

IN THE UNITED STATES DISTRICT COURT
FOR 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

WARNER CHILCOTT COMPANY, INC.
Union Street, Km. 1.1
Fajardo, Puerto Rico 00738

Defendants.

Civil Action No. 1:05-cv-02179-CKK

FINAL ORDER AND STIPULATED PERMANENT INJUNCTION

WHEREAS Plaintiff, Federal Trade Commission (“Commission”), filed its First Amended Complaint on December 5, 2005, pursuant to Section 13(b) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 53(b), seeking injunctive and other equitable relief for violations of Section 5 of the FTC Act, 15 U.S.C. § 45;

AND WHEREAS, in conjunction with the filing of this Final Order and Stipulated Permanent Injunction (“Final Order”), Plaintiff and Warner Chilcott Holdings Company III, Ltd.,

Warner Chilcott Corporation, Warner Chilcott (US) Inc., and Warner Chilcott Company, Inc. (collectively "Warner Chilcott"), by their respective attorneys, have stipulated and agreed to entry by the Court of this Final Order without trial or adjudication of any issue of fact or law;

AND WHEREAS, this Final Order is entered for settlement purposes only and does not constitute any evidence against, or an admission of liability, wrongdoing, or of any issue of fact, other than jurisdictional, or law, by Defendant Warner Chilcott;

AND WHEREAS, Defendant Warner Chilcott agrees to be bound by the provisions of this Final Order pending its approval by the Court;

AND WHEREAS, Defendant Warner Chilcott has waived the exclusivity provisions of the agreements challenged in the Complaint and this Final Order, as described herein, requires Defendant Warner Chilcott to refrain from entering into similar agreements in the future;

AND WHEREAS, Defendant Warner Chilcott has represented to the Plaintiff that the relief required below can and will be made and that Defendant Warner Chilcott will later raise no claim of hardship or difficulty as grounds for asking the Court to modify any of the terms of the relief contained below;

AND WHEREAS, Defendant Warner Chilcott, without admitting that it has violated Section 5 of the FTC Act, 15 U.S.C. § 45, agrees to the entry of this Final Order under Section 13(b) of the FTC Act;

NOW THEREFORE, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is

ORDERED, ADJUDGED AND DECREED THAT:

I. Jurisdiction and Venue

- A. This Court has jurisdiction over Warner Chilcott and the subject matter of this action. Warner Chilcott's activities, including the acts and practices alleged in Plaintiff's Complaint, are in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.
- B. Venue is proper in this Court under Sections 5 and 13(b) of the FTC Act, 15 U.S.C. §§ 45, 53(b). Warner Chilcott transacts and does business in the District of Columbia.
- C. The Complaint states a claim upon which relief may be granted against Warner Chilcott under Sections 5 and 13(b) of the FTC Act, 15 U.S.C. §§ 45, 53(b).
- D. This case is a proper case for the issuance of a permanent injunction pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b). The Commission has authority, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to seek the relief it has requested.
- E. Warner Chilcott waives all rights to appeal or otherwise challenge or contest the validity of this Final Order, and Warner Chilcott waives any claim under the Equal Access to Justice Act, 28 U.S.C. § 2412.
- F. Entry of this order is in the public interest.

II. Definitions

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT, as used in this Final Order:

- A. "Warner Chilcott" means Warner Chilcott Holdings Company III, Ltd., Warner Chilcott Corporation, Warner Chilcott (US) Inc., Warner Chilcott Company, Inc., and its officers,

directors, employees, agents and representatives, successors, and assigns; subsidiaries, divisions, groups, and affiliates controlled by Warner Chilcott; and the officers, directors, employees, agents and representatives, successors, and assigns of each.

- B. "Agreement" means anything that would constitute a contract, combination, or conspiracy within the meaning of Section 1 of the Sherman Act, 15 U.S.C. § 1, regardless of whether such contract, combination, or conspiracy is in restraint of trade.
- C. "ANDA" means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j), *et seq.*
- D. "ANDA Filer" means the party to a Branded/Generic Supply Agreement or a Branded/Generic Agreement who Controls the generic version of the Subject Drug Product.
- E. "Branded/Generic Agreement" means any Agreement in or affecting Commerce, other than a Supply Agreement, in which a party is the NDA Holder and another party is the ANDA Filer.
- F. "Branded/Generic Supply Agreement" means any Supply Agreement in or affecting Commerce in which a party is the NDA Holder and another party is the ANDA Filer.
- G. "Commerce" has the same definition as it has in 15 U.S.C. § 44.
- H. "Commission" means the Federal Trade Commission.
- I. "Control" means, in connection with a Drug Product, to (1) exclusively distribute the Drug Product; or (2) have the rights to the Drug Product that have accrued or would accrue from the FDA's approval of an NDA or ANDA.

- J. "Drug Product" means a finished dosage form (e.g., tablet, capsule, or solution), as defined in 21 C.F.R. § 314.3(b), that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.
- K. "Encouraging" means suggesting, advising, pressuring, inducing, attempting to induce, prompting, or otherwise influencing.
- L. "Enter Into" and "Entering Into" means join, participate in, implement, adhere to, maintain, organize, enforce, or facilitate.
- M. "Existing Inventory" means Regular Ovcon in finished packaging ready for sale to trade customers that has more than nine months left to expiration and that is located in Delaware as of the date of entry of this Final Order.
- N. "FDA" means the United States Food and Drug Administration.
- O. "NDA" means a New Drug Application, as defined under 21 U.S.C. § 355(b), et seq.
- P. "NDA Holder" means the party to a Branded/Generic Agreement or Branded/Generic Supply Agreement that Controls the branded version of the Subject Drug Product.
- Q. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- R. "Regular Ovcon" means all Drug Products marketed or sold by Warner Chilcott as Ovcon-35 under NDA 17-716 or ANDA 76-238.
- S. "Subject Drug Product" means a Drug Product involved in the Branded/Generic Agreement or the Branded/Generic Supply Agreement.
- T. "Supply Agreement" means an Agreement under which one party purchases a Drug Product from another party for ultimate resale in the United States.

