UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS:

Timothy J. Muris, Chairman
Sheila F. Anthony
Mozelle W. Thompson
Orson Swindle
Thomas B. Leary

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

The Federal Trade Commission (ACommission@) having heretofore issued its complaint charging that it had reason to believe that certain acts and practices of Schering-Plough Corporation (ARespondent Schering@), Upsher-Smith Laboratories, Inc. (ARespondent Upsher@), and American Home Products Corporation (ARespondent AHP@) may have violated Section 5 of the Federal Trade Commission Act, and Respondents having been served with a copy of that complaint, together with a notice of contemplated relief, and Respondents having filed answers denying said charges.

Respondent AHP and counsel for the Commission having thereafter executed an Agreement Containing Consent Order; an admission by Respondent AHP of the jurisdictional facts relating to Respondent AHP set forth in the aforesaid complaint; a denial of all other allegations; a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondent AHP that the law has been violated as alleged in such complaint or that any allegation of the complaint is true, other than the jurisdictional facts relating to Respondent AHP; and waivers and other provisions as required by the Commission's Rules; and

The Secretary of the Commission having thereafter withdrawn this matter from adjudication in accordance with ' 3.25(c) of its Rules; and

The Commission having thereafter considered the matter and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days, now in further conformity with the procedure prescribed in ' 3.25(f) of its Rules, the Commission hereby makes the following jurisdictional findings and enters the following order:

1. American Home Products Corporation is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at Five Giralda Farms, Madison, New Jersey.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent American Home Products Corporation, and the Commission has determined that this proceeding is in the public interest.

ORDER

I.

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

A. ARespondent AHP@ means American Home Products Corporation, its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its subsidiaries (including ESI Lederle), divisions, groups, and affiliates controlled by American Home Products Corporation, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

B. ACommission@ means the Federal Trade Commission.

C. A180-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) *et seq.*).

D. AAgreement@ means anything that would constitute an agreement under Section 1 of the Sherman Act or Section 5 of the Federal Trade Commission Act. "Agreement" includes all agreements related to resolving a Patent Infringement Claim.

E. AANDA@ means an Abbreviated New Drug Application, as defined under 21 U.S.C. ' 355(j) *et seq*.

F. AANDA Filer@ means a party who has filed an ANDA.

G. AANDA First Filer@ means the party who the FDA determines is and remains entitled to, or eligible for, a 180-day Exclusivity Period that has not yet commenced running or expired, so long as that status is known, or would be known through the exercise of reasonable due diligence, to Respondent AHP at the time of the Agreement.

H. AANDA Product@ means the product to be manufactured under the ANDA that is the subject of the Patent Infringement Claim.

I. ADrug 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).

J. AFDA@ means the United States Food and Drug Administration.

K. ANDA@ means a New Drug Application, as defined under 21 U.S.C. ' 355(b) *et seq*.

L. ANDA 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 AFDA 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.

N. APatent 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.

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

P. APerson@ means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

Q. AReference Drug Product@ means the Drug Product identified by the ANDA Filer as the Drug Product upon which the ANDA Filer bases its ANDA.

II.

IT IS FURTHER ORDERED that, in any instance where Respondent AHP makes or is subject to a Patent Infringement Claim in which Respondent AHP is either the NDA Holder or the ANDA Filer, Respondent AHP shall cease and desist, either directly or indirectly, in connection with the sale of Drug Products in or affecting commerce, as Acommerce@ is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. ' 44, from being a party to any Agreement in which (a) the parties resolve the Patent Infringement Claim, (b) the NDA Holder provides (i) anything of value to the ANDA First Filer or (ii) anything of value (other than a license to manufacture the ANDA Product) to any ANDA Filer other than the ANDA First Filer, and (c) the ANDA Filer agrees to refrain from selling the Drug Product at issue, or any Drug Product containing the same active chemical ingredient as the Drug Product at issue, for any period of time.

