

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 evidenc

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

- 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.*

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 or equitable relief

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

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 Alparma 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 Alparma'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. Alparma shall notify the Commission of each Agreement Subject to Notification that Alparma 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 b(der.)TjET1.00000 0.00000 0p.00 0.0000 ..0000t6.8400 0.0000 TD(anizes, enfor

- 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 Ave

X. Public Interest

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