UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE K-DUR ANTITRUST LITIGATION	**Civil Action No. 01-1652** **(Consolidated Cases)** **Hon. Joseph A. Greenaway, Jr.**
COMMONWEALTH OF PENNSYLVANIA, By D. Michael Fisher, Attorney General, **Plaintiff,** **v.** **SCHERING-PLOUGH CORPORATION, a New Jersey corporation, KEY PHARMACEUTICALS, INC., a Florida corporation, UPSHER-SMITH LABORATORIES, a Minnesota corporation, ESI LEDERLE INC., a Delaware corporation, and AMERICAN HOME PRODUCTS CORPORATION, a Delaware corporation, jointly and severally,** **Defendants.**	**First Amended Complaint and Demand for Jury Trial** **Civil Action No. 02-36** **Hon. Joseph A. Greenaway, Jr.** **Transferred by JPML from the United States District Court for the Western District of Pennsylvania Erie Division (Transferor Court Case No. 01-328-E)**

COMMONWEALTH'S FIRST AMENDED COMPLAINT

I.

SUMMARY OF COMPLAINT

1. The Commonwealth of Pennsylvania ("Commonwealth"), by and through the Office of Attorney General, brings this action as authorized by law in its sovereign capacity on behalf of the Commonwealth's general economy and in its proprietary capacity on behalf of departments, bureaus and agencies of the Commonwealth as injured purchasers or reimbursers of K-Dur 20, and as representative of, and *as parens* patriae on behalf of, natural persons in the Commonwealth of Pennsylvania (hereinafter at times collectively "the Commonwealth"), as hereinafter described in detail, against Defendants Schering-Plough Corporation ("Schering"), Key Pharmaceuticals, Inc. ("Key"), Upsher-Smith Laboratories ("Upsher"), ESI Lederle, Inc. ("ESI"), and American Home Products Corporation ("AHP").

2. The Commonwealth seeks monetary compensation and additional remedies hereinafter described as a result of Defendants' violations of the antitrust laws of the United States as well as statutes of the Commonwealth and the common law. The Commonwealth

alleges unlawful agreements between and among Schering, its subsidiary Key and Upsher (the "Schering/Key-Upsher Agreement"), and between Schering, Key, AHP, and its subsidiary ESI (the "Schering/Key-AHP/ESI Agreement") 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. The Schering/Key-Upsher Agreement and the Schering/Key-AHP/ESI Agreement are collectively referred to as the "Agreements."

3. When Schering was confronted with the prospect of competition to K-Dur 20 through the entry of generic drugs manufactured and/or marketed by Upsher and ESI, a division of AHP, Schering structured and entered into the Agreements, which kept Upsher, and are keeping ESI and all other potential generic competitors, out of the market.

4. The Agreements and the defendants' conduct as alleged herein violate Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, the Pennsylvania Uniform Trade Practices and Consumer Protection Law, 73 P.S. § 201-1, *et seq.*, and the common law of Pennsylvania.

II.

JURISDICTION AND VENUE

5. This Amended Complaint, which alleges violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, is filed under and jurisdiction is conferred upon this Court by Sections 4, 12 and 16 of the Clayton Act, 15 U.S.C. §§15, 22 and 26, and 28 U.S.C. §§ 1331 and 1337. The court has jurisdiction over the pendent state law claims pursuant to 28 U.S.C § 1367.

6. Venue is proper in the Western District of Pennsylvania, Erie Division under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. § 1391 (b) and (c) because, at all times relevant to the bringing of this action, Defendants transacted business, did business, were found or resided in the Commonwealth of Pennsylvania; or because the claims arose, in part, in this judicial district.

III.