Notwithstanding the above, however, such an Agreement is permissible when entered into in conjunction with a joint stipulation between the parties that the court may enter a permanent injunction, if:

(1) together with the stipulation for a permanent injunction, Respondent AHP provides the court the proposed Agreement, as well as a copy of the Commission=s complaint, order, and Analysis to Aid Public Comment in this matter (which provision may be made to the court in camera or pursuant to any confidentiality order in place in the case);

(2) Respondent AHP has provided Notification, as described in Paragraph V below, to the Commission at least thirty (30) days prior to submitting the stipulation to the court for a permanent injunction;

(3) Respondent AHP does not oppose any effort by the Commission to participate, in any capacity permitted by the court, in the court=s consideration of any stipulation for permanent injunction (with the Commission giving consideration to participating in such proceeding in the event the Commission determines that such participation will expedite the court=s consideration of said stipulated permanent injunction); and

(4) the court issues an order and the parties= Agreement conforms to said order or the Commission determines, at the request of Respondent AHP, that entering into the stipulation and Agreement would not raise issues under Section 5 of the Federal Trade Commission Act. Nothing in Paragraph II shall be interpreted to prohibit or restrict the right of Respondent AHP to seek relief from the court, without notice to the Commission, including, but not limited to, applying for permanent injunctive relief or seeking to extend, or reduce, the 30-month stay pursuant to 21 U.S.C. ' 355(j)(5)(B)(iii).

III.

IT IS FURTHER ORDERED that, in any instance where Respondent AHP makes or is subject to a Patent Infringement Claim in which Respondent AHP is either the NDA Holder or the ANDA Filer, Respondent AHP shall cease and desist, either directly or indirectly, in connection with the sale of Drug Products in or affecting commerce, as Acommerce@ is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. ' 44, 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

(1) could be approved for sale by the FDA pursuant to an ANDA and

(2) is neither the subject of any written claim of Patent Infringement nor supported by a good faith opinion of counsel (the privileged nature of which shall be respected and remain protected) that the Drug Product would be the subject of such a claim if disclosed to the NDA Holder.

IV.

IT IS FURTHER ORDERED that, in any instance where Respondent AHP is a party to an action involving a Patent Infringement Claim in which it is either the NDA Holder or the ANDA Filer, it shall cease and desist, either directly or indirectly, in connection with the sale of Drug Products in or affecting commerce, as Acommerce@ is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. ' 44, from being a party to any Agreement in which (a) the parties do not agree to dismiss the Patent Infringement Claim, (b) the NDA Holder provides anything of value to the ANDA Filer, and (c) the ANDA Filer agrees to refrain during part or all of the course of the litigation from selling the Drug Product at issue, or any Drug Product containing the same active chemical ingredient as the Drug Product at issue.

Notwithstanding the above, however, such an Agreement is permissible 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, if:

(1) together with the stipulation for a preliminary injunction, Respondent AHP provides the court the proposed Agreement, as well as a copy of the Commission=s complaint, order, and Analysis to Aid Public Comment in this matter (which provision may be made to the court in camera or pursuant to any confidentiality order in place in the case);

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

(3) Respondent AHP 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 (with the Commission giving consideration to participating in such proceeding in the event the Commission determines that such participation will expedite the court=s consideration of said preliminary injunction motion); and

(4) the court issues an order and the parties= agreement conforms to said order or the Commission determines, at the request of Respondent AHP, that entering into the stipulation during the pendency of the Patent Infringement action would not raise issues under Section 5 of the Federal Trade Commission Act. Nothing in Paragraph IV shall be interpreted to prohibit or restrict the right of Respondent AHP to seek relief from the court, without notice to the Commission, 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.

The Notification required by Paragraphs II and IV shall be filed with the Secretary of the Commission and shall include the following information, to the extent known and not subject to any legally recognized privilege or immunity: (1) identification of the parties involved in the Agreement; (2) identification of all Drug Products involved in the Agreement; (3) identification of all persons known by Respondent AHP to 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 Agreement; (4) a copy of the proposed Agreement; (5) identification of the court, and a copy of the docket sheet, for any legal action, excluding product liability actions, that involves either party to the Agreement and relates to any Drug Product(s) containing the same chemical entity(ies) involved in the Agreement; and (6) all documents that were prepared by or for any officer(s) or director(s) of Respondent AHP for the purpose of evaluating or analyzing the Agreement.

VI.

IT IS FURTHER ORDERED that Respondent AHP shall file a verified written report within sixty (60) days after the date this order is issued, annually thereafter for five (5) years on the anniversary of the date this order is issued, and at such other times as the Commission may by written notice require, setting forth in detail the manner and form in which Respondent AHP intends to comply, is complying, and has complied with this order. Respondent AHP 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 Respondent AHP shall notify the Commission at least thirty (30) days prior to any proposed change in Respondent AHP 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 AHP 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 Respondent AHP, Respondent AHP 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 its possession or under its control relating to compliance with this order; and

B. To interview officers, directors, employees, agents, and other representatives of Respondent AHP, 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 this order becomes final.

By the Commission.

Donald S. Clark
Secretary

SEAL

ISSUED: