IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
(EASTERN DIVISION)

Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. **Plaintiffs,** **v.** **Teva Pharmaceuticals USA, Inc., Barr Pharmaceuticals LLC, and Barr Laboratories, Inc.** **Defendants.**	**Civil Action No. 1:10-cv-3697** **DEMAND FOR JURY TRIAL**

COMPLAINT

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Attorneys for Plaintiffs Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc.

Plaintiffs Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer") file this Complaint against Defendants Teva Pharmaceuticals USA, Inc., Barr Pharmaceuticals LLC, and Barr Laboratories, Inc. (collectively, "Teva") and allege as follows:

1. This is an action for a temporary restraining order, preliminary and permanent injunctive relief, and for further relief based on (1) false advertising under Section 43(a) of the Lanham Act; and (2) patent infringement under 35 U.S.C. § 271.

PARTIES

2. 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.

3. 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 6 West Belt, Wayne, New Jersey 07470.

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

5. On information and belief, Defendant Barr Pharmaceuticals LLC ("BP LLC"), formerly known as Boron Acquisition LLC, is a Delaware limited liability company having a principal place of business at 225 Summit Avenue, Montvale, New Jersey 07645. Defendant BP LLC develops, manufactures, and markets generic pharmaceutical products through its operating

subsidiary Barr Laboratories, Inc. On information and belief, BP LLC is a wholly owned subsidiary of Teva Pharmaceutical Industries Limited.

6. On information and belief, Defendant Barr Laboratories, Inc. ("Barr Labs") is a Delaware corporation having a principal place of business at 225 Summit Avenue, Montvale, New Jersey 07645. On information and belief, Barr Labs is a wholly owned subsidiary of Defendant BP LLC, and the two have common officers and directors.

7. On information and belief, Defendants Teva USA and BP LLC directed, authorized, participated in, assisted, and cooperated with Defendant Barr Labs in all of the acts complained of herein. Hereinafter, all Defendants shall be collectively referred to as "Teva."

JURISDICTION AND VENUE

8. This action arises under (1) the patent laws of the United States, 35 U.S.C. § 271 et seq.; and (2) the Lanham Act, 15 U.S.C. § 1051 et seq. Accordingly, the Court has jurisdiction over this matter under 28 U.S.C. §§ 1331, 1338(a) and 15 U.S.C. §§ 1116, 1121.

9. This Court has personal jurisdiction over Defendants BP LLC, Barr Labs, and Teva USA. On information and belief, BP LLC, Barr Labs, and Teva USA have continuous and systematic general business contacts that approximate physical presence in the Northern District of Illinois as a result of pervasive activities conducted within Illinois, including without limitation the sale, offer for sale, importation, and distribution of the generic oral contraceptive Gianvi™. Further, Defendants BP LLC, Barr Labs, and Teva USA have committed and continue to commit acts of patent infringement, directly and/or through agents, intermediaries and/or third parties, by shipping, distributing, importing, offering for sale and/or selling certain infringing products in Illinois. Defendants BP LLC, Barr Labs, and Teva USA have purposefully and voluntarily placed Gianvi™ into the stream of commerce and offered Gianvi™

for sale in Illinois and this judicial district with the intent that consumers will purchase Gianvi™ in Illinois and this judicial district. On information and belief, Defendants BP LLC, Barr Labs, and Teva USA have purposefully directed their infringing activities toward Illinois and its residents by promoting Gianvi™ on their internet web sites with the intent of reaching potential customers in Illinois and selling Gianvi™ to Illinois residents and distributors. Accordingly, personal jurisdiction over BP LLC, Barr Labs, and Teva USA is appropriate under the Illinois Long-Arm Statute, 735 Ill. Comp. Stat. 5/2-209(a)-(c) (2008).

10. Venue is proper in the Northern District of Illinois under 28 U.S.C. §§ 1391(b)-(c) and 1400(b) because, *inter alia*, this Court has personal jurisdiction over Teva and Teva's Lanham Act violations and infringing offers to sell have occurred and will continue to occur in this judicial district.

BACKGROUND

11. 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 stabilized by β-cyclodextrin as a clathrate. The United States Food and Drug Administration ("FDA") has approved YAZ® tablets for the prevention of pregnancy in women who elect to use an oral contraceptive and, in women who elect to use an oral contraceptive, for the treatment of acne and premenstrual dysphoric disorder.

12. Bayer HealthCare sells YAZ® tablets in the United States as a 28-day combined oral contraceptive regimen that contains 24 tablets comprising 3 mg of micronized drospirenone and 0.02 mg of micronized 17α-ethinylestradiol stabilized by β-cyclodextrin as a clathrate, plus 4 placebo tablets.

13. A combined oral contraceptive consists of two active ingredients: a progestin and a synthetic estrogen. Other than in Bayer's new Natazia® product, ethinylestradiol is the synthetic estrogen in all currently marketed combined oral contraceptives, including Bayer's YAZ® tablets. But unlike all other combined oral contraceptives, the ethinylestradiol in Bayer's YAZ® tablets is in a clathrate consisting of β-cyclodextrin, also known as "betadex." A clathrate is a molecule that forms a "cage" around another molecule or molecules. The betadex clathrate in YAZ® protects the enclosed ethinylestradiol molecule by stabilizing the product against oxidation. Thus, the betadex clathrate formulation of ethinylestradiol improves YAZ® and makes it a better product. The use of betadex clathrate to stabilize ethinylestradiol is the subject of U.S. Patent No. 5,798,338, as discussed in greater detail below.

14. After receiving FDA approval, YAZ® quickly became one of the best-selling oral contraceptives in the world with several hundred million dollars of sales. Bayer's 24-day YAZ® product is the only oral contraceptive on the market today that is FDA-approved for oral contraception, as well as the treatment of moderate acne and the treatment of premenstrual dysphoric disorder (PMDD) in women also seeking oral contraception. In addition, YAZ® is the only oral contraceptive containing an ethinylestradiol stabilized by a betadex clathrate. As a result of its success, YAZ® became a target for generic drug manufacturers, who copied Bayer's pioneering work and now desire to sell the drug under generic labeling.

15. On information and belief, Barr Labs 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, and/or importation of a generic version of Bayer's YAZ® tablets.

16. As part of the ANDA-approval process, Barr Labs submitted draft labeling to the FDA for its generic YAZ® product. The draft labeling indicated that its proposed drug product would contain ethinylestradiol. But Barr Labs did not indicate that its ANDA drug product included a betadex clathrate to stabilize the ethinylestradiol. In addition, Barr Labs sent Bayer an ANDA notice letter on December 28, 2006, which stated that its ANDA drug product did not use a betadex.

17. On information and belief, on or about June 1, 2010, Teva announced that it commercially launched Barr Labs' ANDA drug product under the name "Gianvi™" as a generic version of Bayer's YAZ® product.

18. Teva's launch materials and package insert for Gianvi™ that have been distributed to wholesalers, distributors, pharmacies and pharmacists indicate that the product contains ethinylestradiol stabilized by a betadex as a clathrate. Teva has also included this information on its website and in the physical package insert for Gianvi™. In addition, the website for the National Institutes of Health also contains the package insert for Gianvi™ and also states that Gianvi™ contains ethinylestradiol stabilized by betadex as a clathrate. Wholesalers, distributors, pharmacies and pharmacists within the pharmaceutical market look to the package insert to provide all relevant information about an FDA-approved drug product, its composition, and its ingredients.

19. On information and belief, Teva's Gianvi™ product does not in fact contain ethinylestradiol stabilized by betadex as a clathrate.

PATENT-IN-SUIT

20. The patent-in-suit is U.S. Patent No. 5,798,338. The '338 patent issued on August 25, 1998. Bayer Schering is the current owner of the '338 patent. Bayer attaches a true and original copy of the '338 patent as Exhibit A.

COUNT ONE: CLAIM FOR FALSE ADVERTISING UNDER 15 U.S.C. § 1125(A)

21. Bayer refers to and incorporates herein the allegations of Paragraphs 1-20.

22. On information and belief, Teva markets Gianvi™ to drug wholesalers, distributors, pharmacies, pharmacists, and others in interstate commerce as containing the identical active ingredients and strengths as YAZ® including the identical and patented betadex clathrate formulation of ethinylestradiol. Teva intends for these drug wholesalers, distributors, pharmacies, pharmacists, and others to rely on this information and to form the belief that the Gianvi™ product is identical to YAZ® and contains ethinylestradiol stabilized by a betadex clathrate.

23. To the extent Gianvi™ does not contain ethinylestradiol stabilized by a betadex clathrate, Teva's statement to the contrary in Gianvi™'s launch materials and package insert is literally false and misleading. Teva's statement in the launch materials and package insert violates Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), which provides in relevant part that "any person who, on or in connection with any goods or services, . . . uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is likely to be damaged by such act."

24. Teva's statement that Gianvi™ contains ethinylestradiol stabilized by a betadex clathrate misrepresents the nature, characteristics and quality of Gianvi™ and has either deceived or has the tendency to deceive drug wholesalers, distributors, pharmacies, pharmacists, and others in interstate commerce. Because Teva represents that Gianvi™ is "stabilized" by the betadex in its product, this misrepresentation influenced or was likely to influence these purchasers' decisions to buy Gianvi™.

25. By reason of Teva's conduct, Bayer has suffered and will continue to suffer immediate damage to its business, reputation and goodwill. Pursuant to 15 U.S.C. § 1117, Teva's Lanham Act violations entitle Bayer to damages, an accounting of profits made by Teva on sales of Gianvi™, and recovery of Bayer's costs and reasonable attorney fees incurred in this action.

26. Teva's acts are willful, wanton, and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling Bayer to recover additional damages and reasonable attorney fees pursuant to 15 U.S.C. § 1117.

27. Unless enjoined by this Court, Teva's acts will immediately and irreparably injure Bayer's goodwill and erode its market share. Pursuant to 15 U.S.C. § 1116, Bayer is entitled to preliminary and permanent injunctive relief to prevent Teva's continuing acts.

28. Unless temporarily restrained by this Court, Teva's acts will immediately and irreparably injure Bayer's goodwill and erode its market share. Pursuant to Federal Rule of Procedure 65(b) and the requirements for a preliminary injunction, Bayer is entitled to a temporary restraining order and preliminary injunction to prevent Teva's continuing acts. Bayer is likely to prevail on the merits of its Lanham Act claim because, among other facts, Teva's statements are literally false. Bayer's injury from Teva's continuing acts is irreparable and not

fully compensable by money damages because the damage to Bayer is irreversible and difficult to calculate. Teva's false statements prevent Bayer from distinguishing and promoting its branded product to its customers based on the advantages of betadex during the critical time period immediately after a generic product launch. Teva's acts also prevent Bayer from quantifying or measuring the effectiveness of such a betadex counter-marketing campaign. Finally, Teva's acts harm third-party purchasers and the public interest by sowing confusion and misinformation as a result of Teva's false statements.

COUNT TWO: CLAIM FOR PATENT INFRINGEMENT OF UNITED STATES PATENT NO. 5,798,338

29. Bayer refers to and incorporates herein the allegations of Paragraphs 1-28.

30. The United States Patent and Trademark Office duly and legally issued the '338 patent in 1998. The '338 patent covers Bayer HealthCare's YAZ® tablets and has been listed for the product in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book").

31. Upon information and belief, Teva has been and is now directly infringing, and/or actively inducing infringement by others, and/or contributing to the infringement by others of U.S. Patent No. 5,798,338 in this District, and elsewhere in the United States. Teva infringes the '338 patent literally and/or under the doctrine of equivalents.

32. By way of example and not limitation, Teva infringes at least claim 1 of the '338 patent, which claims:

> A pharmaceutical composition comprising an effective amount of 17α-ethinylestradiol and an amount of a β-cyclodextrin [betadex] which is effective in reducing the oxidative degradation of the 17α-ethinylestradiol, wherein the composition is a clathrate.

33. Upon information and belief, Teva has offered for sale a combined oral contraceptive known as Gianvi™ as containing 17α-ethinylestradiol stabilized by a betadex as a clathrate – *i.e.*, with a betadex that "is effective in reducing the oxidative degradation of the 17α-ethinylestradiol."

34. Teva has actively infringed, induced infringement, and/or contributed to the infringement and is still actively infringing, inducing, and/or contributing to the infringement of the '338 patent, and will continue to do so unless enjoined by the Court.

35. Teva has had actual notice that a composition of 17α-ethinylestradiol stabilized by a betadex clathrate would infringe the '338 patent since the preparation of its ANDA prior to December 28, 2006.

36. Bayer has suffered and is suffering monetary damages from Teva's unauthorized infringement that are compensable under 35 U.S.C. § 284 in an amount to be determined at trial or hearing.

37. Upon information and belief, Teva's infringement of the '338 patent has been and continues to be willful and deliberate, making this an exceptional case entitling Bayer to recover additional damages and reasonable attorney fees pursuant to 35 U.S.C. § 285.

38. Teva's acts of infringement of the '338 patent have immediately and irreparably harmed and will continue to harm Bayer unless and until this Court permanently enjoins and restrains Teva's acts of infringement.

39. Unless temporarily and preliminarily restrained by this Court, Teva's acts will immediately and irreparably injure Bayer's goodwill and erode its market share. Pursuant to Federal Rule of Procedure 65(b) and the requirements for a preliminary injunction, Bayer is entitled to a temporary restraining order and preliminary injunction to prevent Teva's continuing

infringing acts. Bayer is likely to prevail on the merits of its Patent Infringement claim because, among other facts, Teva's offers to sell infringe at least claim 1 of the '338 patent. Bayer's injury from Teva's continuing infringing acts are irreparable and not fully compensable by money damages because the damage to Bayer is irreversible and difficult to calculate. Teva's false offers to sell prevent Bayer from distinguishing and promoting its branded product to its customers based on the patented advantages of betadex during the critical time period immediately after a generic product launch. Teva's infringing acts also prevent Bayer from quantifying or measuring the effectiveness of such a betadex counter-marketing campaign. Finally, Teva's infringing acts harm third-party purchasers and the public interest by sowing confusion and misinformation as a result of Teva's false statements.

REQUEST FOR RELIEF

WHEREFORE, Bayer requests that the Court enter judgment in its favor and against Teva as follows:

1. A temporary restraining order pursuant to Rule 65(b) of the Federal Rules of Civil Procedure, temporarily restraining Teva and its agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation from directly or indirectly falsely advertising or promoting Gianvi™ by claiming that it contains ethinylestradiol stabilized by a betadex clathrate; from making or inducing others to make any false, misleading or deceptive statement of fact, or representation of fact, in connection with the promotion, advertisement, display, sale, offering for sale, manufacture, production, circulation or distribution of Gianvi™ in such fashion as to suggest that this product contains ethinylestradiol stabilized by a betadex clathrate; from claiming that Gianvi™ contains ethinylestradiol stabilized by a betadex clathrate by placing a label with this claim in any drug information databases,

websites, Gianvi™ packaging, and/or pricing systems in the United States; and from further infringement of U.S. Patent No. 5,798,338;

2. A judgment and order preliminarily and permanently enjoining Teva and its agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation from directly or indirectly falsely advertising or promoting Gianvi™ by claiming that it contains ethinylestradiol stabilized by a betadex clathrate;

3. A judgment and order preliminarily and permanently enjoining Teva and its agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation from making or inducing others to make any false, misleading or deceptive statement of fact, or representation of fact in connection with the promotion, advertisement, display, sale, offering for sale, manufacture, production, circulation or distribution of Gianvi™ in such fashion as to suggest that this product contains ethinylestradiol stabilized by a betadex clathrate;

4. A judgment and order preliminarily and permanently enjoining Teva and its agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation from claiming that Gianvi™ contains ethinylestradiol stabilized by a betadex clathrate by placing a label with this claim in any drug information databases, websites, Gianvi™ packaging, and/or pricing systems in the United States;

5. A judgment and order that Teva take corrective action to correct any erroneous impression persons may have derived concerning the nature, characteristics or qualities of Gianvi™;

6. A judgment and order granting Bayer such other relief as the Court may deem appropriate to prevent the trade and public from deriving any erroneous impression concerning the nature, characteristics or qualities of Gianvi™;

7. A judgment that Teva has infringed one or more claims of U.S. Patent No. 5,798,338 as alleged herein;

8. A judgment and order preliminarily and permanently enjoining Teva and its agents, servants, employees, representatives, successors, and assigns, and all others in active concert or participation from further infringement of U.S. Patent No. 5,798,338;

9. A judgment and order requiring Teva to pay Bayer damages under 35 U.S.C. § 284, including treble damages for willful infringement, and supplemental damages for any continuing post-verdict infringement up until entry of the final judgment with an accounting as needed;

10. A judgment and order requiring Teva to pay Bayer damages under 15 U.S.C. § 1117(a) in the amount of Bayer's actual and consequential damages and any profits Teva obtained from marketing Gianvi™;

11. A judgment and order requiring Teva to pay Bayer reasonable attorney fees, costs and expenses, including those available under 35 U.S.C. § 285, 15 U.S.C. § 1117(a) and any other applicable law;

12. A judgment and order requiring Teva to pay Bayer's pre-judgment and post-judgment interest on the damages awarded and assessing all costs of this action against Teva; and/or

13. A judgment and order providing such other and further relief as the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Bayer hereby demands a jury trial for all issues so triable.

DATED: June 15, 2010

Respectfully submitted,

BAYER SCHERING PHARMA AG
BAYER HEALTHCARE PHARMACEUTICALS INC.

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CERTIFICATE OF SERVICE

I, Adam K. Mortara, an attorney, hereby certify that a true and correct copy of the foregoing document entitled **COMPLAINT** was electronically filed with the Clerk of the Court for the Northern District of Illinois using the CM/ECF System on June 15, 2010.

By: /s/ Adam K. Mortara
Adam K. Mortara