

Complaint

IN THE MATTER OF

AMERICAN HOME PRODUCTS

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket 9297; File No. 9910256

Complaint, March 30, 2002--Decision, April 2, 2002

This consent order addresses allegations in the administrative complaint issued earlier that Respondent American Home Products Corporation, which develops and markets brand name and generic drugs, as well as over-the-counter medications, unlawfully agreed with Schering-Plough Corporation to delay selling its generic version of Schering's K-Dur 20 – an extended-release micro-encapsulated potassium chloride product, marketed as a brand name drug and used to treat patients who suffer from insufficient levels of potassium, which can lead to serious cardiac problems – in exchange for payments from Schering. The order, among other things, prohibits the respondent from entering into agreements to resolve patent infringement disputes wherein a New Drug Application holder makes payments or otherwise transfers something of value to an Abbreviated New Drug Application filer and (2) the ANDA filer agrees not to market its product for some period of time, except under certain limited circumstances. The order also prohibits the respondent from entering into 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. In addition, the order prohibits the respondent from entering into agreements that involve payment to an ANDA filer, in which the ANDA filer agrees not to enter the market for a period of time, but the patent infringement litigation at issue continues.

Participants

For the Commission: *Karen G. Bokat, Phillip M. Eisenstat, David R. Pender, Susan Creighton, and Andrea L. Foster.*

For the Respondent: *Michael N. Sohn and Cathy Hoffman, Arnold & Porter.*

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Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in the agency by said

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Act, the Federal Trade Commission (“Commission”), having reason to believe that respondents Schering-Plough Corporation (“Schering”), Upsher-Smith Laboratories (“Upsher-Smith”), and American Home Products Corporation (“AHP”) have engaged in conduct, as described herein, that violates Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

Nature of the Case

1. This action challenges unlawful agreements by Schering, Upsher-Smith, and AHP to delay the entry of low-cost generic competition to Schering’s highly profitable prescription drug K-Dur 20, a product used to treat patients who suffer from insufficient levels of potassium, a condition that can lead to serious cardiac problems.
2. When confronted with the prospect of competition to K-Dur 20 through generic entry by Upsher-Smith and ESI Lederle, Incorporated (“ESI”), a division of AHP, Schering structured and entered into agreements with Upsher-Smith, AHP, and ESI that are keeping Upsher-Smith, ESI, and all other potential generic competitors out of the market. These agreements have cost consumers in excess of \$100 million.

The Respondents

3. Respondent Schering is a New Jersey corporation with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey. Schering is engaged in the discovery, development, and marketing of brand-name and generic drugs, as well as over-the-counter healthcare and animal care products. Schering’s net sales for 1999 were approximately \$9.2 billion.

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4. Respondent Upsher-Smith is a Minnesota corporation with its principal place of business at 14905 23rd Avenue North, Plymouth, Minnesota. Upsher-Smith is engaged in the discovery, development, and marketing of drugs. Upsher-Smith markets twelve brand-name products, all of which are sold in the United States.
5. Respondent AHP is a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, New Jersey. AHP engages in the discovery, development, and marketing of brand-name and generic drugs, as well as over-the-counter medications. AHP had net sales of \$13.5 billion in 1999.
6. ESI Lederle, Incorporated, a division of AHP, engages in the research, manufacture, and sale primarily of generic drugs.
7. Schering, Upsher-Smith, and AHP, at all relevant times herein, have been, and are now, corporations as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
8. Respondents' acts and practices, including the acts and practices alleged herein, are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

Federal Regulation of Prescription Drugs

9. Under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., approval by the Food and Drug Administration ("FDA") is required before a company may market or sell a prescription drug in the United States.
10. Newly developed prescription drugs are often protected by patents and marketed under proprietary brand names. Such new drugs are referred to as "brand name drugs" or "branded drugs." FDA approval for a branded drug is

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generally sought by filing a New Drug Application (“NDA”) with the FDA.

11. Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (the “Hatch-Waxman Act”), to facilitate entry of generic drugs while maintaining incentives for new drug development.
12. FDA approval for a generic drug is generally sought by filing an Abbreviated New Drug Application (“ANDA”) with the FDA. The ANDA applicant has to demonstrate that the generic drug is bioequivalent to the brand name drug that it references.
13. When a brand name drug is protected by one or more patents, an ANDA applicant that intends to market its generic product prior to expiration of any patents may proceed to seek FDA approval, but must certify in the ANDA either that (1) the generic version does not infringe the patents on the brand name drug or (2) the patents are invalid. This is called a “Paragraph IV Certification.”
14. The ANDA applicant must then notify the NDA holder and the patent holder of the filing of its ANDA. If, within 45 days of receiving such notification, a patent infringement suit is initiated against the ANDA applicant, the FDA must stay its final approval of the ANDA for the generic drug until the earliest of (1) the patent expiration, (2) a judicial determination of the patent litigation, or (3) the expiration of a 30-month waiting period.
15. The Hatch-Waxman Act gives the first firm filing an ANDA for a generic version of a brand name drug with a Paragraph IV Certification a period of protection from competition from other generic versions of the drug. The FDA may not approve other generic versions of the same drug until 180 days after the earlier of the date on which (1) the first firm

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begins commercial marketing of its generic version of the drug, or (2) a court finds the patents claiming the brand name drug are invalid or not infringed. This is referred to as “the 180-day Exclusivity Period.”

16. If the first firm filing an ANDA loses its patent litigation with the patent holder, no firm is given a 180-day Exclusivity Period.

The Impact of Generic Competition

17. Generic entry generally leads to a significant erosion of the branded drug’s market share and unit and dollar sales within the first year. As additional generic drugs enter, the price of the generic drugs typically decreases even further and the branded drug’s market share erodes further.
18. Pharmacists generally are permitted, and in some instances required, to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed.
19. Certain third-party payers of prescription drugs (e.g., managed care plans, Medicaid programs) encourage or insist on the use of generic drugs in lieu of their branded counterparts wherever possible.

Relevant Product and Geographic Market

20. The relevant geographic market in which to evaluate the conduct of Schering, Upsher-Smith, and AHP is the United States.
21. The relevant product markets are the manufacture and sale of all potassium chloride supplements approved by the FDA, and narrower markets contained therein, including the manufacture and sale of 20 milliequivalent extended-release potassium chloride tablets and capsules.

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22. Potassium chloride supplements are used to treat patients with depleted potassium levels, a condition that typically occurs when people take certain anti-hypertensive medications to lower blood pressure. Depleted potassium levels can cause dangerous cardiac problems.
23. Patients who suffer from depleted potassium levels have no practical substitute for potassium chloride supplements.
24. For clinical reasons, among others, physicians and patients prefer 20 milliequivalent extended-release potassium chloride tablets over other forms and dosages of potassium chloride.
25. The existence of other potassium chloride products has not significantly constrained Schering's pricing of K-Dur 20.

Market Power

26. Schering has approximately 69% of the sales of potassium chloride supplements.
27. Schering's K-Dur 20 has 100% of the sales of 20 milliequivalent extended-release potassium chloride tablets and capsules.
28. At all times relevant herein, entry into the relevant markets was restricted and unlikely to diminish Schering's market share. Before entry could occur, potential entrants were required to, *inter alia*, file an NDA or an ANDA with the FDA, and obtain FDA final approval. At all relevant times, only one NDA for a new potassium chloride supplement was pending before the FDA. That NDA, for a powder form, has not been approved; and, even if it were approved, because of the disadvantages of potassium chloride powders compared to tablets, a new potassium chloride powder would be unlikely to diminish Schering's market share. If a

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new NDA were to be filed with the FDA, final approval would likely take a minimum of 12-18 months.

29. 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. 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.
30. At all times relevant herein, the existence of generic versions of branded potassium chloride supplements other than K-Dur 20 has not constrained Schering's market power in the potassium chloride supplement market.

Background

31. Schering manufactures and markets two extended-release microencapsulated potassium chloride products: K-Dur 20 milliequivalent ("K-Dur 20") and K-Dur 10 milliequivalent ("K-Dur 10"). Both products are marketed as brand name drugs.
32. In 1998, sales of Schering's two K-Dur products were over \$220 million.
33. Potassium chloride, the active ingredient in potassium chloride supplements, is not patentable.
34. Schering's K-Dur 20 and K-Dur 10 are covered by a formulation patent owned by Schering, patent number 4,863,743 (the "'743 patent'"), which claims a controlled release potassium chloride tablet. The '743 patent expires on September 5, 2006.

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35. The allegedly novel aspect of the '743 patent is the composition of the coating material applied to previously known potassium chloride crystals.
36. Schering anticipated generic entry prior to expiration of its '743 patent.
37. Prior to 1997, Schering projected that the first year of low-priced generic competition would reduce branded K-Dur 20's sales by over \$30 million.

Schering/Upsher-Smith Agreement Not To Compete

38. On August 6, 1995, Upsher-Smith filed an ANDA with the FDA to market Klor Con M20, a generic version of Schering's K-Dur 20. Upsher-Smith's ANDA was the first for a generic version of K-Dur 20. Upsher-Smith submitted a Paragraph IV Certification with this ANDA and, on November 3, 1995, Upsher-Smith notified Schering of its Paragraph IV Certification and ANDA filing.
39. Schering sued Upsher-Smith for patent infringement in the United States District Court for the District of New Jersey on December 15, 1995, alleging that Upsher-Smith's Klor-Con M20 infringed Schering's '743 patent. This lawsuit triggered the statutory waiting period of up to 30 months for final FDA approval of the Upsher-Smith product.
40. This lawsuit was strongly contested by Upsher-Smith.
41. As the first ANDA filer with a Paragraph IV Certification for a generic version of Schering's K-Dur 20, Upsher-Smith is eligible for the 180-day Exclusivity Period.
42. Because Upsher-Smith is eligible for the 180-day Exclusivity Period, no other generic manufacturer can obtain final FDA approval to market a generic version of K-

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Dur 20 until after the exclusivity period has expired, whether or not the other marketer has a product that infringes the Schering patent.

43. During the first half of 1997, Upsher-Smith prepared to launch commercially Klor Con M20 no later than May 1998, the month in which the 30-month stay of FDA approval was to expire.
44. On June 17, 1997, on the eve of their patent trial, Schering and Upsher-Smith agreed to settle their litigation. Under the settlement, Schering agreed to make unconditional payments of \$60 million to Upsher-Smith; Upsher-Smith agreed not to enter the market, either with the allegedly infringing generic version of K-Dur 20 or with any other generic version of K-Dur 20, regardless of whether such product would infringe Schering's patents, until September 2001; both parties agreed to stipulate to the dismissal of the litigation without prejudice; and Schering received licenses to market five Upsher-Smith products.
45. The \$60 million payment from Schering to Upsher-Smith was unrelated to the value of the products Upsher-Smith licensed to Schering.
46. The licensed products were of little value to Schering. Schering never sold four of the five licensed products, made minimal sales of the fifth, and has no expectation of making additional sales of any of the five products.
47. A court decision in the Schering patent infringement suit against Upsher-Smith would have removed barriers to generic competition, regardless of which party prevailed in the suit. If Upsher-Smith had prevailed, the FDA would have been permitted to grant final approval to Upsher-Smith's generic version of K-Dur 20, allowing Upsher-Smith to offer generic competition to Schering. After Upsher-Smith's 180-day Exclusivity Period had run, other

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potential generic competitors would have been eligible for final FDA approval. If Schering had prevailed, Upsher-Smith would not have been eligible for the 180-day Exclusivity Period. Since no other firm would have been eligible for the 180-day Exclusivity Period, there would have been no 180-day Exclusivity Period blocking final FDA approval of other generic competitors. Thus, the settlement agreement between Schering and Upsher-Smith preserved a barrier to generic competition to K-Dur 20.

48. In November 1998, Upsher-Smith received final FDA approval to market its Klor Con M20 generic version of Schering's K-Dur 20.
49. Pursuant to its agreement with Schering, Upsher-Smith has not marketed Klor Con M20, nor has it attempted to develop another generic version of Schering's K-Dur 20.
50. Under the Hatch-Waxman Act, the FDA is not permitted to grant final approval to a generic version of K-Dur 20, other than Upsher-Smith's Klor Con M20, until the 180-day Exclusivity Period has run.

Schering/AHP/ESI Agreement Not To Compete

51. On December 29, 1995, ESI submitted an ANDA to the FDA to market a generic version of Schering's K-Dur 20. ESI submitted a Paragraph IV Certification with this filing and notified Schering of its Paragraph IV Certification and ANDA filing.
52. ESI planned to launch its generic version of K-Dur 20 after Upsher-Smith's 180-day Exclusivity Period expired.
53. Schering sued ESI for patent infringement in the United States District Court for the Eastern District of Pennsylvania on February 16, 1996, alleging that ESI's generic version of Schering's K-Dur 20 infringed Schering's '743 patent.

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Schering's lawsuit triggered the statutory waiting period of up to 30 months for FDA approval of the ESI product.

54. By the end of January 1998, Schering, AHP, and ESI had reached an agreement in principle to settle their patent litigation.
55. Pursuant to their agreement in principle, 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 with 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; and AHP and ESI agreed not to conduct, sponsor, file or support a study of the bioequivalence of any product to K-Dur 20 prior to September 2006, when the K-Dur 20 patent will expire. 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 of two generic products that ESI was developing. The payments for the licenses included \$5 million to be paid within ten days of execution of the agreement, plus \$10 million to be paid in annual installments over seven years.
56. Schering has made no sales to date of the two products it licensed from ESI.
57. Instead of being based on the value of the licensed products, the \$15 million license payment is based on the amount that ESI wanted in order to settle its patent litigation with Schering.

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58. On June 19, 1998, Schering and ESI executed their final settlement agreement. Their patent litigation had previously been dismissed with prejudice.
59. Schering has paid ESI over \$20 million and continues to make annual payments to ESI under the terms of their agreement.
60. ESI received tentative approval of its ANDA from the FDA on May 11, 1999, but is not eligible for final approval until Upsher-Smith's 180-day Exclusivity Period expires.

Other Potential Generic Competition

61. Andrx Corporation ("Andrx") filed an ANDA for a generic version of Schering's K-Dur 20 on June 2, 1999. Schering has not sued Andrx for infringement of the '743 patent.
62. Andrx cannot market its product until Upsher-Smith's 180-day Exclusivity Period has run.

Effects Of Respondents' Conduct

63. The acts and practices of the respondents as herein alleged have had the purpose and effect to restrain competition unreasonably and to injure competition by preventing or discouraging the entry of generic K-Dur 20 products into the relevant markets.
64. By making cash payments to Upsher-Smith and ESI, Schering induced them to agree to delay launching generic versions of K-Dur 20. Absent those payments, neither Upsher-Smith nor ESI would have agreed to delay its entry for so long.
65. By making cash payments to Upsher-Smith and ESI, Schering protected itself from competition in the relevant

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markets from Upsher-Smith and ESI until 2001 and 2004, respectively.

66. Upsher-Smith's agreement with Schering not to compete with a generic version of K-Dur 20 until September 2001 has the effect of delaying entry into the relevant market by any other potential generic competitor. As the first ANDA filer for a generic version of K-Dur 20, Upsher-Smith is entitled to 180 days of market exclusivity before any other generic competitor may enter with its own generic version of K-Dur 20. By avoiding a court decision that would have either (a) triggered this 180-day Exclusivity Period (in the event Upsher-Smith prevailed) or (b) resulted in its forfeiture (in the event Schering prevailed), the challenged agreement delays 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.
67. As a result of respondents' conduct as herein alleged, consumers are being deprived of the benefits of competition from Upsher-Smith, ESI, or other generic competitors. Without this lower-priced generic competition, consumers, pharmacies, hospitals, insurers, wholesalers, government agencies, managed care organizations, and others are forced to purchase Schering's more expensive K-Dur 20 product.

First Violation Alleged

68. The agreement between Schering and Upsher-Smith that Upsher-Smith will not compete by marketing any generic version of Schering's K-Dur 20 until September 2001 unreasonably restrains commerce, and is therefore an unfair method of competition, in violation of Section 5 of the FTC Act.

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Second Violation Alleged

69. The agreement between Schering, AHP, and ESI that ESI will not compete by marketing any generic version of Schering's K-Dur 20 until January 2004, market more than one generic version of Schering's K-Dur 20 between January 2004 and September 2006, or support any study of the bioequivalence or therapeutic equivalence of a product to K-Dur 20 until September 5, 2006, unreasonably restrains commerce, and is therefore an unfair method of competition, in violation of Section 5 of the FTC Act.

Third Violation Alleged

70. Schering has monopoly power in the manufacture and sale of potassium chloride supplements approved by the FDA and narrower markets contained therein, and engaged in conduct intended to unlawfully preserve such monopoly power in violation of Section 5 of the FTC Act.

Fourth Violation Alleged

71. Schering conspired separately with Upsher-Smith and AHP that Schering monopolize the manufacture and sale of potassium chloride supplements approved by the FDA and narrower markets contained therein, and all three respondents acted with specific intent and engaged in overt acts in furtherance of these conspiracies to monopolize the relevant markets, in violation of Section 5 of the FTC Act.

NOTICE

Proceedings on the charges asserted against you in this complaint will be held before an Administrative Law Judge (ALJ) of the Federal Trade Commission, under Part 3 of the Commission's Rules of Practice, 16 C.F.R. Part 3. A copy of Part 3 of the Rules is enclosed with this complaint.

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You may file an answer to this complaint. Any such answer must be filed within 20 days after service of the complaint on you. If you contest the complaint's allegations of fact, your answer must concisely state the facts constituting each ground of defense, and must specifically admit, deny, explain, or disclaim knowledge of each fact alleged in the complaint. You will be deemed to have admitted any allegations of the complaint that you do not so answer.

If you elect not to contest the allegations of fact set forth in the complaint, your answer shall state that you admit all of the material allegations to be true. Such an answer will constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the ALJ will file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. Such an answer may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice.

If you do not answer within the specified time, you waive your right to appear and contest the allegations of the complaint. The ALJ is then authorized, without further notice to you, to find that the facts are as alleged in the complaint and to enter an initial decision and a cease and desist order.

The ALJ will schedule an initial prehearing scheduling conference to be held not later than 7 days after the last answer is filed by any party named as a respondent in the complaint. Unless otherwise directed by the ALJ, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

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A hearing on the complaint will begin on July 2, 2001, at 10:00 A.M. in Room 532, or such other date as determined by the ALJ. At the hearing, you will have the right to contest the allegations of the complaint and to show cause why a cease and desist order should not be entered against you.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in an adjudicative proceeding in this matter that the respondents are in violation of Section 5 of the Federal Trade Commission Act, as alleged in the complaint, the Commission may order such relief as is supported by the record and is necessary and appropriate including, but not limited to, an order that requires the following:

1. Each respondent shall cease and desist from being a party to any settlement of patent infringement litigation which involves collateral restraints, such as a restraint on the research, development, manufacture, marketing, or sale of a “non-infringing” drug product – *i.e.*, a drug product not at issue in the patent infringement litigation.
2. Each respondent shall cease and desist from being a party to any agreement in which one party agrees to refrain from conducting or assisting a study of the bioequivalence or therapeutic equivalence of a product to the NDA holder’s drug product.
3. Each respondent shall cease and desist from being a party to any agreement in which the NDA holder provides anything of value to the alleged infringer and the alleged infringer agrees to refrain from selling a drug product for any period of time.
4. Schering shall immediately license for no compensation its ‘743 patent to Upsher-Smith and to ESI so as to allow the latter two companies to make, produce, and market commercially generic versions of Schering’s K-Dur 20 and K-Dur 10. Said license must eliminate any and all legal claims that Schering

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would have for patent infringement by Upsher-Smith and ESI for selling the generic potassium chloride products for which each has already applied to the FDA for an ANDA.

5. Upsher-Smith shall immediately and without delay notify the FDA, in writing, that Upsher-Smith relinquishes its right to a 180-day Exclusivity Period for Klor Con M20 (its generic version of K-Dur 20).
6. Each respondent shall mail a copy of the Commission's complaint and order in this matter, along with a letter from such respondent's chief executive officer stating that it will abide by the terms of this order, to each of its employees who has the authority to enter into agreements concerning the research, development, manufacture, marketing, or sale of a drug product.
7. Each respondent shall take such other measures as are appropriate to correct or remedy, or prevent the recurrence of, the anticompetitive practices engaged in by respondents.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirtieth day of March, 2001, issues its complaint against said respondents.

By the Commission.

Decision and Order

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

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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.

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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.

M. “Patent Infringement” means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part,

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reexamination, patent term restoration, patents of addition and extensions thereof.

N. "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.

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

P. "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:

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- (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).

Decision and Order

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.

Decision and Order

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

Decision and Order

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.

Decision and 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 on April 2, 2012.

By the Commission, Chairman Muris not participating.

Analysis

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.

Analysis

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 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

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

Analysis

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

Analysis

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.

Analysis

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

Analysis

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

Analysis

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

Analysis

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, through 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

Analysis

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.

Analysis

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.

Complaint

IN THE MATTER OF
TECHNOBRANDS, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4041; File No. 9923034
Complaint, April 15, 2002--Decision, April 15, 2002

This consent order addresses practices used by Respondent TechnoBrands, Inc., and its president, Respondent Charles J. Anton, related to the advertising, offering for sale, sale, and distribution of products such as the Hollywood 48-Hour Miracle Diet; the Enforma System; the BMI Magnetic Kit; the Nisim New Hair Biofactors System; and the Clarion Ionic Filter Ceiling Fan and the Sila Ionic Air Purifier. The order, among other things, prohibits the respondents from representing – unless they possess competent and reliable evidence that substantiates the representations – (1) that consumers who use the Hollywood Diet, or any substantially similar product, can lose 10 lbs. in 48 hours; or (2) that by using Enforma, or any substantially similar product, consumers can achieve substantial weight loss, or avoid weight gain, without a restricted calorie diet or exercise. The order also prohibits the respondents from representing that celebrities have lost substantial weight by using the Hollywood Diet, unless they possess competent and reliable evidence that substantiates the representations. In addition, the order prohibits the respondents from making unsubstantiated representations about the comparative or absolute benefits, performance, or efficacy of any product or service, and from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research. The order also requires the respondents to pay the Commission the sum of \$200,000.

Participants

For the Commission: *Carol Jennings, Pablo M. Zylberglait, Louise R. Jung, Heather Hipsley, James Reilly Dolan, Elaine D. Kolish and Charles Pidano.*

For the Respondent: *W. Jeffery Edwards and Kelly Faglioni, Hunton & Williams.*