UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Timothy J. Muris, Chairman**
Mozelle W. Thompson
Orson Swindle
Thomas B. Leary
Pamela Jones Harbour

In the Matter of	
SCHERING-PLOUGH CORPORATION, **a corporation,**	
UPSHER-SMITH LABORATORIES, INC., **a corporation,**	**Docket No. 9297**
and	
AMERICAN HOME PRODUCTS CORPORATION, **a corporation.**	

FINAL ORDER

The Commission has heard this matter on the appeal of Counsel Supporting the Complaint from the Initial Decision and on briefs and oral argument in support of and in opposition to the appeal. For the reasons stated in the accompanying Opinion of the Commission, the Commission has determined to reverse and vacate the Initial Decision and enter the following order. Accordingly,

I.

IT IS ORDERED that for the purposes of this Order, the following definitions shall apply:

A. "Respondent Schering" means Schering-Plough Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Schering-Plough Corporation, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

B. "Respondent Upsher" means Upsher-Smith Laboratories, Inc., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Upsher-Smith, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "Commission" means the Federal Trade Commission.

D. "180-day Exclusivity Period" means the period of time established by Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(5)(B)(iv) (2003)).

E. "AB-rated Generic Version" means an ANDA found by the Food and Drug Administration to be bioequivalent to the Referenced Drug Product, as defined under 21 U.S.C. § 355(j)(8)(B) (2003).

F. "Agreement" means anything that would constitute an agreement under Section 1 of the Sherman Act, 15 U.S.C. § 1 (2003), or Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45 (2003).

G. "ANDA" means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j).

H. "ANDA Filer" means a party who has filed an ANDA with the FDA.

I. "ANDA Product" means the product to be manufactured under the ANDA that is the subject of the Patent Infringement Claim.

J. "Drug Product" means a finished dosage form (*e.g.*, tablet, capsule, or solution) that 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).

K. "Effective Date" means the date of entering into the Agreement.

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

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

N. "NDA Holder" means: (1) the party that received FDA approval to market a Drug Product pursuant to an NDA, (2) a party owning or controlling enforcement of the patent(s) listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the "FDA Orange Book") in connection with the NDA, or (3) the predecessors, subsidiaries, divisions, groups and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (1) and (2) above (such control to be presumed by direct or indirect share ownership of 50% or greater), as well as the licensees, licensors, successors, and assigns of each of the foregoing.

O. "Patent Infringement" means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.

P. "Patent Infringement Claim" means any allegation made to an ANDA Filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA Product may infringe any patent held by, or exclusively licensed to, the NDA Holder of the Reference Drug Product.

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

R. "Reference Drug Product" means the Drug Product identified by the ANDA Filer as the Drug Product upon which the ANDA Filer bases its ANDA.

S. "Relinquish" means abandon, waive, or relinquish.

T. "Sale of Drug Products" means the sale of Drug Products in or affecting commerce, as commerce is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44 (2003).

II.

IT IS FURTHER ORDERED that in connection with the Sale of Drug Products, each Respondent shall cease and desist, directly or indirectly, from being a party to any Agreement resolving or settling a Patent Infringement Claim in which:

A. an ANDA Filer receives anything of value; and

B. the ANDA Filer agrees not to research, develop, manufacture, market, or sell the ANDA Product for any period of time.

PROVIDED, HOWEVER, that nothing in this Paragraph shall prohibit a resolution or settlement of a Patent Infringement Claim in which:

(1) a Respondent is either the NDA Holder or the ANDA Filer;

(2) the value paid by the NDA Holder to the ANDA Filer as a part of the resolution or settlement of the Patent Infringement Claim includes no more than (1) the right to market the ANDA Product prior to the expiration of the patent that is the basis for the Patent Infringement Claim, and (2) the lesser of the NDA Holder's expected future litigation costs to resolve the Patent Infringement Claim or $2 million; and

(3) Respondent has notified the Commission, as described in Paragraph V.

III.

IT IS FURTHER ORDERED that, when a Respondent makes or is subject to a Patent Infringement Claim in which such Respondent is either the NDA Holder or the ANDA Filer, Respondent shall cease and desist, in connection with the Sale of Drug Products, from being a party to any Agreement in which the ANDA Filer agrees to refrain from researching, developing, manufacturing, marketing, or selling any Drug Product that:

A. could be approved for sale by the FDA pursuant to an ANDA; and

B. is neither the subject of any written claim or allegation of Patent Infringement nor supported by a good faith opinion of counsel that the Drug Product would be the subject of such a claim or allegation if disclosed to the NDA Holder.