III. Prohibited Supply Agreements

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT: Until the expiration of this Final Order as provided in Paragraph VIII, Warner Chilcott is enjoined from Entering Into, or attempting to Enter Into, directly or indirectly, or through any corporate or other device, any Branded/Generic Supply Agreement where an ANDA Filer agrees to refrain from, or to limit, for any period of time, the research, development, manufacturing, marketing, distribution or sale of a generic version of a Subject Drug Product.

IV. Other Prohibited Agreements

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT: Until the expiration of this Final Order as provided in Paragraph VIII, Warner Chilcott is enjoined from Entering Into, or attempting to Enter Into, directly or indirectly, or through any corporate or other device, any Branded/Generic Agreement where:

- A. The NDA Holder provides anything of value to the ANDA Filer,
- B. The ANDA Filer refrains from, or limits, for any period of time, the research, development, manufacturing, marketing, distribution or sale of a generic version of the Subject Drug Product; and
- C. Such Branded/Generic Agreement unreasonably restrains competition.

V. Agreements Subject to Notification

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT:

- A. Until the expiration of this Final Order as provided in Paragraph VII, Warner Chilcott shall provide notice to the Commission of (i) any Branded/Generic Agreement, or (ii) any Branded/Generic Supply Agreement that is not prohibited pursuant to Paragraph III (“Agreements Subject to Notification”).
- B. The notification required by Paragraph V.A. shall be made within the later of: (i) thirty (30) days after the entry of this Final Order or (ii) within five (5) business days after the Agreement Subject to Notification is executed or otherwise goes into effect.
- C. The notification required by Paragraph V.A. of this Final Order shall be in the form of a letter (“Notification Letter”) submitted to the Commission containing the following information:
1. a statement that the purpose of the Notification Letter is to give the Commission notification of an Agreement Subject to Notification as required by Paragraph V of this Final Order;
 2. identification of all Persons involved in the Agreement Subject to Notification;
 3. identification of all Persons (to the extent known) who have filed an ANDA with the FDA (including the status of such application(s)) for a generic version of the Drug Product involved in the Agreement Subject to Notification; and
 4. a copy of the Agreement Subject to Notification, or written descriptions of any Agreement that has not been reduced to writing.

- D. The Notification Letters to be submitted pursuant to Paragraph V.A. of this Final Order shall be submitted to the Office of the Secretary, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580, and copies of such letters and documents shall be submitted to the Assistant Director for Compliance, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580, and to the Assistant Director for Health Care Services and Products, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580.

VI. Other Prohibited Conduct

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT: Warner Chilcott is enjoined from:

- A. Deleting the National Drug Code for Regular Ovcon from the National Drug Data File until the expiration of this Final Order as provided in Paragraph VIII;
- B. Destroying Existing Inventory of Regular Ovcon, or Encouraging others to do so for a period of three (3) months from the date this Final Order is entered;
- C. Buying back, offering to buy back, or otherwise inducing the return of, Regular Ovcon that has been distributed to retailers, wholesalers, or other customers for a period of three (3) months from the date this Final Order is entered, except in the case of recalls made to ensure patient safety; and
- D. Failing to fill orders from retailers, wholesalers, or other customers for Regular Ovcon in a commercially reasonable and timely manner from Warner Chilcott's Existing Inventory

of Regular Ovcon for a period of three (3) months from the date this Final Order is entered.

VII. Notice and Reporting Requirements

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT: Warner

Chilcott shall:

- A. File a verified, written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with this Final Order: (1) within ninety (90) days from the date this Final Order is entered, (2) annually thereafter for five (5) years on the anniversary of the date this Final Order is entered, and (3) at such other times as the Commission may request by written notice.
- B. For a period of five (5) years from the date this Final Order is entered, maintain and make available to Commission staff for inspection and copying upon reasonable notice, records sufficient to describe in detail any action taken in connection with the activities covered by this Final Order.
- C. Until expiration of this Final Order as provided in Paragraph VIII, notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of Warner Chilcott, (2) acquisition, merger or consolidation of Warner Chilcott, or (3) any other change in Warner Chilcott that may affect compliance obligations arising out of this Final Order, including but not limited to assignment or the creation or dissolution of subsidiaries.
- D. Address each notice and report required by Paragraph VII of the Final Order to the Office of the Secretary, Federal Trade Commission, 600 Pennsylvania Avenue, NW,

Washington, DC 20580; and send a copy of each such notice and report to the Assistant Director for Compliance, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580.

VIII. Termination of Final Order

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT: This Final Order shall take effect on, and expire ten (10) years from, the date this Final Order is entered.

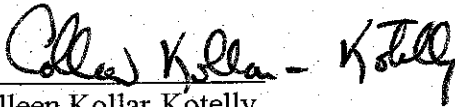
IX. Retention of Jurisdiction

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT: The Court retains jurisdiction of this matter for purposes of construction, modification and enforcement of this Final Order.

X. Costs

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT: Each party shall bear its own costs of this action.

Entered this 23rd day of Oct., 2006.


Colleen Kollar-Kotelly
U.S. District Judge