

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

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and

STATE OF VERMONT
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PLAINTIFFS,

v.

BARR PHARMACEUTICALS, INC.
2 Quaker Road
Box 2900
Pomona, New York 10970

DEFENDANT.

STIPULATED FINAL ORDER AND 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, 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;

AND WHEREAS, in conjunction with the filing of this Final Order and Stipulated Permanent Injunction (“Final Order”), Plaintiff States 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, Barr agrees to make a monetary payment to the Plaintiff States in the amount of \$5.9 million, subject to the terms and conditions provided herein;

AND WHEREAS, Defendant Barr has represented to the Plaintiff States 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 Plaintiff States (at the Plaintiff States' discretion), pursuant to Fed. R. Civ. P. 60(b)(6);

AND WHEREAS, Defendant Barr, 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. 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 Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. §§ 1391(b) and (c).
- C. The parties waive all rights to appeal or otherwise challenge or contest the validity of this Final Order.
- 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 the Clayton Act, 15 U.S.C. § 12.

- H. “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.
- I. “Enter Into” and “Entering Into” means join, participate in, implement, adhere to, maintain, organize, enforce, or facilitate.
- J. “FDA” means the United States Food and Drug Administration.
- K. “Generic Product” means a Drug Product manufactured under an ANDA.
- L. “Plaintiff States’ Liaison Counsel” or “Liaison Counsel” means counsel for the States of Colorado and New York, unless the Plaintiff States appoint other counsel to serve as Liaison Counsel and so advise Barr in writing; in no event shall there be more than two Liaison Counsel at a time.
- 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 a Branded/Generic Supply Agreement that controls the NDA for the Subject Drug Product, or has the exclusive right to distribute 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 VII, 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,

- 1) 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”);
- 2) 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;
- 3) 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;
- 4) 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;

- 5) the Qualifying Pharmaceutical Company has agreed to cooperate with any inquiry made by a Plaintiff State relating to the activities covered by the provision; and
- 6) Barr has provided notice to the Plaintiff States 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

A. Commencing with the date of entry of this Final Order and for a period of ten years, Barr shall provide notice to the Plaintiff States' Liaison Counsel of:

- 1) any Branded/Generic Supply Agreement entered into after the date of entry of this Final Order, and
 - 2) 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 (except as otherwise provided by this Final Order).
- ("Agreements Subject to Notification").

B. The notification required by Paragraph IV.A. shall be made within the later of:

- 1) Thirty days after the entry of this Final Order, or
- 2) within ten 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 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 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. In addition to the Notification required by Paragraphs A-C. above, and until the expiration of this Final Order, Barr shall provide to the Plaintiff States’ Liaison Counsel copies of all materials required to be submitted to the Federal Trade Commission pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003 (including any subsequent modifications of the notification provisions created by such Act) (“MMA Materials”). The MMA Materials shall be provided to the Liaison Counsel within the time frame and in the form applicable to submissions to the Federal Trade Commission under the Medicare Prescription Drug Improvement and Modernization Act of 2003.
- E. All Notification Letters and MMA Materials shall be submitted to the Plaintiff States’ Liaison Counsel at the addresses listed in Paragraph V.D.

V. Notice and Reporting Requirements

- A. Barr shall 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) within ninety days from the date this Final Order is entered;
 - 2) annually thereafter for three years on the anniversary of the date this Final Order is entered; and
 - 3) at any such other times as the Plaintiff States' Liaison Counsel may request by written notice.
- B. For a period of three years from the date this Final Order is entered, Barr shall maintain and make available to 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 VII, Barr shall notify the Plaintiff States' Liaison Counsel at least thirty days prior to any
- 1) proposed 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 IV of the Final Order to Plaintiff States' Liaison Counsel at the below addresses unless otherwise directed in writing by such Liaison Counsel:

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

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

VI. Monetary Relief

Not later than ten business days after receiving the Payment Information (defined below), Barr shall pay the sum of \$5.9 million to the Plaintiff States (the “Payment”) under the following terms and conditions:

A. The Payment must be made by wire transfer or ACH transfer made payable and delivered as directed by the Plaintiff States. The Plaintiff States shall advise undersigned counsel for Barr in writing of the information necessary for Barr to effectuate the wire transfer or ACH transfer within five business days after entry of this Final Order (“Payment Information”). Barr 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).

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

B. Barr shall have no right to challenge the Plaintiff States' distribution of the Payment. Barr shall have no right to contest the manner in which the funds are utilized.

VII. Termination of Final Order

This Final Order shall take effect on, and expire ten years from, the date this Final Order is entered.

VIII. Retention of Jurisdiction

The Court retains jurisdiction of this matter for purposes of construction, modification and enforcement of this Final Order.

IX. Dismissal and Costs

This action shall be dismissed with prejudice. Unless specifically set forth in this agreement, each party shall bear its own costs of this action.

Entered this 25th day of February, 2008.


Colleen Kollar-Kotelly
U.S. District Judge

by the Attorney General for future consumer education, consumer fraud or antitrust enforcement efforts.