IV.

IT IS FURTHER ORDERED that, in any instance where a Respondent is a party to a Patent Infringement lawsuit in which it is either the NDA Holder or the alleged infringer ANDA Filer, such Respondent shall cease and desist, directly or indirectly, in connection with the Sale of Drug Products, from being a party to any Agreement in which:

A. the parties do not agree to dismiss the litigation;

B. the NDA Holder provides anything of value to the alleged infringer; and

C. the ANDA Filer agrees to refrain during part or all of the course of the litigation from selling the ANDA Product, or any Drug Product containing the same active chemical ingredient as the ANDA Product.

PROVIDED, HOWEVER, such an Agreement is not prohibited by this Order when entered into in conjunction with a joint stipulation between the parties that the court may enter a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, Fed. R. Civ. P. 65, if:

(1) together with the stipulation for a preliminary injunction Respondent provides the court with the proposed Agreement, as well as a copy of the Commission's Complaint and Order in this matter;

(2) Respondent has notified the Commission, as described in Paragraph V, at least thirty (30) days prior to submitting the stipulation for a preliminary injunction;

(3) Respondent does not oppose any effort by the Commission to participate, in any capacity permitted by the court, in the court's consideration of any such action for preliminary relief; and

(4) (a) the court issues an order and the parties' agreement conforms to said order; or

(b) the Commission determines, at the request of Respondent, that entering into the stipulation would not raise issues under Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

PROVIDED FURTHER THAT nothing in Paragraph IV shall be interpreted to prohibit or restrict the right of Respondent unilaterally to seek relief from the court (including, but not limited to, applying for preliminary injunctive relief or seeking to extend, or reduce, the 30-month stay pursuant to 21 U.S.C. § 355(j)(5)(B)(iii)).

V.

IT IS FURTHER ORDERED that:

A. Each Respondent shall notify the Commission, as required by Paragraphs II and IV, in the form of a letter ("Notification Letter")

submitted to the Secretary of the Commission at least thirty (30) days prior to consummating the proposed Agreement (hereinafter, the "First Waiting Period") and containing the following information:

(1) the docket number and caption name of this Order;

(2) a statement that the purpose of the Notification Letter is to give the Commission prior notification of a proposed Agreement as required by this Order;

(3) identification of the parties involved in the proposed Agreement;

(4) identification of all Drug Products involved in the proposed Agreement;

(5) identification of all Persons (to the extent known) who have filed an ANDA with the FDA (including the status of such application) for any Drug Product containing the same chemical entity(ies) as the Drug Product(s) involved in the proposed Agreement;

(6) a copy of the proposed Agreement;

(7) identification of the court, and a copy of the docket sheet, for any legal action which involves either party to the proposed Agreement and relates to any Drug Product(s) containing the same chemical entity(ies) involved in the Agreement; and

(8) all documents which were prepared by or for any officer(s) or director(s) of Respondent for the purpose of evaluating or analyzing the proposed Agreement.

B. If the Notification Letter is provided pursuant to:

(1) Paragraph II, representatives of the Commission may make a written request for additional information or documentary material (as if the request were within the meaning of 16 C.F.R.

§ 803.20) prior to expiration of the First Waiting Period. If such a request for additional information is made, Respondent shall not execute the proposed Agreement until expiration of thirty (30) days following complete submission of such additional information or documentary material.

(2) Paragraph IV, Respondent may execute the proposed Agreement upon expiration of the First Waiting Period.

A Respondent may request early termination of the First Waiting Periods in this Paragraph V from the Director of the Commission's Bureau of Competition.

VI.

IT IS FURTHER ORDERED that each Respondent shall file a verified written report within sixty (60) days after the date this Order becomes final, annually thereafter for five (5) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require, setting forth in detail the manner and form in which Respondent intends to comply, is complying, and has complied with this Order. Each Respondent shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with this Order.

VII.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least thirty (30) days prior to any proposed change in Respondent such as dissolution, assignment, sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in Respondent that may affect compliance obligations arising out of this Order.

VIII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order and subject to any legally recognized privilege or immunity, and upon written request with reasonable notice to Respondents, Respondents shall permit any duly authorized representative of the Commission:

A. Access, during office hours and in the presence of counsel, to all facilities, and to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in their possession or under their control relating to compliance with this Order; and

B. To interview officers, directors, employees, agents, and other representatives of Respondents, who may have counsel present regarding such compliance issues.

IX.

IT IS FURTHER ORDERED that this Order shall terminate ten (10) years from the date on which it becomes final.

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED: December 8, 2003