IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION, Plaintiff, v. BARR PHARMACEUTICALS, INC., Defendant.	Civil Action No. 1:05-cv-02179-CKK-AK Judge Collen Kollar-Kotelly Magistrate Judge Alan Kay

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 alleged 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 Barr Pharmaceuticals, Inc. ("Barr"), 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 or law, by Defendant Barr;

AND WHEREAS, the parties agree to be bound by the provisions of this Final Order pending its approval by the Court;

AND WHEREAS, Defendant Barr has launched the generic product at issue in the Complaint and this Final Order, as described herein, requires Defendant Barr to refrain from entering into certain identified types of agreements in the future;

AND WHEREAS, Defendant Barr has represented to the Plaintiff that the relief required below can and will be made and that Defendant Barr 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, Barr retains the right to seek to modify this Final Order, either unilaterally or jointly with the Commission (at the Commission's discretion), pursuant to Fed. R. Civ. P. 60(b)(6).

AND WHEREAS, Defendant Barr, 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. Solely for purposes of entry of this Final Order and enforcement thereof, this Court has jurisdiction over the parties and the subject matter of this action.

B. Solely for purposes of entry of this Final Order and enforcement thereof, venue is proper in this Court under Sections 5 and 13(b) of the FTC Act, 15 U.S.C. §§ 45, 53(b).

C. The parties waive all rights to appeal or otherwise challenge or contest the validity of this Final Order, including but not limited to any claim under the Equal Access to Justice Act, 28 U.S.C. § 2412.

D. Entry of this order is in the public interest.

II. Definitions

As used in this Final Order:

A. "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.

B. "ANDA" means an abbreviated new drug application filed under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.§ 355(j).

C. "ANDA Filer" means the party to a Branded/Generic Supply Agreement or a Branded/Generic Agreement who controls an ANDA for the Subject Drug Product or has the exclusive right to distribute the Generic Product.

D. "Barr" means Barr Pharmaceuticals, Inc., and its officers, directors, employees, agents and representatives, successors, and assigns; United States subsidiaries, divisions, groups, and affiliates controlled by Barr; and the officers, directors, employees, agents and representatives, successors, and assigns of each.

E. "Branded/Generic Agreement" means any Agreement in or affecting Commerce in the United States in which a party is the NDA Holder and another party is the ANDA Filer for the same Subject Drug Product.

F. "Branded/Generic Supply Agreement" means any supply agreement in or affecting Commerce in the United States in which a party is the NDA Holder and another party is the ANDA Filer for the same Subject Drug Product, and the ANDA Filer agrees to supply Generic Product to the NDA Holder.

G. "Commerce" has the same definition as it has in 15 U.S.C. § 44.

H. "Commission" means the Federal Trade Commission.

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

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

L. "Generic Product" means a Drug Product manufactured under an ANDA.

M. "NDA" means a New Drug Application, as defined under 21 U.S.C. § 355(b), et seq.

N. "NDA Holder" means the party to a Branded/Generic Agreement or Branded/Generic Supply Agreement that controls the NDA for the Subject Drug Product or has the exclusive right to distribute the branded Subject Drug Product.

O. "Patent Infringement Claim" means any written allegation of patent infringement, whether or not included in a complaint filed with a court of law, including but not limited to where the alleged infringer challenges only patent validity.

P. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

Q. "Qualifying Pharmaceutical Company" means a pharmaceutical company, other than the NDA Holder or Barr, that (i) has annual gross sales of generic pharmaceutical products in the United States of at least $250 million; and (ii) neither controls an ANDA for a Subject Generic Equivalent nor has the exclusive right to distribute a Subject Generic Equivalent.

R. "Subject Drug Product" means a Drug Product that is the subject of the Branded/Generic Agreement or the Branded/Generic Supply Agreement.

S. "Subject Generic Equivalent" means a Generic Product that is bioequivalent to the branded Subject Drug Product.

T. "Subject Generic Product" means a Generic Product that is the subject of the Branded/Generic Agreement or the Branded/Generic Supply Agreement.

III. Prohibited Agreements

Until the expiration of this Final Order as provided in Paragraph VI, Barr is enjoined from Entering Into, or attempting to Enter Into, directly or indirectly, or through any corporate or other device:

A. Any Branded/Generic Supply Agreement where:

1. Barr is the ANDA Filer; and

2. Barr agrees to refrain from or limit for any period of time the research, development, manufacturing, marketing, distribution or sale of the Subject Generic Product.

B. Any Branded/Generic Agreement where:

1. Barr is the ANDA Filer;

2. Barr receives monetary or other valuable consideration;

3. Barr agrees to refrain from or limit for any period of time the research, development, manufacturing, marketing, distribution or sale of the Subject Generic Product; and

4. Such Branded/Generic Agreement unreasonably restrains competition.

Provided, however, that nothing in Paragraph III.A. shall prohibit Barr from entering into such Branded/Generic Supply Agreement, if, prior to or contemporaneously with entering into such Branded/Generic Supply Agreement, (i) Barr has, in good faith, assigned, transferred, or otherwise given, to a Qualifying Pharmaceutical Company, the rights as Barr may possess them necessary to manufacture, market, distribute, and sell the Subject Generic Product ("Transfer Agreement"; (ii) the Qualifying Pharmaceutical Company has agreed, in good faith and as part

of the Transfer Agreement, to use commercially reasonable efforts to exploit such rights as soon as practicable; (iii) Barr has agreed in good faith to supply (which includes, if applicable, acting in good faith to obtain the regulatory and other approvals necessary to supply) the Subject Generic Product to such Qualifying Pharmaceutical Company on such terms and conditions that will allow the Qualifying Pharmaceutical Company to compete effectively for sales of the Subject Generic Equivalent until such time as the Qualifying Pharmaceutical Company can manufacture commercial quantities of the Subject Generic Product on its own or obtain commercial quantities of the Subject Generic Equivalent from another source; (iv) Barr has provided a copy of this Final Order and Stipulated Permanent Injunction to the persons responsible for assisting with the Transfer Agreement, of the Qualifying Pharmaceutical Company; (v) the Qualifying Pharmaceutical Company has agreed to cooperate with any Commission inquiry relating to the activities covered by the provision; and (vi) Barr has provided notice to the Commission of any such Transfer Agreement with a Qualifying Pharmaceutical Company, in the form specified in Paragraph IV.C.

Provided, further, that nothing in this Paragraph III shall prohibit Barr from entering into a Branded/Generic Agreement, including a Branded/Generic Supply Agreement, that resolves a Patent Infringement Claim involving the Subject Drug Product where such Branded/Generic Agreement does not unreasonably restrain competition.

IV. Agreements Subject to Notification

It is further ordered that:

A. Commencing with the date of entry of this Final Order and for a period of ten (10) years, Barr shall provide notice to the Commission of (i) any Branded/Generic Supply Agreement entered into after the date of entry of this Final Order, and (ii) any Branded/Generic Agreement entered into after the date of entry of this Final Order in

which Barr is the ANDA Filer and agrees to refrain from or limit for any period of time the research, development, manufacturing, marketing, distribution, or sale of the Subject Drug Product, except those that resolve a Patent Infringement Claim ("Agreements Subject to Notification").

B. The notification required by Paragraph IV.A. shall be made within the later of: (i) thirty (30) days after the entry of this Final Order, or (ii) within ten (10) business days after the Agreement Subject to Notification is executed.

C. The notification required by Paragraph IV.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 IV of this Final Order; (2) identification of all Persons involved in the Agreement Subject to Notification; and (3) a copy of the Agreement Subject to Notification, and in the event that any Agreement Subject to Notification has not been reduced to text, written descriptions of such Agreement Subject to Notification that are sufficient to disclose all the terms and conditions of the Agreement Subject to Notification.

D. The Notification Letters to be submitted pursuant to Paragraph IV.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.

V. Notice and Reporting Requirements

It is further ordered that:

A. Barr shall 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 three (3) years on the anniversary of the date this Final Order is entered, and (3) at any such other times as the Commission may request by written notice.

B. For a period of three (3) years from the date this Final Order is entered, Barr shall 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 VII, Barr shall notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of Barr, (2) acquisition, merger or consolidation of Barr, or (3) any other change in Barr that may affect compliance obligations arising out of this Final Order.

D. Barr shall address each notice and report required by Paragraph VI 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.

VI. 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.

VII. 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.

VIII. Dismissal and Costs

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

Entered this 27th day of Nov., 2007.

Colleen Kollar-Kotelly
U.S. District Judge