

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.

PERRIGO COMPANY
515 Eastern Avenue
Allegan, MI 49010,

and

ALPHARMA INC.
One Executive Drive
Fort Lee, NJ 07024,

Defendants.

Civil Action No.

FINAL ORDER AND STIPULATED PERMANENT INJUNCTION

WHEREAS Plaintiff, Federal Trade Commission (“Commission”), filed its Complaint on August 17, 2004, 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 Defendant Alpharma Inc., 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 or of any issue of fact, other than jurisdictional, or law, by Defendant Alharma Inc.;

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

AND WHEREAS, Defendant Alharma Inc. has rescinded the agreement challenged in the Complaint and this Final Order requires Defendant Alharma Inc. to refrain from entering into similar agreements in the future to remedy the competition lost as alleged in the Complaint;

AND WHEREAS, another aspect of this Final Order is the payment by Defendant Alharma Inc. of \$2,500,000 pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b);

AND WHEREAS, Defendant Alharma Inc. has represented to the Plaintiff that the relief required below can and will be made and that Defendant Alharma Inc. 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 Alharma Inc., 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 Alpharma and the subject matter of this action. Alpharma'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).
- C. The Complaint states a claim upon which relief may be granted against Alpharma 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. Alpharma waives all rights to appeal or otherwise challenge or contest the validity of this Final Order, and Alpharma waives any claim under the Equal Access to Justice Act, 28 U.S.C. § 2412.

II. Definitions

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

- A. “Alpharma” means Alpharma, Inc., and its officers, directors, employees, agents and representatives, successors, and assigns; subsidiaries, divisions, groups, and affiliates controlled by Alpharma, Inc.; and the officers, directors, employees, agents and representatives, successors, and assigns of each.
- B. “180-day Exclusivity Period” means the six month market exclusivity period provided to the First Filer of an ANDA under 21 U.S.C. § 355(j), *et seq.*
- C. “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.
- D. “Agreement Subject to Notification” means an Agreement in or affecting Commerce in which a party to the Agreement agrees to refrain from, or to limit, for any period of time, the research, development, manufacture, marketing, distribution or sale of an ANDA Drug Product that it Controls and that is Of The Same Kind as another ANDA Drug Product Controlled by another party to the Agreement.
- E. “ANDA” means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j), *et seq.*
- F. “ANDA Drug Product” means a finished Dosage Form that (1) contains a drug substance, generally, but not necessarily, in association with one or more other ingredients, as defined in 21 C.F.R. § 314.3(b), and (2) is the subject of an ANDA filed with or approved by the FDA.

- 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 an ANDA Drug Product, to (1) exclusively distribute an ANDA Drug Product, (2) have the rights to an ANDA Drug Product accruing from the FDA’s approval of an ANDA, or (3) be in position to obtain such rights if the FDA were to approve an ANDA that has been filed with the FDA.
- J. “Date of the Agreement” means the date the Agreement is executed or otherwise goes into effect.
- K. “Dosage Form” means a category of drug delivery, including, but not limited to, the following categories: (1) tablets, (2) capsules, (3) liquids administered orally, (4) liquids administered intravenously or subcutaneously, (5) nasal sprays, (6) transdermal patches, and (7) suppositories.
- L. “Enter into” means join, participate in, implement, adhere to, maintain, organize, enforce, or facilitate.
- M. “First Commercial Marketing” has the same meaning it has in 21 C.F.R. § 314.107(c)(4).
- N. “First Filer of an ANDA” means the party whom the FDA determines is entitled to or eligible for, under 21 U.S.C. § 355(j), *et seq.*, a right to a 180-day Exclusivity Period that has not yet expired.
- O. “FDA” means the United States Food and Drug Administration.
- P. “NDA” means a New Drug Application, as defined under 21 U.S.C. § 355(b), *et seq.*

- Q. “Of The Same Kind” means to
1. have the same Dosage Form,
 2. contain the same, and only the same, active pharmaceutical ingredient(s), and
 3. be of the same Marketing Type.
- R. “Patent Infringement Claim” means any written allegation of patent infringement, whether or not included in a complaint filed with a court of law.
- S. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- T. “Marketing Type” means the following two categories: over-the-counter (“OTC”) and prescription (“Rx”). For purposes of this Final Order, an ANDA Drug Product is in the OTC category if its ANDA references an NDA for an OTC drug product, and is in the Rx category if its ANDA references an NDA for an Rx drug product.

III. Monetary Relief

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT, not later than three (3) days after entry of this Final Order, Alpharma shall pay to the Plaintiff the sum of Two Million Five Hundred Thousand Dollars (\$2,500,000), under the following terms and conditions:

- A. The payment must be made by wire transfer in accord with directions provided by the Plaintiff or by certified check or other guaranteed funds made payable to and delivered to the Plaintiff and shall not accrue interest. Alpharma shall have, or retain, no dominion, control

or title to the monies transferred to the Plaintiff, and all legal and equitable title to said monies shall be vested in the Plaintiff, for use according to the terms of this Final Order.

- B. All funds paid pursuant to this Final Order shall be deposited into a fund administered by the Plaintiff or its agent to be used for equitable relief, including but not limited to, compensation for antitrust injury and to pay any attendant costs for the administration of any such compensation fund. If direct compensation for antitrust injury is wholly or partially impracticable or funds remain after such compensation is completed, the Plaintiff may apply any remaining funds for such other equitable relief as it determines to be reasonably related to the unlawful acts or practices alleged in the Complaint. Any funds not used for such equitable relief shall be deposited to the United States Treasury as disgorgement. Alpharma shall have no right to challenge the Plaintiff's choice of remedies under Paragraph III of this Final Order. Alpharma shall have no right to contest the manner of distribution chosen by the Plaintiff.
- C. Alpharma shall not make any claim to or demand for return of the funds, directly or indirectly, through counsel or otherwise; and in the event of Alpharma's bankruptcy, the funds shall not be part of the debtor's estate, nor shall the estate have any claim or interest therein.
- D. In accordance with 31 U.S.C. § 7701, Alpharma is hereby required, unless it has done so already, to furnish to the Plaintiff its taxpayer identifying number, which shall be used for collecting and reporting on any delinquent amount arising out of Alpharma's relationship with the government.

IV. Prohibited Agreements

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT Alpharma is enjoined from Entering into, or attempting to Enter into, directly or indirectly, or through any corporate or other device, any Agreement in or affecting Commerce with any other Person in which:

- A. a party to the Agreement agrees to refrain from, or to limit, for any period of time, the research, development, manufacture, marketing, distribution or sale of an ANDA Drug Product that it Controls and that is Of The Same Kind as another ANDA Drug Product Controlled by another party to the Agreement, and
- B. a party to the Agreement is the First Filer of an ANDA with respect to:
 - 1. any ANDA Drug Product that is a subject of such Agreement, or
 - 2. any ANDA Drug Product that is Of The Same Kind as any ANDA Drug Product that is a subject of such Agreement.

PROVIDED, HOWEVER, THAT for purposes of Paragraph IV only, an ANDA Drug Product shall not include an ANDA withdrawn from the FDA more than six (6) months prior to the Date of the Agreement.

PROVIDED FURTHER THAT nothing in Paragraph IV shall prohibit the First Filer of an ANDA from agreeing to refrain from marketing, distributing, or selling the ANDA Drug Product referenced by such ANDA (“the First Filer’s ANDA Drug Product”) for a period of time lasting no more than 180 days after the First Commercial Marketing of any ANDA Drug Product Of The Same Kind as the First Filer’s ANDA Drug Product if:

- (1) such First Filer of an ANDA also agrees to (a) abandon, waive, selectively waive, or relinquish its 180-day Exclusivity Period under such ANDA, or (b) grant to another party to the Agreement the right to exclusively distribute such ANDA Drug Product for a period of time not to exceed the 180-day Exclusivity Period under such ANDA.
- (2) Alharma notifies the Commission of such Agreement in accordance with Paragraph V of this Final Order.

PROVIDED FURTHER THAT nothing in Paragraph IV shall prohibit the resolution of a Patent Infringement Claim in which any party to an Agreement resolving such Patent Infringement Claim agrees to refrain from, or to limit, for any period of time prior to the expiration of the patent that is the basis for the Patent Infringement Claim, such party's research, development, manufacturing, marketing, distribution, or sale of an ANDA Drug Product that is the subject of such Patent Infringement Claim if:

- (1) the amount received by such party ("Receiving Party") has a value of no more than two million dollars (\$2,000,000),
- (2) the total amount given to Receiving Parties by each party to the Agreement resolving such Patent Infringement Claim ("Paying Party") has a value of no more than the Paying Party's expected future litigation costs to resolve such Patent Infringement Claim, and
- (3) Alharma notifies the Commission of such Agreement in accordance with Paragraph V of this Final Order.

PROVIDED FURTHER THAT, nothing in Paragraph IV shall prohibit Alharma from Entering into any Agreement, if such Agreement is subject to the reporting obligations of Section 7A of the Clayton Act, 15 U.S.C. 18a ("HSR Act"), and Alharma submits a complete and

accurate Notification Letter (as specified in Paragraph V of this Final Order) and a Notification and Report Form pursuant to the HSR Act for such Agreement. Nothing in this Final Order shall be construed to relieve Alpharma of any obligation to comply with the requirements of the HSR Act or any other law of the United States; and any Agreement that violates any law of the United States will continue to be subject to separate legal action for violation of any such law, without regard to whether it violates this Final Order.

PROVIDED FURTHER THAT, nothing in this Paragraph IV shall prohibit, in connection with resolving *Apotex, Inc. v. Food and Drug Administration*, No. 04-5211 (D.C. Cir. filed Jun. 09, 2004), any Person from agreeing to refrain from marketing, distributing, or selling any ANDA Drug Product that references NDA No. 020235 for a period lasting no more than 180 days after Alpharma's first Commercial Marketing of its ANDA Drug Product that references NDA No. 020235.

V. Agreements Subject to Notification

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT:

- A. Alpharma shall notify the Commission of each Agreement Subject to Notification that Alpharma joins, participates in, implements, adheres to, maintains, organizes, enforces, or facilitates at any time after the entry of this Final Order.
- B. The notification required by Paragraph V.A. shall be made within thirty (30) days after the entry of this Final Order or within five (5) business days after the Agreement Subject to Notification is executed or otherwise goes into effect, whichever is later.

- 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. the docket number and caption name of this Final Order;
 2. a statement that the purpose of the Notification Letter is to give the Commission notification of an Agreement as required by Paragraph V of this Final Order;
 3. identification of all parties involved in the Agreement;
 4. identification of all ANDA Drug Products involved in the Agreement;
 5. identification of all Persons (to the extent known) who have filed an ANDA with the FDA (including the status of such application(s)) for any ANDA Drug Product Of The Same Kind as the ANDA Drug Product(s) involved in the Agreement;
 6. a copy of the Agreement; and
 7. identification of the court, and a copy of the docket sheet, for every legal action that involves any party to the Agreement and that relates to any ANDA Drug Product Of The Same Kind as the ANDA Drug Product(s) involved in the Agreement.
- D. Within thirty (30) days of the receipt of a written request from a representative of the Commission, Alpharma shall submit to the Commission all documents which were prepared by or for any officer(s) or director(s) of Alpharma for the purpose of evaluating or analyzing any Agreement covered by Paragraph V.A. of this Final Order. Alpharma shall retain such documents for the full term of this Order.
- E. The Notification Letters to be submitted pursuant to Paragraph V.A. of this Final Order and the documents to be submitted pursuant to Paragraph V.D. 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. Notice and Reporting Requirements

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT Alpharma 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. Notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of Alpharma, (2) acquisition, merger or consolidation of Alpharma, or (3) any other change in Alpharma 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 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.

VII. 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.

VIII. 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.

IX. Costs

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

X. Public Interest

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT entry of this Final Order is in the public interest.

Dated: _____, 2004.

United States District Judge