UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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 AGREEMENT CONTAINING CONSENT ORDER

The Agreement herein, by and between American Home Products Corporation ("Respondent AHP"), by its duly authorized officer and its attorney, and counsel for the Federal Trade Commission, is entered into in accordance with the Commission's Rules governing consent order procedures. In accordance therewith, the parties hereby agree that:

1. Respondent 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. Respondent AHP has been served with a copy of the complaint issued by the Federal Trade Commission charging it with violations of Section 5(a) of the Federal Trade Commission Act, and has filed an answer to the complaint denying said charges.

3. Respondent AHP admits all the jurisdictional facts relating to it set forth in the complaint.

4. Respondent AHP waives:

   (a) any further procedural steps;

   (b) the requirement that the Commission's Decision and Order ("Decision and Order"), here attached and made a part hereof, contains a statement of findings of fact and conclusions of law;

   (c) all rights to seek judicial review or otherwise to challenge or contest the validity of the Order entered pursuant to this Consent Agreement; and

   (d) any claim under the Equal Access to Justice Act.

5. This Consent Agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this Consent Agreement is accepted by the Commission, it will be placed on the public record for a period of thirty (30) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this Consent Agreement and so notify Respondent AHP, in which event it will take such action as it may consider appropriate, or issue and serve its decision in disposition of the proceeding.

6. This Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent AHP that the law has been violated as alleged in the Complaint, or that the facts as alleged in the Complaint, other than jurisdictional facts, are true.

7. This Consent Agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Commission Rule 3.25(f), 16 C.F.R. § 3.25 (f), the Commission may, without further notice to Respondent AHP, (1) issue the attached Decision and Order to cease and desist in disposition of the proceeding, and (2) make information public in respect thereto. When final, the Order will have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for Commission orders. The Order shall become final upon service. Delivery of the Decision and Order to Respondent AHP's Counsel by any means specified in Commission Rule 4.4(a), 16 C.F.R. § 4.4(a), shall constitute service. Respondent AHP waives any right it may have to any other manner of service. The Complaint may be used in construing the terms of the Order, and no agreement, understanding, representation, or interpretation not contained in the Decision and Order or the Consent Agreement may be used to vary or contradict the terms of the Decision and Order.

8. By signing this Consent Agreement, Respondent AHP represents and warrants that it can accomplish the full relief contemplated by this Consent Agreement, and that all parents, subsidiaries, affiliates, and successors necessary to effectuate the full relief contemplated by this Consent Agreement are bound thereby as if they had signed this Consent Agreement and were made parties to this proceeding and to the Decision and Order.

9. Respondent AHP has read the Complaint and Decision and Order contemplated hereby. Respondent AHP understands that once the Decision and Order has been issued, it will be required to file one or more compliance reports showing that it has fully complied with the Decision and Order. Respondent AHP agrees to comply with the terms of the proposed order from the date it signs this Consent Agreement. Respondent AHP further understands that it may be liable for civil penalties in the amount provided by law for each violation of the Decision and Order after the Decision and Order becomes final.

Signed this ____ day of October, 2001.

American Home Products Corporation

By: Louis L. Hoynes, Jr.
Louis L. Hoynes, Jr.
Executive Vice President
and General Counsel

Counsel for American Home Products Corporation

By: _____
Michael N. Sohn
Cathy Hoffman
Arnold & Porter

Federal Trade Commission

By: Philip M. Eisenstat by ORP
Karen G. Bokat
Philip M. Eisenstat

Approved:

David R. Pender
David R. Pender
Deputy Assistant Director

Susan Creighton
Susan Creighton
Deputy Director

Joseph J. Simons
Joseph J. Simons
Director
Bureau of Competition

Signed this 9th day of October, 2001.

American Home Products Corporation

By: _____
Louis L. Hoynes, Jr.
Executive Vice President
and General Counsel

Counsel for American Home Products Corporation

By: Cathy Hoffman
Michael N. Sohn
Cathy Hoffman
Arnold & Porter

Federal Trade Commission

By: Philip M. Eisenstat by
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Approved:

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Director
Bureau of Competition

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 ("Commission") having heretofore issued its complaint charging that it had reason to believe that certain acts and practices of Schering-Plough Corporation ("Respondent Schering"), Upsher-Smith Laboratories, Inc. ("Respondent Upsher"), and American Home Products Corporation ("Respondent 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. "Respondent 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. "Commission" means the Federal Trade Commission.

C. "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) *et seq.*).

D. "Agreement" 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. "ANDA" means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j) *et seq.*

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

I. "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).

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

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

L. "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.

N. "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.

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

Q. "Reference 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 "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'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:

ANALYSIS TO AID PUBLIC COMMENT

The Federal Trade Commission has accepted for public comment an agreement and proposed consent order with American Home Products Corporation. The proposed consent order would settle charges that AHP unlawfully agreed with Schering-Plough Corporation to delay selling its generic version of Schering's K-Dur 20, in exchange for payments from Schering. The proposed consent order has been placed on the public record for 30 days to receive comments by interested persons. The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by AHP that it violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true. In July 2001, AHP advised its customers that it intends to phase out its oral generic drug product line.

Background

Schering develops and markets brand name and generic drugs, as well as over-the-counter health care and animal care products. Schering manufactures and markets an extended-release micro-encapsulated potassium chloride product, K-Dur 20. K-Dur 20, marketed as a brand name drug, has sales over $200 million per year. K-Dur 20 is used to treat patients who suffer from insufficient levels of potassium, a condition that can lead to serious cardiac problems.

AHP develops and markets brand name and generic drugs, as well as over-the-counter medications. ESI Lederle, Incorporated, a division of AHP, received tentative approval from the Food and Drug Administration in May 1999 for a generic version of Schering's K-Dur 20.

Upsher-Smith Laboratories, Inc. develops and markets brand name and generic drugs. Upsher-Smith received final approval from the Food and Drug Administration in November 1998 for a generic version of Schering's K-Dur 20.

Generic drugs are chemically identical to their branded counterparts, but typically are sold at substantial discounts from the branded price. A Congressional Budget Office Report estimates that purchasers saved an estimated $8-10 billion on prescriptions at retail pharmacies in 1994 by purchasing generic drugs instead of the brand name product.[1]

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as "the Hatch-Waxman Act," establishes certain rights and procedures in situations where a company, such as AHP or Upsher, seeks FDA approval to market a generic product prior to the expiration of a patent or patents relating to a brand name drug upon which the generic is based. In such cases, the applicant must: (1) certify to the FDA that the patent in question is invalid or is not infringed by the generic product (known as a "paragraph IV certification"); and (2) notify the patent holder of the filing of the certification. If the holder of patent rights files a

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[1] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* at xiii, 13 (July 1998).

patent infringement suit within 45 days of the notification, FDA approval to market the generic drug is automatically stayed for 30 months, unless before that time the patent expires or is judicially determined to be invalid or not infringed. This automatic 30-month stay allows the patent holder time to seek judicial protection of its patent rights before a generic competitor is permitted to market its product.

In addition, the Hatch-Waxman Act provides an incentive for generic drug companies to bear the cost of patent litigation that may arise when they challenge invalid patents or design around valid ones. The Act, as currently interpreted, grants the first company to file an ANDA in such cases a 180-day period during which it has the exclusive right to market a generic version of the brand name drug. No other generic manufacturer may obtain FDA approval to market its product until the first filer's 180-day exclusivity period has expired.

Upsher-Smith was the first company to file an ANDA for a generic version of Schering's K-Dur 20. Upsher-Smith filed a paragraph IV certification with the FDA, stating that its product did not infringe any valid patent held by Schering covering K-Dur 20. In 1995, Schering sued Upsher-Smith for patent infringement. The complaint alleges that at all times relevant herein, FDA final approval of an ANDA for a generic version of K-Dur 20 for anyone other than Upsher-Smith was blocked. Pursuant to the Hatch-Waxman Act, Upsher-Smith was eligible for the right to a 180-day Exclusivity Period for the sale of a generic version of K-Dur 20. The complaint further alleges that as a result, no company could obtain final FDA approval of an ANDA to market or sell a generic version of K-Dur 20 until 180 days after Upsher-Smith first sold its product, or until Upsher-Smith's exclusivity right is relinquished, forfeited or otherwise expired.

ESI was the second company to file an ANDA for K-Dur 20. ESI also filed a paragraph IV certification with the FDA stating that its product did not infringe any valid patent held by Schering covering K-Dur 20. In 1996, Schering sued ESI for patent infringement.

The Challenged Agreements

The complaint challenges unlawful agreements between Schering and Upsher-Smith and among Schering, AHP and ESI to delay the entry of low-cost generic competition to Schering's highly profitable prescription drug K-Dur 20. According to the complaint, when confronted with the prospect of competition to K-Dur 20 through generic entry by Upsher-Smith and ESI, Schering entered into these agreements that kept Upsher, ESI and all other potential generic competitors out of the market. The complaint alleges that the Upsher-Smith/Schering agreement delayed the start of Upsher-Smith's 180-day Exclusivity Period until September 2001 and, as a result, the entry of competition from other generic manufacturers until March 2002.

With respect to AHP and ESI, the complaint alleges that in January 1998, Schering, AHP, and ESI reached an agreement to settle their patent litigation. Pursuant to that agreement: Schering agreed to pay ESI up to $30 million; AHP and ESI agreed to refrain from marketing the

allegedly infringing generic version of K-Dur 20 or any other generic version of K-Dur 20, regardless of whether such product would infringe Schering's patents, until January 2004; AHP and ESI agreed to refrain from marketing more than one generic version of K-Dur 20 between January 2004 and September 2006, when the K-Dur 20 patent will expire; and AHP and ESI agreed not to conduct, sponsor, file or support a study of the bio-equivalence of any product to K-Dur 20 prior to September 2006. Schering agreed to pay ESI $5 million up front; an additional $10 million if ESI could demonstrate that its generic version of K-Dur 20 was able to be approved by the FDA under an ANDA on or before June 30, 1999; and another $15 million for licenses to two generic products that ESI was developing.

The complaint further alleges that the patent litigation between Schering and ESI was dismissed. Schering has paid ESI over $20 million and continues to make payments under the terms of their agreement. Schering has made no sales to date of the two products it licensed from ESI.

Competitive Analysis

Generic drugs can have a swift marketplace impact, because pharmacists generally are permitted, and in some instances are required, to substitute lower-priced generic drugs for their branded counterparts, unless the prescribing physician directs otherwise. In addition, there is a ready market for generic products because certain third-party payers of prescription drugs (*e.g.*, state Medicaid programs and many private health plans) encourage or insist on the use of generic drugs wherever possible.

The complaint charges that the challenged agreement among Schering, AHP and ESI injured competition by preventing or discouraging the entry of generic K-Dur 20. The complaint also alleges that by making cash payments to ESI, Schering induced it to agree to delay launching its generic version of K-Dur 20. According to the complaint, absent those payments, ESI would not have agreed to delay its entry for so long. The complaint charges that by making cash payments to ESI, Schering protected itself from competition from ESI until 2004. The complaint also alleges that without lower-priced generic competition from Upsher-Smith and ESI, consumers, pharmacies, hospitals, insurers, wholesalers, government agencies, managed care organizations, and others are forced to purchase Schering's more expensive K-Dur 20 product.

The Proposed Order

The proposed order is designed to remedy the unlawful conduct charged against AHP in the complaint and prevent recurrence of such conduct. As described more fully below, the proposed order would essentially prohibit two categories of conduct:

- agreements in which the NDA holder makes payments to an ANDA filer and the ANDA filer agrees not to market its product for some period of time (except in certain limited circumstances) (Paragraph II deals with agreements that resolve a patent infringement

dispute and Paragraph IV covers "interim" agreements that apply during the pendency of ongoing patent litigation); and

- agreements between the NDA holder and an ANDA filer in which the generic competitor agrees not to enter the market with a non-infringing generic product (Paragraph III).

The proposed order would apply to AHP whether it is acting as potential generic competitor (an ANDA filer) or as a branded drug seller (an NDA holder). As noted above, AHP has advised its customers that it intends to phase out its oral generic pharmaceutical product line. It will continue to develop, manufacture, and market brand name drugs and injectable generic drugs. Notwithstanding AHP's plans to phase out its oral generic products – the line of business that includes its generic version of K-Dur 20 an order is appropriate here to prevent a recurrent violation.

Paragraph II of the order covers agreements to resolve patent infringement disputes. It bars agreements wherein (1) the NDA holder makes payments or otherwise transfers something of value to the ANDA filer and (2) the ANDA filer agrees not to market its product for some period of time, except under certain limited circumstances described below. The ban in Paragraph II includes not only settlements of ongoing patent infringement litigation, but also agreements resolving claims of patent infringement that have not resulted in a lawsuit (see Paragraph I.O.). In addition, by virtue of the definition of "Agreement" in Paragraph I.D., the order makes it clear that the prohibition on payments for delayed generic entry would cover such arrangements even if they are achieved through separate agreements (for example, where one agreement resolves the patent infringement dispute and another provides for the payment for delayed entry).

The order prohibits not merely cash payments to induce delayed entry, but, more broadly, agreements in which the NDA holder provides something of value to the potential generic entrant, and the ANDA filer agrees in some fashion not to sell its product. Although all of the pharmaceutical agreements that the Commission has challenged to date have involved cash payments, a company could easily evade a prohibition on such agreements by substituting other things of value for cash payments. Thus, to protect against a recurrent violation, the order is not limited to cash payments.

The proposed order distinguishes between the first ANDA filer (the party eligible for the 180-day market exclusivity period under the Hatch-Waxman Act) and later filers. It bars giving "anything of value" to the first ANDA filer, but would permit NDA holders to grant other ANDA filers a delayed license to manufacture the ANDA product. The proposed order makes this distinction because an agreement by a later filer to refrain from entering does not block entry by other potential competitors. Where the only value granted by the NDA holder is the license to sell the ANDA product, there is no payment to distort the generic's incentive to seek the earliest possible entry date. In the case of the first ANDA filer, however, any agreement with an NDA holder that involves a promise by the generic firm not to enter the market risks blocking entry by

other potential generic competitors, and therefore such agreements are subject to the general prohibition of Paragraph II of the proposed order.

As noted above, the proposed order would create a limited exception to Paragraph II's ban on giving value for delayed entry. This exception addresses the possibility that there might be some agreements that fall within the terms of the prohibition in Paragraph II that the Commission would not wish to prohibit. For example, as was previously discussed, the proposed order would ban not only agreements involving cash payments of the type that the Commission has challenged to date, but also the giving of other things of value. It is possible, however, that the giving of some non-cash items in a settlement that did not provide for immediate entry by the ANDA filer could promote competition. Thus, the order includes a mechanism that would permit consideration of such arrangements.

The exception that has been crafted in this matter could arise only in situations where Respondent AHP presents the agreement to a court in connection with a joint stipulation for a permanent injunction. In that circumstance, Paragraph II will not bar an otherwise prohibited agreement, if the following conditions are met:

- First, Respondent must follow certain procedures designed to provide notice and information both to the Commission and the court: (1) along with the joint stipulation for permanent injunction and the proposed agreement, Respondent must provide the court with a copy of the Commission's complaint, order, and the Analysis to Aid Public Comment in this matter; (2) at least 30 days before submitting the stipulation to the court, Respondent must provide written notice (as set forth in Paragraph V of the order) to the Commission; and (3) Respondent may not oppose Commission participation in the court's consideration of the request for permanent injunction; and

- Second, either: (1) the court issues a permanent injunction and the parties' agreement conforms to the court's permanent injunction order; or (2) the Commission determines that the agreement does not raise issues under Section 5 of the FTC Act.

The proviso to Paragraph II also makes it clear that the order would not prevent Respondent AHP from unilaterally seeking relief from the court. The proviso sets forth conditions under which AHP could seek to avoid, though court action, the bar on agreements that is set forth in the core prohibition of Paragraph II of the proposed order. These conditions would not affect AHP's ability to take action that did not involve an agreement otherwise prohibited in Paragraph II.

The Commission recognizes that, outside of the class action context, final settlements between private litigants ordinarily are not scrutinized by courts. Unlike the case of a court-ordered preliminary injunction based on a stipulation of the parties (the situation addressed in Paragraph IV, discussed below), the court in the final settlement context has no express legal mandate to consider the public interest. Thus, there remains some degree of risk that an

anticompetitive agreement could escape the prohibition of Paragraph II if the parties were able to persuade a court to issue their agreement as a permanent injunction. On the other hand, it is also relatively rare for courts in ordinary private litigation to issue settlement agreements as permanent injunction orders. This is likely to reduce the risk that an anticompetitive agreement would evade the order, because, as noted above, the exception to the prohibitions of Paragraph II does not arise unless the court issues a permanent injunction order. On balance, in light of all the circumstances of this proposed consent order (including that it is the first involving a challenge to a final settlement with a second ANDA filer), the Commission believes that the exception contained in Paragraph II is appropriate here.

Paragraph III prohibits agreements between an NDA holder and an ANDA filer in which the ANDA filer agrees not to develop or market a generic drug product that is not the subject of a claim of patent infringement. The Commission has previously considered this type of restraint in the context of an agreement between an NDA holder and an ANDA first filer (that is, the party possessing an unexpired right to Hatch-Waxman 180-day exclusivity), and had limited the bans in previous orders to that context. Having now considered a similar restraint in an agreement involving a later ANDA filer, the Commission believes it is appropriate to extend this prohibition to agreements between an NDA holder and any ANDA filer.

Paragraph IV addresses what are sometimes referred to as interim settlement agreements. It covers agreements that involve payment to an ANDA filer and in which the ANDA filer agrees not to enter the market for a period of time, but the patent infringement litigation continues. AHP would be barred from entering into such interim agreements. As in Paragraph II, it extends beyond cash payments to cover the NDA holder's providing "anything of value" to the ANDA filer, and provides an exception in limited circumstances, similar to those described in connection with Paragraph II of the proposed order. Although the challenged conduct here was an agreement in connection with a final settlement of litigation, rather than an interim agreement, this provision is appropriate in light of the serious antitrust concerns raised by interim agreements and the need to impose an order to prevent recurrence of violations similar to that with which AHP is charged.

The form of notice that Respondent AHP must provide to the Commission under Paragraphs II and IV of the order is set forth in Paragraph V. In addition to supplying a copy of the proposed agreement, AHP is required to provide certain other information to assist the Commission in assessing the potential competitive impact of the agreement. Accordingly, the order requires Respondent to identify, among other things, all others known by AHP to have filed an ANDA for a product containing the same chemical entities as the product at issue, as well as the court that is hearing any relevant legal proceedings involving Respondent. In addition, Respondent AHP must provide the Commission with certain documents that evaluate the proposed agreement.

The proposed order also contains certain reporting and other provisions that are designed to assist the Commission in monitoring compliance with the order and are standard provisions in

Commission orders.

The proposed order would expire in 10 years.

Opportunity for Public Comment

The proposed order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the agreement. The analysis is not intended to constitute an official interpretation of the agreement, the complaint, or the proposed consent order, or to modify their terms in any way.