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Perrigo - Final Order and Stipulated Permanent Injunction

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

STATE OF MARYLAND, et al.
by Attorney General J. Joseph Curran, Jr.
200 St. Paul Place
Baltimore, Maryland 21202

Plaintiffs,

v.

PERRIGO COMPANY, et al.
515 Eastern Avenue
Allegan, MI 49010

Defendants.

Civ No. 1:04CV01398 (RMC)

FINAL ORDER AND STIPULATED PERMANENT INJUNCTION

WHEREAS Plaintiffs, the States and Commonwealths of Maryland, Colorado, Ohio, Florida, Michigan, Alabama, Alaska, Arizona, Arkansas, California, Connecticut, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Northern Mariana Islands, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virgin Islands, Virginia, Washington, West Virginia, Wisconsin and Wyoming ("Plaintiff States" or "States"), filed their Complaint on August 17, 2004 pursuant to Section 1 of the Sherman Act, 15 U.S.C. § 1 and Section 16 of the Clayton Act, 15 U.S.C. § 26, and 28 U.S.C. §§ 1331, 1337, and seeking civil penalties, injunctive and other equitable relief for

violations of state antitrust, consumer protection and/or unfair competition statutes and related state laws;

AND WHEREAS, in conjunction with the filing of this Final Order and Stipulated Permanent Injunction ("Final Order"), Plaintiff States 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 any issue of fact or law, other than jurisdictional, by Defendant Alpharma, Inc.;

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

AND WHEREAS, Defendant Alpharma, Inc. has rescinded the agreement challenged in the Complaint and this Final Order requires Defendant Alpharma, Inc. to refrain from entering into similar agreements in the future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 Alpharma, Inc. of 1) \$166,666.50 to the Plaintiff States and of 2) \$333,333.50 to the National Association of Attorneys General Antitrust Enforcement Training and Education Fund Account, representing equitable relief and/or settlement payments in lieu of civil penalties;

AND WHEREAS, Defendant Alpharma, Inc. will pay \$248,863.25 to Liaison Counsel for the Plaintiff States in attorneys' fees and costs of investigation;

AND WHEREAS, Defendant Alpharma, Inc. has represented to the Plaintiff States that the relief required below can and will be made and that Defendant Alpharma, 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 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 Defendant Alharma, Inc. ("Alharma") and the subject matter of this action. Alharma'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. § 44.
- 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 Alharma pursuant to the statutes cited therein.
- 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. Alpharma 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. "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 a 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: (a) tablets, (b) capsules, (c) liquids administered orally, (d) liquids administered intravenously or subcutaneously, (e) nasal sprays, (f) transdermal patches, and (g) 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. "Liaison Counsel for the Plaintiff States" means counsel for the States of Maryland, Colorado, Ohio, Florida and Michigan.
- Q. "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.
- R. "NDA" means a New Drug Application, as defined under 21 U.S.C. § 355(b).
- S. "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.
- T. "Patent Infringement Claim" means any written allegation of patent infringement, whether or not included in a complaint filed with a court of law.
- U. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- V. "Plaintiff States" means the States and Commonwealths of Maryland, Colorado, Ohio, Florida, Michigan, Alabama, Alaska, Arizona, Arkansas, California, Connecticut, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Northern Mariana Islands, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virgin Islands, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

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 1) the sum of \$166,666.50 to the Plaintiff States and 2) the sum of \$333,333.50 to the National Association of Attorneys General Antitrust Training and Education Fund Account ("ATE Fund Account") under the following terms and conditions:

- A. The payment to the Plaintiff States must be made by wire transfer, certified check or other guaranteed funds made payable to and delivered as directed by the Plaintiff States. Alpharma shall have or retain no dominion, control or title to the monies transferred to or at the direction of the Plaintiff States, and said monies shall be used at the sole discretion of the Attorney General in each Plaintiff State and according to the terms of this Final Order. The Attorney General in each Plaintiff State may use these funds consistently with his/her state laws for any of the following purposes: 1) payment of investigative fees and costs; 2) antitrust or consumer protection law enforcement; 3) deposit into a state antitrust or consumer protection revolving fund; or 4) use in accordance with state law.¹ All funds paid to the Plaintiff States or to the Liaison Counsel for the Plaintiff States pursuant to this Final Order shall be deposited into funds administered by the Plaintiff States or their escrow agent.
- B. The payment to the ATE Fund Account must be made by wire transfer, certified check or other guaranteed funds made payable to the ATE Fund Account and delivered as directed by the Plaintiff States. Upon entry of this Order, Alpharma relinquishes all dominion, control

¹With 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 in trust by the Attorney General for future consumer education, consumer fraud or antitrust enforcement efforts.

and title to the monies transferred to the ATE Fund Account and agrees that said monies shall constitute a contribution to the ATE Fund Account.

- C. Alpharma shall have no right to challenge the Plaintiff States' choice of remedies under Paragraph III of this Final Order. Alpharma shall have no right to contest the manner in which the funds are utilized.
- D. Alpharma warrants that, as of the date of this Final Order, neither it nor any of its affiliates, is insolvent, nor will any payment to the Plaintiff States and the ATE Fund Account render it or any of its affiliates insolvent, within the meaning of and/or for the purposes of the United States Bankruptcy Code. If a case is commenced with respect to Alpharma or any of its affiliates, under Title 11 of the United States Code (Bankruptcy), or a trustee, receiver or conservator is appointed under any similar law, and in the event of the entry of a final order of a court of competent jurisdiction determining the payment of the principal amount of the payment to the Plaintiff States or the ATE Fund Account, and any accrued interest, or any portion thereof, by or on behalf of Alpharma or any affiliate of Alpharma, to be a preference, voidable transfer, fraudulent transfer or similar transaction, and if pursuant to an order of a court of competent jurisdiction monies paid by Alpharma or any of its affiliates, to the Plaintiff States or to the ATE Fund Account pursuant to this Final Order either not delivered or are returned to Alpharma or any of its affiliates, or the trustee, receiver, or conservator appointed by a court in any bankruptcy proceeding with respect to Alpharma or any of its affiliates, then this Final Order shall be subject to termination and cancellation. Such termination and cancellation will be the sole and exclusive remedy of the Plaintiff States for breach of this warranty.

- E. In accordance with 31 U.S.C. § 7701, Alpharma is hereby required, unless it has done so already, to furnish to the Plaintiff States its taxpayer identification 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 the 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, and
- (2) Alpharma notifies the Plaintiff States 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) Alpharma notifies the Plaintiff States of such settlement in accordance with Paragraph V of this Final Order.

PROVIDED FURTHER THAT, nothing in Paragraph IV shall prohibit Alpharma 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 Alpharma 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 or of any Plaintiff State; and any Agreement that violates any law of the United States or of any Plaintiff State 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 Paragraph IV shall prohibit, in connection with resolving *Apotex, Inc. v. Food and Drug Administration*, No. 04-5211 (D.C. Cir. filed June 9, 2004), any Person from agreeing to refrain from marketing, distributing or selling any ANDA Drug Product that references NDA No. 020235 for a period no longer than 180 days following 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 Plaintiff States 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 counsel for the State of Maryland, one of the Liaison Counsel for the Plaintiff States, no more than five (5) days after executing any Agreement covered by Paragraph IV and 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 Plaintiff States notification of an Agreement as required by Paragraph V 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 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 Liaison Counsel for the Plaintiff States, Alpharma shall submit to the requesting Liaison Counsel for the Plaintiff States all documents which were prepared by or for any officer(s) or director(s) of Alpharma for the purpose of evaluating or analyzing the Agreement covered by Paragraph V.A of this Final Order. Alpharma shall retain such documents for the full term of this Final Order.

VI. Notice and Reporting Requirements

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT Alpharma shall:

- A. File a verified, written report with the Plaintiff States setting forth in detail the manner and form in which it has complied and is complying with the 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 Plaintiff States 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 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. Notify the Plaintiff States 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 this Final Order to:

State of Maryland
Chief, Antitrust Division
200 St. Paul Place
Baltimore, MD 21202

State of Colorado
Chief, Antitrust Division
1525 Sherman St.
Denver, CO 80203

State of Ohio
Chief, Antitrust Section
150 E. Gay Street
Columbus, OH 43215

State of Florida
Director, Antitrust Division
PL-01 The Capitol
Tallahassee, FL 32399

State of Michigan
Assistant in Charge
Special Litigation Division
525 W. Ottawa
P.O. Box 30755
Lansing, MI 48913

- E. Waive any objection to the Plaintiff States' sharing of information obtained pursuant to this Final Order with the Federal Trade Commission and the Commission's sharing with the Plaintiff States information obtained pursuant to the Commission's Final Order and Stipulated Injunction resolving the Commission's complaint against Alparma filed on August 17, 2004.

VII. Termination of Final Order

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT the Final Order shall take effect on, and expire ten (10) years from the date this Final Order is entered.

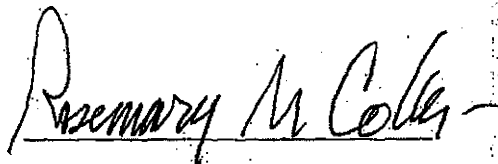
VIII. Retention of Jurisdiction

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 Alpharma shall pay to Liaison Counsel for the Plaintiff States \$248,863.25 in attorneys' fees and costs of investigating this matter.

Dated: 25 August 2004.



United States District Judge