

UNITED STATES DISTRICT COURT FOR  
THE SOUTHERN DISTRICT OF NEW YORK

TEVA PHARMACEUTICALS USA, INC. and  
BARR LABORATORIES, INC.,

Plaintiffs,

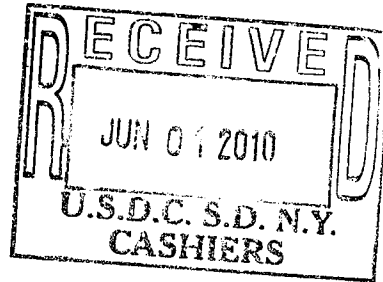
v.

BAYER SCHERING PHARMA AG and  
BAYER HEALTHCARE  
PHARMACEUTICALS INC.,

Defendants.

10 CIV 4340

Civil Action No. \_\_\_\_\_



COMPLAINT BY TEVA PHARMACEUTICALS USA, INC.  
AND BARR LABORATORIES, INC. FOR DECLARATORY JUDGMENT

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*Counsel for Plaintiffs Teva Pharmaceuticals  
USA, Inc. and Barr Laboratories, Inc.*

Plaintiffs Teva Pharmaceuticals USA, Inc. (“Teva”) and Barr Laboratories, Inc. (“Barr”) hereby complain of Defendants Bayer Schering Pharma AG and Bayer Healthcare Pharmaceuticals Inc. (“Bayer”), and allege as follows:

### **JURISDICTION AND VENUE**

1. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

2. This Court has subject matter jurisdiction over this action under the Declaratory Judgments Act, 28 U.S.C. § 2201.

3. On information and belief, this Court has personal jurisdiction over Bayer inasmuch as Bayer is doing business in this State and District, and it has significant contacts with this State and District.

4. On May 28, 2010, Teva commenced sales of Gianvi™, which is a generic formulation of Bayer’s Yaz® product. This generic product was approved by the United States Food and Drug Administration on March 30, 2009.

5. By its June 1, 2010 news article (Exhibit 1), Bayer is quoted as saying it will file an infringement suit against Plaintiffs related to Plaintiffs’ launch of a generic version of Bayer’s Yaz® birth control drug. Bayer stated: “We believe this constitutes an act of infringement on intellectual property.” A copy of the news article is attached to the Complaint as Exhibit 1.

6. Plaintiffs contend that their launch of a generic formulation of the Yaz® product infringes no valid patent claim. There is, therefore, a dispute between Bayer and Plaintiffs that is definite and concrete, that requires the resolution of specific factual and legal issues as to which Bayer and Plaintiffs take different views, and that admits of specific relief through a judgment of

a conclusive character. Accordingly, there is subject matter jurisdiction under Article III of the Constitution and 28 U.S.C. §2201.

7. Venue is proper under 28 U.S.C. § 1391(b) and (c), and § 1400(b).

### **PARTIES**

8. Plaintiff Teva is a corporation organized and existing under the laws of the state of Delaware with its principal place of business in North Wales, Pennsylvania.

9. Plaintiff Barr is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Barr is an indirect, wholly owned subsidiary of Teva.

10. On information and belief, Defendant Bayer Schering Pharma AG, formerly known as Schering AG, is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

11. On information and belief, Defendant Bayer HealthCare Pharmaceuticals Inc., formerly known as Berlex, Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

### **PATENTS-IN SUIT**

12. United States Reissue Patent No. 37,838 (“the ‘838 reissue patent”), entitled Composition for Contraception, is attached to the Complaint as Exhibit 2. Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their application for this patent on February 15, 2000. The ‘838 reissue patent was issued September 10, 2002. On information and belief, Bayer is the current owner of the ‘838 reissue patent. The ‘838 reissue patent is listed in the

Orange Book for Yaz®. Bayer has asserted this patent against other pharmaceutical companies seeking to market a generic version of Yaz®.

13. United States Reissue Patent No. 37,564 (“the ‘564 reissue patent”), entitled Composition for Contraception, is attached to the Complaint as Exhibit 3. Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their application for this patent on February 15, 2000. The ‘564 reissue patent was issued February 26, 2002. On information and belief, Bayer is the current owner of the ‘564 reissue patent. The ‘564 reissue patent is listed in the Orange Book for Yaz®. Bayer has asserted this patent against other pharmaceutical companies seeking to market a generic version of Yaz®.

14. United States Reissue Patent No. 38,253 (“the ‘253 reissue patent”), entitled Composition for Contraception, is attached to the Complaint as Exhibit 4. Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their application for this patent on February 25, 2002. The ‘253 reissue patent was issued on September 16, 2003. On information and belief, Bayer is the current owner of the ‘253 reissue patent. The ‘253 reissue patent is listed in the Orange Book for Yaz®.

### **CLAIM ONE**

(Declaratory Judgment of Invalidity and Noninfringement of the ‘838 Reissue Patent)

15. Plaintiffs incorporate Paragraphs 1-14 by reference.

16. Plaintiffs now seek a declaratory judgment pursuant to 28 U.S.C 2201(a) that the ‘838 reissue patent is invalid. Plaintiffs further seek a declaratory judgment pursuant to 28 U.S.C. 2201(a) that Plaintiffs do not infringe the ‘838 reissue patent.

17. A judicial declaration is necessary and appropriate at this time in order that Plaintiffs may ascertain their rights and duties with respect to the ‘838 reissue patent.

**CLAIM TWO**

(Declaratory Judgment of Invalidity and Noninfringement of the '564 Reissue Patent)

18. Plaintiffs incorporate Paragraphs 1-17 by reference.

19. Plaintiffs now seek a declaratory judgment pursuant to 28 U.S.C 2201(a) that the '564 reissue patent is invalid. Plaintiffs further seek a declaratory judgment pursuant to 28 U.S.C. 2201(a) that Plaintiffs do not infringe the '564 reissue patent.

20. A judicial declaration is necessary and appropriate at this time in order that Plaintiffs may ascertain their rights and duties with respect to the '564 reissue patent.

**CLAIM THREE**

(Declaratory Judgment of Invalidity and Noninfringement of the '253 Reissue Patent)

21. Plaintiffs incorporate Paragraphs 1-20 by reference.

22. Plaintiffs now seek a declaratory judgment pursuant to 28 U.S.C 2201(a) that the '253 reissue patent is invalid. Plaintiffs further seek a declaratory judgment pursuant to 28 U.S.C. 2201(a) that Plaintiffs do not infringe the '253 reissue patent.

23. A judicial declaration is necessary and appropriate at this time in order that Plaintiffs may ascertain their rights and duties with respect to the '253 reissue patent.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs request entry of judgment in its favor and against Defendants for:

**FIRST CLAIM FOR RELIEF**

- a. a declaration that the '838 reissue patent is invalid;
- b. a declaration that Plaintiffs do not infringe the '838 reissue patent;

- c. a permanent injunction against Defendants, their successors-in-interest, agents, representatives, and attorneys asserting or otherwise seeking to enforce the '838 reissue patent against Plaintiffs, their successors-in-interest, or any of their customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers;
- d. a finding that this case is exceptional under 35 U.S.C. § 285, and an award of attorney fees and costs of suit; and
- e. such other and further relief as may be appropriate.

**SECOND CLAIM FOR RELIEF**

- a. a declaration that the '564 reissue patent is invalid;
- b. a declaration that Plaintiffs do not infringe the '564 reissue patent;
- c. a permanent injunction against Defendants, their successors-in-interest, agents, representatives, and attorneys asserting or otherwise seeking to enforce the '564 reissue patent against Plaintiffs, their successors-in-interest, or any of their customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers;
- d. a finding that this case is exceptional under 35 U.S.C. § 285, and an award of attorney fees and costs of suit; and
- e. such other and further relief as may be appropriate.

**THIRD CLAIM FOR RELIEF**

- a. a declaration that the '253 reissue patent is invalid;
- b. a declaration that Plaintiffs do not infringe the '253 reissue patent;

- c. a permanent injunction against Defendants, their successors-in-interest, agents, representatives, and attorneys asserting or otherwise seeking to enforce the '253 reissue patent against Plaintiffs, their successors-in-interest, or any of their customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers;
- d. a finding that this case is exceptional under 35 U.S.C. § 285, and an award of attorney fees and costs of suit; and
- e. such other and further relief as may be appropriate.

Dated: June 1, 2010



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