PARTIES

7. The Commonwealth brings this action by and through its Attorney General, D. Michael Fisher, as authorized by law under 71 P.S. § 732-204(c), and on behalf of the Commonwealth's general economy in its sovereign capacity and as representative of, and *as parens* patriae on behalf of, natural persons in the Commonwealth of Pennsylvania, and in the Commonwealth's proprietary capacity on behalf of departments, bureaus and agencies of the Commonwealth, as injured purchasers of K-Dur 20 (direct or as assignees) or as reimbursers under medical or pharmaceutical reimbursement programs to which Defendants contractually remit a rebate payment directly to the appropriate Commonwealth department, bureau or agency.

8. Defendant Schering-Plough Corporation 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 products. Schering's net sales for 1999 were approximately $9.2 billion. Schering manufactured and sold substantial quantities of K-Dur 20 in a continuous flow of interstate trade and commerce, and Schering's activities complained of herein were within the flow of and substantially affected interstate trade and commerce.

9. Defendant Key Pharmaceuticals, Inc. is a Florida corporation and a subsidiary of defendant Schering. Key's principal place of business is at One Giralda Farms, P.O. Box 1000, Madison, New Jersey. Key is the assignee of the 743 patent, as defined later in this Complaint, which is the patent covering Schering's brand name drug K-Dur 20.

10. Defendant Upsher-Smith Laboratories is a Minnesota corporation with its principal place of business at 14905 23rd Avenue North, Plymouth, Minnesota. Upsher is engaged in the discovery, development and marketing of drugs. Upsher markets twelve brand-name products, all of which are sold in the United States. Upon information and belief, Upsher's revenues for 1999 were approximately $80 million. Upsher's activities complained of herein were within the flow of and substantially affected interstate trade and commerce.

11. Defendant American Home Products Corporation 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. AHP's activities complained of herein were within the flow of and substantially affected interstate trade and commerce.

12. Defendant ESI Lederle, Inc. is a Delaware corporation and a division of defendant AHP. Upon information and belief, ESI's principal place of business is at 130 Radnor Chester Road, St. Davids Centre, St. Davids, Pennsylvania. ESI engages in the research, manufacture and sale of primarily generic drugs.

IV.

PRESCRIPTION DRUGS

A. Federal Regulation of Prescription Drugs

13. 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.

14. Newly developed prescription drugs are often protected by patents and marketed under proprietary brand names. These new drugs are commonly 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.

15. Congress, in an attempt to facilitate entry of generic drugs while maintaining incentives for new drug development, enacted the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 (the "Hatch-Waxman Act").

16. FDA approval for a generic drug is generally sought by filing an Abbreviated New Drug Application ("ANDA") with the FDA. The ANDA application has to demonstrate that the generic drug is the bioequivalent of the brand name drug that it references. 21 U.S.C. § 355(j).

17. When a brand name drug is protected by one or more patents, an ANDA applicant who intends to market its generic competitor product prior to the expiration of any patents may proceed to seek FDA approval, but must certify in the ANDA either that (1) the generic competitor does not infringe the patents on the brand name drug or (2) the patents are invalid. This is called a "Paragraph IV Certification." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

18. 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. 21 U.S.C. § 355 (j)(5)(iii).

19. The Hatch-Waxman Act gives the first firm filing an ANDA seeking Paragraph IV Certification a period of protection from other generic competition. The FDA may not approve other generic competitors of the brand name drug until 180 days after the earlier of (1) the date on which the first firm begins commercial marketing of its generic competitor of the brand name drug, or (2) a court finds the patents claiming the brand name drug are invalid or not infringed. This is commonly known as "the 180-day Exclusivity Period." 21 U.S.C. § 355 (j)(5)(B)(iv).

20. If the first firm filing an ANDA loses its patent litigation with the patent holder, the 180-day Exclusivity Period is not available to any firm.

B. The Effect of Generic Competition in the Market

21. Generic entry generally leads to a significant erosion of the brand name drug's market share in both unit and dollar sales within the first year. As additional generic competitors enter the market, the price of generic drugs typically decreases even further and the brand name drug's market share erodes further.

22. Pharmacists are permitted, and in some circumstances required, to substitute generic drugs for their brand name counterparts, unless the prescribing physician has directed that the brand name drug be dispensed.

23. Certain third-party payers of prescription drugs (i.e., managed care plans, Medicaid) encourage or insist on the use of generic drugs over their brand name counterparts wherever possible.

V.

TRADE AND COMMERCE

24. At all times relevant to this Complaint, Defendants Schering, Key, Upsher, AHP, and ESI participated in the market for prescription drugs throughout the United States.

25. Defendant Schering and its subsidiary Key, developed, manufactured, marketed, sold and distributed prescription drug products throughout the United States.

Schering's and Key's products were transported across state lines and were sold in the various states, including the Commonwealth. The products sold and distributed by Defendants Schering and Key were shipped in interstate commerce.

26. Defendant Upsher developed, manufactured, marketed, sold and distributed prescription drug products throughout the United States. Upsher's products were transported across state lines and were sold in the various states, including the Commonwealth. The products sold and distributed by Defendant Upsher were shipped in interstate commerce.

27. Defendant AHP and its division ESI, developed, manufactured, marketed, sold and distributed prescription drug products throughout the United States. AHP's and ESI's products were transported across state lines and were sold in the various states, including the Commonwealth. The products sold and distributed by Defendants AHP and ESI were shipped in interstate commerce.

28. The activities of the Defendants, including manufacturing, marketing, distributing and selling prescription drug products, were in the regular, continuous and substantial flow of interstate commerce and have had, and continue to have, a substantial effect on interstate commerce.

VI.

SCHERING'S POTASSIUM CHLORIDE SUPPLEMENTS AND SCHERING'S DOMINANCE IN THE RELEVANT MARKET

29. 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. In 1998, sales of Schering's two K-Dur products were more than $220 million.

30. The relevant geographic market for purposes of this case is the United States.

31. The relevant product market is for 20 milliequivalent dosage extended-release potassium chloride tablets and capsules approved for manufacture and sale by the FDA.

32. 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.

33. Patients who suffer from depleted potassium levels have no practical substitute for potassium chloride supplements.

34. For clinical reasons, among others, physicians and patients prefer 20 milliequivalent dosage extended-release potassium chloride tablets to other forms and dosages of potassium chloride. Other sizes of extended release potassium chloride tablets and other non-extended release potassium chloride tablets are not substitutes.

35. The existence of other potassium chloride products has not significantly constrained Schering's pricing of K-Dur 20.

VII.

ANTICOMPETITIVE CONDUCT

A. Schering's K-Dur Patent Monopoly and the Effect of Generic Competition Prior to the Expiration of the Patent

36. Potassium chloride, the active ingredient in potassium chloride supplements, is not patentable.

37. The formulation for Schering's products K-Dur 20 and K-Dur 10 are covered by a formulation patent issued to Charles Hsiao and Chi T. Chou, and assigned to Schering's subsidiary Key. The patent, number 4,863,743 (the "743 patent"), is for a controlled release potassium chloride tablet. The 743 patent expires on September 5, 2006.

38. The allegedly novel aspect of the 743 patent is the composition of the coating material applied to previously known potassium chloride crystals.

39. Schering anticipated generic entry prior to the expiration of its 743 patent.

40. Upon information and belief, the first year of low-priced generic competition would reduce branded K-Dur 20's sales by as much as 50 percent.

B. Schering/Key-Upsher Agreement Not to Compete

41. On August 6, 1995, Upsher filed an ANDA with the FDA to market Klor Con M20, a generic competitor of Schering's K-Dur 20. Upsher's ANDA was the first for a generic competitor drug to K-Dur 20. Upsher submitted a Paragraph IV Certification with its ANDA and, on November 3, 1995, Upsher notified Schering and Key of its Paragraph IV Certification and ANDA filing. The notice triggered the statutory waiting period of up to 30 months for final FDA approval of the Upsher product. 21 U.S.C. § 355 (j)(5)(B)(iii).

