



other than jurisdictional, or law, by Defendant Warner Chilcott;

Final Order pending its approval by the Court;

agreements challenged in the Complaint and this Final Order, as described herein, requires

AND WHEREAS D.C. LAW

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

**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

B. Venue is proper in this Court under Sections 5 and 13(b) of the FTC Act, 15 U.S.C.

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, 52(a).

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

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.

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

- 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

- 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.

K. "Encouraging" means suggesting, advising, pressuring, inducing, attempting to induce,

L. "Enter Into" and "Entering Into" means join, participate in, implement, adhere to, maintain, organize, enforce, or facilitate.

Delaware as of the date of entry of this Final Order.

N. "FDA" means the United States Food and Drug Administration.

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

Agreement or the Branded/Generic Supply Agreement.

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

~~entering into, or attempting to enter into, directly or indirectly, or through any representative,~~

~~to limit, for any period of time, the research, development, manufacturing, marketing,~~

**IV. Other Prohibited Agreements**

**IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT:** Until the

- 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,

C. Such Branded/Generic Agreement unreasonably restrains competition.

### V. Agreements Subject to Notification

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT

(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 of the entry of this Final Order.

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;

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 determination of the Commission that the Agreement Subject to Notification is not enforceable.

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

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

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

ensure patient safety; and

D. Failing to fill orders from retailers, wholesalers, or other customers for Regular Ovcon in



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

## VII Notice and Reporting Requirements

form in which it has complied and is complying with this Final Order: (1) within ninety

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.

sufficient to describe in detail compliance with this Final Order.

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.

~~IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT:~~ This Final

X. Costs

~~IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT:~~ Each party

shall bear its own costs of this action.

Entered this 23<sup>rd</sup> day of Oct., 2006.

  
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U.S. District Judge