

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

STATE OF COLORADO
by Attorney General John W. Suthers
1525 Sherman Street, Fifth Floor
Denver, Colorado 80203

Civil Action No. 1:05-cv-02182-CKK-AK

COMMONWEALTH OF VIRGINIA
by Attorney General Robert F. McDonnell
900 East Main Street
Richmond, Virginia 23219

STATE OF MARYLAND
by Attorney General Douglas F. Gansler
200 St. Paul Street
Baltimore, Maryland 21202

STATE OF ALASKA
by Attorney General Talis J. Colberg
1031 W. 4th Avenue #200
Anchorage, Alaska 99501

STATE OF ARIZONA
by Attorney General Terry Goddard
1275 West Washington
Phoenix, Arizona 85007-2926

STATE OF ARKANSAS
by Attorney General Dustin McDaniel
323 Center Street, Suite 200
Little Rock, Arkansas 72201

STATE OF CALIFORNIA
by Attorney General Edmund G. Brown, Jr.
1515 Clay St.
Oakland, California 94612

STATE OF DELAWARE
by Attorney General Joseph R. Biden III
Carvel State Office Building
820 N. French Street
Wilmington, Delaware 19801

DISTRICT OF COLUMBIA
by Attorney General Linda Singer
441 Fourth Street, NW, Suite 450N
Washington, District of Columbia 20001

STATE OF FLORIDA
by Attorney General Bill McCollum
PL-01 The Capitol
Tallahassee, Florida 32399

STATE OF IDAHO
by Attorney General Lawrence Wasden
650 W. State Street, Lower Level
Boise, Idaho 83720-0010

STATE OF ILLINOIS
by Attorney General Lisa Madigan
100 West Randolph Street, 13th Floor
Chicago, Illinois 60601

STATE OF IOWA
by Attorney General Thomas J. Miller
2nd Floor, Hoover Office Building
East 13th and Walnut
Des Moines, Iowa 50319

STATE OF KANSAS
by Attorney General Paul Morrison
120 SW 10th Street, 2nd Floor
Topeka, Kansas 66612

COMMONWEALTH OF KENTUCKY
by Attorney General Gregory D. Stumbo
1024 Capital Center Drive
Frankfort, Kentucky 40601

STATE OF LOUISIANA
by Attorney General Charles C. Foti, Jr.
1885 N. 3rd Street, 4th Floor
Baton Rouge, Louisiana 70802

STATE OF MAINE
by Attorney General G. Steven Rowe
6 State House Station
Augusta, Maine 04333-0006

COMMONWEALTH OF
MASSACHUSETTS
by Attorney General Martha Coakley
One Ashburton Place
Boston, Massachusetts 02108

STATE OF MICHIGAN
by Attorney General Michael A. Cox
G. Mennen Williams Building, 6th Floor
525 W. Ottawa Street
Lansing, Michigan 48913

STATE OF MINNESOTA
by Attorney General Lori Swanson
102 State Capitol
St. Paul, Minnesota 55155-1609

STATE OF MISSISSIPPI
by Attorney General Jim Hood
Post Office Box 22947
Jackson, Mississippi 39225

STATE OF MISSOURI
by Attorney General Jeremiah (Jay) W. Nixon
P.O. Box 899
Jefferson City, MO 65102

STATE OF NEVADA
By Attorney General Catherine Cortez Masto
555 East Washington Avenue, Suite 3900
Las Vegas, Nevada 89101

STATE OF NEW YORK
by Attorney General Andrew Cuomo
120 Broadway, Suite 26C
New York, New York 10271-0332

STATE OF NORTH CAROLINA
by Attorney General Roy Cooper
9001 Mail Service Center
Raleigh, NC 27699-9001

STATE OF NORTH DAKOTA
by Attorney General Wayne Stenehjem
P.O. Box 1054
Bismarck, North Dakota 58502-1054

STATE OF OHIO
by Attorney General Marc Dann
150 East Gay Street, 20th Floor
Columbus, Ohio 43215

STATE OF OKLAHOMA
by Attorney General W.A. Drew Edmonson
4545 N. Lincoln Boulevard, Suite 260
Oklahoma City, Oklahoma 73105

STATE OF OREGON
by Attorney General Hardy Myers
1162 Court Street NE
Salem, Oregon 97301

STATE OF RHODE ISLAND
by Attorney General Patrick C. Lynch
150 South Main Street
Providence, Rhode Island 02903

STATE OF SOUTH CAROLINA
by Attorney General Henry D. McMaster
Rembert C. Dennis Building
1000 Assembly Street, Suite 501
Columbia, South Carolina 29211-1549

STATE OF TENNESSEE
by Attorney General Robert E. Cooper, Jr.
P.O. Box 20207
Nashville, Tennessee 37202-0207

STATE OF TEXAS
by Attorney General Greg Abbott
P.O. Box 12548
Austin, Texas 78711

STATE OF UTAH
by Attorney General Mark L. Shurtleff
160 East 300 South, Fifth Floor
Salt Lake City, Utah 84111

and

STATE OF VERMONT
by Attorney General William H. Sorrell
109 State Street
Montpelier, Vermont 05609-1001

PLAINTIFFS,

v.

WARNER CHILCOTT HOLDINGS
COMPANY III, LTD.
100 Enterprise Drive
Rockaway, New Jersey 07866

WARNER CHILCOTT CORPORATION
100 Enterprise Drive
Rockaway, New Jersey 07866

WARNER CHILCOTT (US) INC.
100 Enterprise Drive
Rockaway, New Jersey 07866

and

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

DEFENDANTS.

FINAL ORDER AND STIPULATED PERMANENT INJUNCTION

WHEREAS Plaintiffs, the states of Colorado, Alaska, Arizona, Arkansas, California, Delaware, Florida, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nevada, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Utah, and Vermont, the commonwealths of Kentucky, Massachusetts and Virginia, and the District of Columbia, by their

Attorneys General, (“Plaintiff States” or “States”), filed their Second Amended Complaint (“Complaint”) against Warner Chilcott Holdings Company III, Ltd., Warner Chilcott Corporation, Warner Chilcott (US) Inc., and Warner Chilcott Company Inc. (“Warner Chilcott”) on October 3, 2006, pursuant to Section 1 of the Sherman Act, 15 U.S.C. § 1, Section 16 of the Clayton Act, 15 U.S.C. § 26, and 28 U.S.C. §§ 1331, 1337, and state antitrust, consumer protection and/or unfair competition statutes and related state laws, seeking civil penalties, injunctive and other equitable relief (the “State Action”);

AND WHEREAS, in conjunction with the filing of this Final Order and Stipulated Permanent Injunction (“Final Order”), Plaintiff States and 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 any issue of fact or law, other than jurisdictional, by Warner Chilcott;

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

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

AND WHEREAS, another aspect of this Final Order is the payment by Warner Chilcott of a monetary payment to the Plaintiff States in the amount of \$5.5 million representing equitable relief, settlement of claims for civil penalties, and/or attorneys' fees and costs;

AND WHEREAS, Warner Chilcott has represented to the Plaintiff States that the relief required can and will be made and that 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, Warner Chilcott, without admitting that it has violated any provision of federal or state law, agrees to the entry of this Final Order;

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 States' Complaint, are in or affecting commerce, as "commerce" is defined in 15 U.S.C. § 12.
- B. Venue is proper in this Court under Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. §§ 1391(b) and (c).
- C. The Complaint states a claim upon which relief may be granted against Warner Chilcott.

- D. This case is a proper case for the issuance of a permanent injunction. The Plaintiff States have authority pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26 and pursuant to state statutes cited in the Complaint to seek the relief requested.
- E. Warner Chilcott waives all rights to appeal or otherwise challenge or contest the validity of this Final Order.

II. Definitions

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

- A. “Warner Chilcott” comprises Warner Chilcott (as defined above) 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 the Clayton Act, 15 U.S.C. § 12.
- H. “Control” means, in connection with a Drug Product, to (1) exclusively distribute the Drug Product; or (2) have the rights to the Drug Product accruing from the FDA’s approval of an NDA or ANDA.
- I. “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.
- J. “Enter Into” means join, participate in, implement, adhere to, maintain, organize, enforce, or facilitate.
- K. “FDA” means the United States Food and Drug Administration.
- L. “Plaintiff States’ Liaison Counsel” means counsel for the States of Colorado, New York, Maryland, and Oregon.
- M. “NDA” means a New Drug Application, as defined under 21 U.S.C. § 355(b).

- N. “NDA Holder” means the party to a Branded/Generic Supply Agreement or a Branded/Generic Agreement who Controls the branded version of the Subject Drug Product.
- O. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- P. “Plaintiff States” is defined in the preamble.
- Q. “Regular Ovcon” means all Drug Products marketed or sold by Warner Chilcott as Ovcon 35 under NDA 17 716 or ANDA 76 238.
- R. “Subject Drug Product” means a Drug Product involved in the Branded/Generic Agreement or the Branded/Generic Supply Agreement.
- S. “Supply Agreement” means an Agreement under which one party purchases a Drug Product from another party for ultimate resale in the United States.

III. Monetary Relief

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT, not later than five (5) business days after receiving the payment information pursuant to Paragraph III.A., Warner Chilcott shall pay the sum of \$5,500,000 to the Plaintiff States (the “Payment”) under the following terms and conditions:

- A. The Payment must be made by wire transfer made payable and delivered as directed by the Plaintiff States. The Plaintiff States shall advise undersigned counsel for Warner Chilcott in writing of the information necessary for Warner Chilcott to effectuate the wire

transfer within five (5) business days after entry of this Final Order. Warner Chilcott shall have no dominion, control or title to the Payment. The Payment shall be used by the Attorney General of each Plaintiff State at his/her sole discretion according to the terms of this Final Order. The Attorney General of each Plaintiff State shall use these funds consistently with his/her state laws for any of the following purposes: 1) payment of attorneys' fees and costs; 2) antitrust or consumer protection law enforcement; 3) deposit into a state antitrust or consumer protection revolving fund; or 4) as otherwise provided by state law.¹ All funds paid to the Plaintiff States pursuant to this Final Order shall be deposited into accounts administered by the Plaintiff States or their agent(s).

- B. Warner Chilcott shall have no right to challenge the Plaintiff States' distribution of the Payment under Paragraph III.A of this Final Order. Warner Chilcott shall have no right to contest the manner in which the funds are utilized.

IV. Prohibited Supply Agreements

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT, until the expiration of this Final Order, 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.

¹ With respect to the State of Colorado, its apportionment shall be used first for reimbursement of Colorado's actual costs and attorneys fees and second, to be held along with any interest thereon, in trust by the Attorney General for future consumer education, consumer fraud or antitrust enforcement efforts.

V. Other Prohibited Agreements

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT, until the expiration of this Final Order, 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; and
- 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.

VI. Agreements Subject to Notification

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT:

- A. Until the expiration of this Final Order, Warner Chilcott shall provide notice (the “Notification”) to the Plaintiff States’ Liaison Counsel of (i) any Branded/Generic Agreement, or (ii) any Branded/Generic Supply Agreement (“Agreements Subject to Notification”).
- B. The Notification shall be made within the later of: (i) thirty (30) days after the entry of this Final Order or (ii) five (5) business days after the Agreement Subject to Notification is executed or otherwise goes into effect.
- C. The Notification shall be in the form of a letter (“Notification Letter”) submitted to the Plaintiff States’ Liaison Counsel containing the following information:

1. A statement that the purpose of the Notification Letter is to give the Plaintiff States notification of an Agreement Subject to Notification as required by 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. All Notification Letters shall be submitted to the Plaintiff States' Liaison Counsel at the addresses listed in Paragraph VIII.D.

VII. Other Prohibited Conduct

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT Warner Chilcott is enjoined from deleting the National Drug Code for Regular Ovcon from drug databases administered by First DataBank, Inc. (e.g., the National Drug Data File), Medi-Span (a division of Wolters Kluwer Health, Inc.), or any successor databases or companies until the expiration of this Final Order. Nothing herein shall require Warner Chilcott to continue to market, sell or offer for sale Regular Ovcon.

VIII. Notice and Reporting Requirements

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT Warner Chilcott shall:

- A. File a verified, written report with the Plaintiff States' Liaison Counsel setting forth in detail the manner and form in which it has complied and is complying with this Final Order: (1) annually for five (5) years on or before the date that written, verified reports are due to the Federal Trade Commission, October 23, of each year, and (2) at such other times as the Plaintiff States' Liaison Counsel 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 the Plaintiff States 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 X, notify the Plaintiff States' Liaison Counsel 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 the Final Order to Plaintiff States' Liaison Counsel at the below addresses:

Office of the Colorado Attorney General
Antitrust Enforcement
1525 Sherman Street, Seventh Floor
Denver, Colorado 80203

Office of the Maryland Attorney General
Chief, Antitrust Division
200 St. Paul Place, 19th Floor
Baltimore, Maryland 21202

Office of the New York Attorney General
Chief, Antitrust Bureau
120 Broadway, 26th Floor
New York, New York 10271

Oregon Department of Justice
Attorney-In-Charge, Antitrust Enforcement
1162 Court Street, NE
Salem, Oregon 97310

IX. Release by Plaintiff States

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT:

- A. Plaintiff States fully, finally, and forever release, relinquish, and discharge all claims in the State Action against Warner Chilcott; provided, however, that the foregoing release shall not relieve Warner Chilcott of its obligations under this Final Order.
- B. Nothing in this Order shall affect, release, relinquish or discharge any claims of the Plaintiff States against any other Person (including, without limitation, Barr Pharmaceuticals, Inc.). All such claims are expressly reserved by each of the Plaintiff States.


X. 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.

XI. 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.

Entered this 29th day of June, 2007.


Colleen Kollar-Kotelly
U.S. District Judge