IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION 600 Pennsylvania Avenue, N.W. Washington, D.C. 20580 Plaintiff, v. WARNER CHILCOTT HOLDINGS COMPANY III, LTD. 100 Enterprise Drive Rockaway, N.J. 07866-2129 WARNER CHILCOTT CORPORATION 100 Enterprise Drive Rockaway, N.J. 07866-2129 WARNER CHILCOTT (US) INC. 100 Enterprise Drive Rockaway, N.J. 07866-2129 GALEN (CHEMICALS) LTD. Unit 4 Burton Hall Pk. Sandyford Industrial Estate Foxrock, Ireland and BARR PHARMACEUTICALS, INC. 2 Quaker Road, P.O. Box 2900 Pomona, N.Y. 10970-0519 Defendants.	Civil Action No.

Complaint for Injunctive and Other Equitable Relief

Plaintiff, the Federal Trade Commission (FTC), by its designated attorneys, petitions this Court, pursuant to Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b)

(2005), for a permanent injunction against defendants Warner Chilcott Holdings Company III, Ltd., Warner Chilcott Corporation, Warner Chilcott (US) Inc., Galen (Chemicals) Ltd. (collectively "Warner Chilcott"), and Barr Pharmaceuticals, Inc. ("Barr"), to undo and prevent their unfair methods of competition in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a) (2005).

I. Introduction

1. This case involves a horizontal agreement not to compete between Warner Chilcott and Barr, two sellers of prescription drugs. Warner Chilcott sells Ovcon 35 ("Ovcon"), an oral contraceptive used to prevent pregnancy. Barr is the only company approved by the United States Food and Drug Administration ("FDA") to sell a generic version of Ovcon in competition with Warner Chilcott's branded Ovcon.

2. Prior to the challenged agreement, Barr planned to compete with Warner Chilcott by selling Barr's lower-priced generic Ovcon once Barr received FDA approval. Both Warner Chilcott and Barr predicted that entry of Barr's lower-priced generic into the market would reduce Warner Chilcott's higher-priced branded Ovcon's sales, by capturing approximately 50 percent of Ovcon's business in the first year alone.

3. To forestall this competitive threat and to protect its Ovcon sales, Warner Chilcott entered into an agreement with Barr preventing entry of Barr's generic Ovcon into the United States for five years. In exchange for Barr's agreement to keep its generic Ovcon off the market, Warner Chilcott paid Barr $20 million.

4.

is vested with authority and responsibility for enforcing, *inter alia*, Section 5 of the FTC Act, 15 U.S.C. § 45 (2005), and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b) (2005), to initiate court proceedings to enjoin violations of any law the FTC enforces.

11. Defendant Warner Chilcott Holdings Company III, Ltd. is a privately-owned, for-profit company organized, existing, and doing business under and by virtue of the laws of Bermuda, with its office and principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey 07866-2129.

12. Warner Chilcott Holdings Company III, Ltd., through its direct and indirect subsidiaries, is engaged in the discovery, development, manufacturing, and distribution of pharmaceutical products in the United States, including Ovcon.

13. Defendant Warner Chilcott Corporation is a wholly-owned indirect subsidiary of Warner Chilcott Holdings Company III, Ltd. and is the direct 100% shareholder of Warner Chilcott (U.S.) Inc. Warner Chilcott Corporation is organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey 07866-2129.

14. Defendant Warner Chilcott (U.S.) Inc., is a wholly-owned subsidiary of Warner Chilcott Corporation. Warner Chilcott (U.S.) Inc., is organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey 07866-2129.

15. Galen (Chemicals) Ltd., is organized, existing, and doing business under and by virtue of the laws of the Republic of Ireland. Galen Chemicals is directly or indirectly owned or

controlled by Warner Chilcott Holdings Company III, Ltd. Galen Chemicals entered into the anticompetitive agreement that prevents Barr's generic Ovcon entry challenged herein.

16. In the twelve months ending September 30, 2004, Warner Chilcott had net revenues of approximately $490.2 million. During that same period, Warner Chilcott's gross profit margin on product net sales was approximately 89 percent.

17. Defendant Barr is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware. Barr's office and principal place of business is located at 2 Quaker Road, P.O. Box 2900, Pomona, New York 10970-0519.

18. Barr is engaged in the business of, among other things, developing, manufacturing, marketing, and distributing generic oral contraceptive products. In the twelve months ending June 30, 2004, Barr had net revenues of approximately $349 million and net income of approximately $123 million.

IV. Background

A. The Regulatory System Governing Pharmaceuticals in the United States

19. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, codified at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e) (2005), establishes procedures designed to facilitate competition from lower-priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.

20. A company seeking FDA approval to market a new drug (i.e., a branded drug) must file a New Drug Application (NDA) demonstrating the safety and efficacy of its product. 21 U.S.C. § 355(b) (2005).

21. An "AB-rated" generic drug is one that the FDA has determined to be bioequivalent to a branded drug. A generic drug is considered bioequivalent to a branded drug if it contains the same active pharmaceutical ingredient as the branded drug, and if there is no significant difference in the formulation, quality, and effectiveness of the two drugs. *See* 21 U.S.C. § 355(j)(8)(B) (2005).

22. A company seeking to market an "AB-rated" generic version of a branded drug may file an Abbreviated New Drug Application (ANDA) with the FDA. 21 U.S.C. § 355(j) (2005).

23. FDA approval of an ANDA takes, on average, about 18 months, although the approval process can take two years or more.

B. The Consumer Benefits of Generic Drugs

24. Almost all states (and the District of Columbia) encourage generic competition through laws that allow pharmacists to dispense an AB-rated generic drug when presented with a prescription for its branded equivalent, unless a physician directs, or the patient requests, otherwise. These state laws facilitate substitution of the lower-priced AB-rated generic drugs for the higher-priced branded drugs.

25. Many third party payers of prescription drugs (e.g., health insurance plans, Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts, when an AB-rated generic is available.

26. As a result of these lower prices and the ease of substitution, many consumers routinely switch from a branded drug to an AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs, after their introduction, typically promptly capture a significant share of their branded counterparts' sales, causing a significant reduction of the branded drug's unit and dollar sales.

27. Competition from generic drugs generates large savings for consumers. A 1998 Congressional Budget Office Report estimates that in 1994 alone, purchasers saved $8-10 billion on prescriptions at retail pharmacies by purchasing generic drugs instead of the equivalent brand name drugs. A 2004 FDA study calculates that patients could reduce the daily costs of their medications by more than 50 percent by purchasing generic drugs when available.

C. Warner Chilcott's Ovcon Oral Contraceptive

28. alone, purchasers saved $8-10 billion)Tj ET BT 1 Tf 12 108 395.5 Td Ovcon was originally a branded oral contraceptive 36 Td(on prescriptions

32. Ovcon is highly profitable for Warner Chilcott. For the twelve months ending September 30, 2004, Warner Chilcott's net sales of Ovcon were approximately $71.5 million.

D. The Threat of Barr's Generic Ovcon Entry to Warner Chilcott

33. In September 2001, Barr filed an ANDA with the FDA for approval to manufacture and sell an AB-rated generic version of Ovcon.

34. In January 2003, Barr publicly announced its intention to market generic Ovcon by the end of that year.

35. Barr planned to price generic Ovcon at approximately 30 percent less than the price that Warner Chilcott charges for branded Ovcon.

36. Barr projected that its generic Ovcon would capture approximately 50 percent of Warner Chilcott's branded Ovcon sales within the first year of introduction.

37. Warner Chilcott expected that Barr would price its generic Ovcon at approximately 30 percent less than the price Warner Chilcott charges for branded Ovcon.

38. Warner Chilcott projected that generic Ovcon would capture at least 50 percent of Ovcon's new prescriptions within the first year of introduction. Warner Chilcott calculated that, as a result of these lost prescriptions, its net revenues from the sale of branded Ovcon would decline by at least $100 million over a three year period.

39. Warner Chilcott had planned to protect its Ovcon revenues from generic competition by introducing a chewable form of the product (Ovcon Chewable) before generic Ovcon entry occurred. Warner Chilcott's strategy was to convert its Ovcon customers to Ovcon Chewable and to stop selling Ovcon. Prescriptions for Ovcon Chewable could not be filled at the

pharmacy with a generic Ovcon product (absent express approval of the patient's physician), because any generic version of Ovcon would not be AB-rated to Ovcon Chewable.

40. By mid-2003, however, Warner Chilcott's "switch" strategy to protect its Ovcon revenues – by converting customers to Ovcon Chewable before generic Ovcon entry – was in jeopardy. Barr's generic Ovcon entry appeared imminent, and Ovcon Chewable had not obtained FDA approval.

41. In May 2003, Warner Chilcott's chief financial officer warned the company's Board of Directors that generic Ovcon entry was the "biggest risk to the company."

V. The Defendants' Horizontal Agreement Not to Compete

42. By the summer of 2003, Warner Chilcott believed that Barr's generic Ovcon entry could occur as early as September of that year.

43. In August 2003, Warner Chilcott and Barr discussed a possible business arrangement under which Barr would agree to refrain from competing in the United States with its generic Ovcon product.

44. On September 10, 2003, Warner Chilcott and Barr executed a letter of intent. According to the letter of intent, Warner Chilcott would pay Barr $20 million and Barr would not compete in the United States for five years with its generic Ovcon product when Barr received final FDA approval. Instead of entering and competing, Barr would agree to be available as a second supplier of Ovcon to Warner Chilcott if Warner Chilcott so requested.

45. In February 2004, FTC staff notified Warner Chilcott and Barr that it intended to investigate the non-compete agreement outlined in the defendants' letter of intent because of its potential to significantly reduce competition by eliminating the only generic alternative to Ovcon.

46. On March 24, 2004, the defendants signed their Final Agreement implementing the letter of intent. Warner Chilcott paid Barr $1 million upon signing the Final Agreement.

47. Under the Final Agreement, within 45 days after the FDA approved Barr's generic Ovcon ANDA, Warner Chilcott could elect to pay the remaining $19 million to secure Barr's agreement to refrain from marketing generic Ovcon in the United States, either by itself or through a licensee, for five years. The Final Agreement referred to this arrangement as Warner Chilcott's option to an exclusive license to Barr's ANDA for generic Ovcon.

48. In addition, the Final Agreement gave Warner Chilcott the ability to purchase Ovcon supply from Barr, pursuant to specified payment terms. The ability to purchase supply from Barr would arise, however, only after Barr received final FDA approval for its generic Ovcon. Both Warner Chilcott and Barr understood that if, upon receiving FDA approval, Ba

53. Warner Chilcott did not begin purchasing Ovcon supply from Barr at that time, but instead continued to purchase Ovcon supply solely from Bristol-Myers Squibb Co., until about May 2005.

54. Under the terms of the Final Agreement, Barr cannot sell generic Ovcon in the United States for five years, or until approximately May 2009. Absent its agreement not to compete with Warner Chilcott, Barr would have started selling generic Ovcon shortly after receiving final FDA approval in April 2004.

55. Entry of Barr's generic Ovcon into the United States would have quickly and significantly reduced the sales of Warner Chilcott's branded Ovcon, and led to a significant reduction in the average price purchasers paid for Ovcon products.

56. Barr has abided by its agreement not to sell generic Ovcon in the United States.

57. As of the date of this complaint, Barr remains the only company that has received approval from the FDA to make an AB-rated generic version of Ovcon.

VII. The Defendants' Agreement Not to Compete Harms Competition and Consumer Welfare

58. Entry of Barr's generic Ovcon would give consumers the choice between branded Ovcon and Barr's lower-priced generic Ovcon.

59. Had Barr entered the 5.05 0 Td(nt i7>BDC BT/TT0 1 r-r)Tj7.0108 392.43 0 Td(Oj17.2 0)TjET0

66. Even under a broader inquiry, the agreement not to compete is anticompetitive. The purpose and effect of this agreement is to prevent Barr – which has the only FDA-approved generic Ovcon product – from offering consumers a lower-priced, therapeutically equivalent alternative to Warner Chilcott's higher-priced branded Ovcon. Consequently, as a result of defendants' agreement not to compete, an agreement that lacks any countervailing efficiency-enhancing justification, many purchasers – including consumers, insurers, pharmacies, wholesalers, government agencies, managed care organizations, and others – are paying higher prices in the market for Ovcon and its AB-rated generic equivalents than would otherwise prevail absent the agreement not to compete.

67. By entering into this illegal horizontal agreement not to compete, defendants Warner Chilcott and Barr have engaged, and are engaging, in unfair methods of competition in or affecting commerce, in violation of Section 5 of the FTC Act. 15 U.S.C. § 45 (2005).

IX. The Court's Power to Grant Relief

68. Section 13(b) of the FTC Act empowers this Court to issue a permanent injunction against violations of the FTC Act and, in the exercise of its equitable jurisdiction, to order ancillary equitable relief to remedy the injury caused by defendants' violations.

X. Prayer for Relief

WHEREFORE, the FTC requests that this Court, as authorized by 15 U.S.C. § 53(b) (2005), 15 U.S.C. § 26 (2005), and pursuant to its own equitable powers, enter final judgment against defendants, declaring, ordering, and adjudging: