UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, a corporation,	)	Docket No. 9297
and	)	
American Home Products Corporation, a corporation.	)	

COMPLAINT

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

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 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 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.

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 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 until180 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.

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

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 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. 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.

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 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

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.

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

days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request**.**

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 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.

Donald S. Clark
Secretary