IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BAYER SCHERING PHARMA AG and BAYER HEALTHCARE PHARMACEUTICALS INC., Plaintiffs, v. TEVA PHARMACEUTICAL INDUSTRIES LIMITED, and TEVA PHARMACEUTICALS USA, INC., BARR PHARMACEUTICALS LLC, and BARR LABORATORIES, INC. Defendants.	C.A. No. **DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiffs Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc., for their Complaint for patent infringement herein against Defendants Teva Pharmaceutical Industries Limited, Teva Pharmaceuticals USA, Inc., Barr Pharmaceuticals, LLC, and Barr Laboratories, Inc. allege as follows:

PARTIES

1. Plaintiff Bayer Schering Pharma AG ("Bayer Schering"), 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.

2. Plaintiff Bayer HealthCare Pharmaceuticals Inc. ("Bayer HealthCare"), 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, PO Box 1000, Montville, New Jersey 07045-1000.

3. On information and belief, Defendant Teva Pharmaceutical Industries Limited ("Teva Industries") is an Israeli corporation with its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel.

4. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva USA is a wholly-owned subsidiary of Defendant Teva Industries.

5. On information and belief, Defendant Barr Pharmaceuticals LLC ("BP LLC") (formerly known as Boron Acquisition LLC) is a Delaware limited liability company having its principal place of business at 223 Summit Avenue, Montvale, New Jersey 07645. Defendant BP LLC develops, manufactures, and markets generic pharmaceutical products through its operating subsidiary Barr Labs. Upon information and belief, BP LLC is a wholly-owned subsidiary of Defendant Teva Industries, Ltd.

6. On information and belief, Defendant Barr Labs is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 223 Summit Avenue, Montvale, New Jersey 07645.

7. On information and belief, Defendant Barr Labs is a wholly-owned subsidiary of Defendant Barr Pharmaceuticals LLC, and the two have common officers and directors.

8. On information and belief, Defendants Teva Industries and BP LLC directed, authorized, participated in, assisted, and cooperated with Defendant Barr Labs in all of the acts complained of herein. On information and belief, BP LLC is a wholly-owned subsidiary of Teva Industries. Hereinafter, all Defendants shall be collectively referred to as "Barr."

JURISDICTION AND VENUE

9. 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).

10. This Court has personal jurisdiction over Defendants Barr Pharmaceuticals LLC, Barr Laboratories, Inc. and Teva Pharmaceuticals USA, Inc. by virtue of, *inter alia*, their incorporation in Delaware.

11. The activities of Defendants Teva Pharmaceuticals USA, Barr Laboratories, Inc., and Barr Pharmaceuticals LLC that are the basis for this Complaint, have been and remain, upon information and belief, under the control and direction of their parent company, Teva Pharmaceutical Industries Ltd. Accordingly, Teva Pharmaceutical Industries Ltd. is subject to personal jurisdiction in this District under 10 Del. Code § 3104.

12. Furthermore, upon information and belief, Teva Industries regularly transacts business within this District, including but not limited to Teva Industries' direction of the operation and management of Teva USA, and BP LLC, as well as shipping drugs to Teva USA, and BP LLC from locations outside the United States for distribution by Teva USA, and BP LLC within the United States generally and this District specifically.

13. On information and belief, Teva USA, BP LLC, and Barr Labs have acted and will continue to act as agents of Teva Industries with respect to the acts complained of herein.

14. The acts and contacts of Teva USA, BP LLC, and Barr Labs, as an agent of Teva Industries, are attributable to Teva Industries for jurisdictional purposes.

15. Teva Industries is subject to personal jurisdiction in this District by virtue of, *inter alia*, its incorporation of Teva USA, BP LLC, and Barr Labs in Delaware, its conduct of business in this District, its purposeful availment of the rights and benefits of Delaware law, and its substantial and continuing acts within the State.

16. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

BACKGROUND

17. Bayer HealthCare is the holder of approved New Drug Application ("NDA") No. 21-676, for YAZ® tablets, which contain as active ingredients micronized drospirenone and micronized 17α-ethinylestradiol. YAZ® tablets have been approved by the United States Food and Drug Administration ("FDA") for the prevention of pregnancy in women who elect to use an oral contraceptive and the treatment of acne and premenstrual dysphoric disorder. YAZ® tablets are sold in the United States by Bayer HealthCare as a 28-day oral contraceptive

regimen that contains 24 tablets comprising 3 mg of micronized drospirenone and 0.02 mg of micronized 17α-ethinylestradiol plus 4 placebo tablets.

18. On information and belief, Barr submitted to the FDA an Abbreviated New Drug Application ("ANDA") under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Bayer HealthCare's YAZ® tablets.

19. On information and belief, the composition of the product that is the subject of Barr's ANDA contains 3 mg of drospirenone and 0.02 mg of 17α-ethinylestradiol in tablet form for oral contraception in a human female.

20. On information and belief, Barr's ANDA seeks approval of a 28-day oral contraceptive regimen that contains 24 tablets comprising 3 mg drospirenone and 0.02 mg 17α-ethinylestradiol plus 4 placebo tablets (hereinafter "Barr's ANDA product").

21. On information and belief, on or about December 28, 2006, Barr sent a Notice Letter to Plaintiffs Bayer Schering and Bayer HealthCare, purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) and the FDA regulations relating thereto.

22. On information and belief, on or about March 20, 2009, Barr received FDA approval for its ANDA product.

23. On information and belief, Barr has manufactured, tested, used, sold and offered to sell its generic ANDA product.

24. On information and belief, on or about June 1, 2010, Teva Pharmaceutical Industries Ltd. announced that it commercially launched Gianvi (Drospirenone and Ethinyl Estradiol) Tablets, its generic version of Bayer's Yaz® Tablets.

PATENTS

25. The patents-in-suit are as follows:

26. United States Reissue Patent No. 37,564 ("the '564 reissue patent") (attached as Exhibit 1). 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. Bayer Schering is the current owner of the '564 reissue patent.

27. United States Reissue Patent No. 37,838 ("the '838 reissue patent") (attached 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. Bayer Schering is the current owner of the '838 reissue patent.

28. United States Reissue Patent No. 37,253 ("the '253 reissue patent") (attached as Exhibit 3). Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their application for this patent on February 15, 2002. The '253 reissue patent was issued September 16, 2003. Bayer Schering is the current owner of the '838 reissue patent.

COUNT ONE: CLAIM FOR PATENT INFRINGEMENT OF UNITED STATES REISSUE PATENT NO. 37,564

29. Plaintiffs incorporate paragraphs 1 – 28 of this Complaint as if fully set forth herein.

30. On information and belief, Barr's ANDA product directly and indirectly infringes one or more claims of the '564 reissue patent.

31. The '564 reissue patent covers Bayer HealthCare's YAZ® tablets and has been listed for the product in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book").

32. On information and belief, Barr submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA product before the expiration of the '564 reissue patent.

33. On information and belief, Barr made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '564 reissue patent is invalid or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA product.

34. While Barr alleged noninfringement of several of the '564 reissue patent's claims in its Notice Letter, Barr did not allege noninfringement of all the '564 reissue patent's claims.

35. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA product before the expiration of the '564 reissue patent, Barr has committed an act of infringement under 35 U.S.C. § 271(e)(2).

36. Plaintiffs Bayer Schering and Bayer HealthCare are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Barr's ANDA shall be a date which is not earlier than June 30, 2014, the current expiration date of the '564 reissue patent, or any later date of exclusivity to which Plaintiffs become entitled.

COUNT TWO: CLAIM FOR PATENT INFRINGEMENT OF UNITED STATES REISSUE PATENT NO. 37,838

37. Plaintiffs incorporate paragraphs 1 – 28 of this Complaint as if fully set forth herein.

38. On information and belief, Barr's ANDA product directly and indirectly infringes one or more claims of the '838 reissue patent.

39. The '838 reissue patent covers Bayer HealthCare's YAZ® tablets and has been listed for the product in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book").

40. On information and belief, Barr submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA product before the expiration of the '838 reissue patent.

41. On information and belief, Barr made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '838 reissue patent is invalid or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA product.

42. While Barr alleged noninfringement of several of the '838 reissue patent's claims in its Notice Letter, Barr did not allege noninfringement of all the '838 reissue patent's claims.

43. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA product before the expiration of the '838 reissue patent, Barr has committed an act of infringement under 35 U.S.C. § 271(e)(2).

44. Plaintiffs Bayer Schering and Bayer HealthCare are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Barr's ANDA shall be a date which is not earlier than June 30, 2014, the current expiration date of the '838 reissue patent, or any later date of exclusivity to which Plaintiffs become entitled.

COUNT THREE: CLAIM FOR PATENT INFRINGEMENT OF UNITED STATES REISSUE PATENT NO. 38,253

45. Plaintiffs incorporate paragraphs 1 – 28 of this Complaint as if fully set forth herein.

46. On information and belief, Barr's ANDA product directly and indirectly infringes one or more claims of the '253 reissue patent.

47. The '253 reissue patent covers Bayer HealthCare's YAZ® tablets and has been listed for the product in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book").

48. On information and belief, Barr submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA product before the expiration of the '253 reissue patent.

49. On information and belief, Barr made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '253 reissue patent is invalid or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA product.

50. While Barr alleged noninfringement of several of the '253 reissue patent's claims in its Notice Letter, Barr did not allege noninfringement of all the '253 reissue patent's claims.

51. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA product before the expiration of the '253 reissue patent, Barr has committed an act of infringement under 35 U.S.C. § 271(e)(2).

52. Plaintiffs Bayer Schering and Bayer HealthCare are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Barr's ANDA shall be a date which is not earlier than June 30, 2014, the current expiration date of the '253 reissue patent, or any later date of exclusivity to which Plaintiffs become entitled.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Barr has infringed one or more claims of the '564 reissue patent, the '838 reissue patent, and the '253 reissue patent by filing its ANDA relating to Barr's generic product containing drospirenone and ethinylestradiol;

B. Judgment that Barr has infringed one or more claims of the '564 reissue patent, the '838 reissue patent, and the '253 reissue patent by making, using, selling and offering to sell its generic product containing drospirenone and ethinylestradiol;

C. An award to Bayer of damages adequate to compensate Bayer for Barr's acts of infringement together with prejudgment interest;

D. An award to Bayer of enhanced damages, up to and including trebling of Bayer's damages pursuant to 35 U.S.C. § 284, for Barr's willful infringement;

E. An award of Bayer's costs of suit and reasonable attorneys' fees pursuant to 35 U.S.C. § 285 due to the exceptional nature of this case, or as otherwise permitted by law;

F. A preliminary and permanent injunction restraining and enjoining Barr and its officers, agents, attorneys, employees, and those acting in privity or concert with it, from

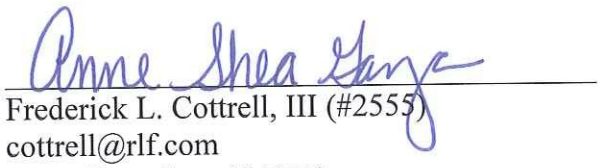
engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Barr's ANDA product;

G. An order that the effective date of any approval of Barr's ANDA relating to Barr's generic product containing drospirenone and ethinylestradiol be a date which is not earlier than the expiration date of the latter of the '564 reissue patent, the '838 reissue patent, and '253 reissue patent, or any later date of exclusivity to which Plaintiffs become entitled; and

H. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a jury trial on all issues so triable.



Frederick L. Cottrell, III (#2555)
cottrell@rlf.com
Anne Shea Gaza (#4093)
gaza@rlf.com
Richards, Layton & Finger, P.A.
One Rodney Square
920 North King Street
Wilmington, Delaware 19801
(302) 651-7500
Attorneys for Plaintiffs
Bayer Schering Pharma AG
and Bayer HealthCare Pharmaceuticals Inc.

Of Counsel:

Peter B. Bensinger, Jr.
Adam K. Mortara
Paul J. Skiermont
Sundeep K. Addy
Matthew R. Ford
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
54 West Hubbard Street
Chicago, Illinois 60610

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