

**UNITED STATES OF AMERICA  
BEFORE FEDERAL TRADE COMMISSION**

The Secretary of the Commission having thereafter withdrawn this matter from adjudication in accordance with ' 3.25(c) of its Rules; and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

- F. **ANDA Filer** means a party who has filed an ANDA.
- G. **ANDA First Filer** means the party who the FDA determines is and remains entitled

## 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 ~~commerce~~ 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 ~~commerce~~ 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 ~~commerce~~ 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=

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: