of Teva USA in this jurisdiction are attributed to Teva Ltd.

12. Teva USA is subject to personal jurisdiction in Delaware because, among other things, Teva USA is a resident and citizen of the State of Delaware and has submitted itself to the jurisdiction of courts in Delaware by virtue of its incorporation under Delaware law.

13. In addition, this Court has personal jurisdiction over Teva because Teva has consented to jurisdiction in this judicial district in previous litigation and because Teva has affirmatively availed itself of the Courts of this district by filing claims in this district.

14. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b)-(d) and 1400(b).

BACKGROUND

15. LEVITRA® (active ingredient vardenafil HCl) is a selective inhibitor of cyclic guanosine monophosphate-specific phosphodiesterase type 5. LEVITRA®'s indication is for the treatment of erectile dysfunction.

16. United States Patent No. 6,362,178 ("the '178 patent"), entitled "2-Phenyl Substituted Imidazotriazinones As Phosphodiesterase Inhibitors," was duly and legally issued on March 26, 2002. The '178 patent is attached as Exhibit A hereto.

17. Bayer Schering Pharma AG is the assignee of the '178 patent.

18. Bayer HealthCare Pharmaceuticals Inc. is the holder of New Drug Application No. 021400 for LEVITRA®, which has been approved by the U.S. Food and Drug Administration. Pursuant to 21 U.S.C. § 355, the '178 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with LEVITRA®.

19. Schering Corporation has been granted an exclusive license under the '178 patent and markets and sells LEVITRA® in the United States.

20. By letter dated September 4, 2009 (the "Notice Letter"), Teva notified Plaintiffs Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. that Teva had submitted to the FDA ANDA No. 91-347 for Teva's Vardenafil Hydrochloride Tablets, Eq. 2.5 mg Base ("Teva's 2.5 mg ANDA Product"). Teva's 2.5 mg ANDA Product is a generic version of LEVITRA®. The purpose of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's 2.5 mg ANDA Product prior to the expiration of the '178 patent.

21. In the Notice Letter, Teva also notified Plaintiffs that, as part of its ANDA, 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 '178 patent. Upon information and belief, Teva submitted ANDA No. 91-347 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '178 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, or sale of Teva's 2.5 mg ANDA Product.

22. The Notice Letter provides no valid basis for concluding that the '178 patent is invalid, unenforceable or not infringed.

23. One or more claims of the '178 patent (attached as Exhibit A), incorporated by reference herein, cover LEVITRA® and its active ingredient, the chemical compound vardenafil hydrochloride ("vardenafil HCl"). The claims of the '178 patent also cover a method of treating erectile dysfunction using vardenafil HCl.

24. By letter dated September 4, 2009, Teva notified Plaintiffs Bayer Schering Pharma AG and Bayer Healthcare Pharmaceuticals Inc. that Teva's 2.5 mg ANDA Product contains vardenafil HCl.

25. On information and belief, in ANDA No. 91-347, Teva seeks approval to market and sell Teva's 2.5 mg ANDA Product to treat erectile dysfunction.

26. Teva had knowledge of the '178 patent prior to its filing of ANDA No. 91-347.

CLAIM FOR PATENT INFRINGEMENT

(Patent Infringement – Teva's 2.5 mg ANDA Product)

27. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

28. Teva's 2.5 mg ANDA Product contains the chemical compound vardenafil HCl.

29. Teva's submission of ANDA No. 91-347 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's 2.5 mg ANDA Product before the expiration of the '178 patent was an act of infringement of the '178 patent under 35 U.S.C. § 271(e)(2)(A).

30. Upon information and belief, Teva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's 2.5 mg ANDA Product immediately and imminently upon approval of ANDA No. 91-347.

31. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's 2.5 mg ANDA Product would infringe one or more claims of '178 patent.

32. Upon information and belief, Teva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's 2.5 mg ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 91-347.

33. Upon information and belief, use of Teva's 2.5 mg ANDA Product in accordance with and as directed by Teva's proposed labeling for that product would infringe one or more claims of the '178 patent.

34. Upon information and belief, Teva plans and intends to, and will, actively induce infringement of the '178 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

35. Upon information and belief, Teva knows that Teva's 2.5 mg ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '178 patent, and that Teva's 2.5 mg 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 '178 patent immediately and imminently upon approval of ANDA No. 91-347.

36. The foregoing actions by Teva constitute and/or will constitute infringement of the '178 patent, active inducement of infringement of the '178 patent, and contribution to the infringement by others of the '178 patent.

37. Upon information and belief, Teva has acted with full knowledge of the '178 patent and without a reasonable basis for believing that it would not be liable for infringing the '178 patent, actively inducing infringement of the '178 patent, and contributing to the infringement by others of the '178 patent.

38. Unless Teva is enjoined from infringing the '178 patent, actively inducing infringement of the '178 patent, and contributing to the infringement by others of the '178 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Teva has infringed the '178 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 2.5 mg ANDA Product, or any product or compound that infringes the '178 patent, be not earlier than the expiration date of the '178 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 2.5 mg ANDA Product, or any product or compound that infringes the '178 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '178 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

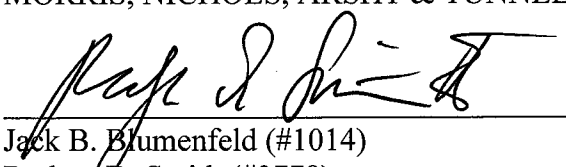
(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Teva's 2.5 mg ANDA Product, or any product or compound that infringes the '178 patent, prior to the expiration date of the '178 patent, will infringe, actively induce infringement of, and contribute to the infringement by others of the '178 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 Plaintiffs' costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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