42. On December 15, 1995, Key filed a patent infringement suit in the United States District Court for the District of New Jersey alleging that Upsher's Klor Con M20 infringed on Key's 743 patent.

43. As the first ANDA filer with a Paragraph IV Certification for a generic competitor of Schering's K-Dur 20, Upsher became eligible for the 180-day Exclusivity Period.

44. Since Upsher became eligible for the 180-day Exclusivity Period, no other generic manufacturer could obtain final FDA approval to market a generic competitor drug to K-Dur 20 until after the exclusivity period had expired, even if the generic competitor did not infringe on the 743 patent.

45. During the first half of 1997, Upsher prepared to commercially launch Klor Con M20 no later than May 1998, the month the 30-month stay of FDA approval was to expire. 21 U.S.C. § 355(j)(5)(B)(iv).

46. On June 17, 1997, on the eve of their patent trial, Key and Upsher settled their litigation and entered into the Schering/Key-Upsher Agreement. Under the Schering/Key-Upsher Agreement, Schering agreed to make unconditional payments of $60 million to Upsher in exchange for Upsher's promise not to enter the market, either with the allegedly infringing generic competitor drug to K-Dur 20 or with any other generic competitor drug to K-Dur 20, regardless of whether such product would infringe on Key's patents, until September 2001. Key and Upsher agreed to a dismissal of the case without prejudice and Schering received licenses to market five Upsher products.

47. Upon information and belief, the $60 million payment from Schering to Upsher was unrelated to the value of the products Upsher licensed to Schering.

48. The licensed products were of little value to Schering. Schering never sold four of the five products, made minimal sales of the fifth, and has no expectation of making additional sales of any of the five products.

49. Whatever the outcome of the Key-Upsher patent litigation, by entering into the Schering/Key-Upsher Agreement, Schering achieved at least two things that a verdict in the patent suit could not. First, the Schering/Key-Upsher Agreement allowed Schering to preserve its monopoly in the relevant market to a greater extent than it could have even if Key won the patent suit, because no generic competitor, whether infringing or not, could enter the market until 180 days after Upsher began to market its generic competitor drug. Second, if Upsher had won the patent suit, the FDA would have been able to grant final approval to Upsher's generic competitor drug to K-Dur 20, thereby allowing Upsher to market its generic, competitor to Schering's K-Dur 20. Moreover, after Upsher's 180-day Exclusivity Period had

run, other potential generic competitors would have been eligible for final FDA approval. Thus, entering into the Schering/Key-Upsher Agreement assured Schering that its monopoly would continue almost four more years until September, 2001, a better result for Schering than either winning or losing the litigation would have produced.

50. In November 1998, Upsher received final FDA approval to market its Klor Con M20 generic competitor of Schering's K-Dur 20.

51. Pursuant to the Schering/Key-Upsher Agreement, Upsher did not market Klor Con M20 prior to September 1, 2001, and upon information and belief, Upsher has not attempted to develop another generic competitor drug to Schering's K-Dur 20.

52. Under the Hatch-Waxman Act, the FDA is not permitted to grant final approval to a generic competitor drug to K-Dur 20, other than Upsher's Klor Con M20, until March 2002.

C. Schering/Key-AHP/ESI Agreement Not to Compete

53. On December 29, 1995, AHP/ESI submitted an ANDA to the FDA to market a generic competitor drug to Schering's K-Dur 20. ESI submitted a Paragraph IV Certification with its filing and notified Schering and Key of its Paragraph IV Certification and ANDA filing.

54. ESI planned to launch its generic competitor to K-Dur 20 after Upsher's 180-day Exclusivity Period expired.

55. On February 16, 1996, Schering sued AHP/ESI in the United States District Court for the Eastern District of Pennsylvania alleging ESI's generic competitor drug to Schering's K-Dur 20 infringed Schering/Key's 743 patent. Schering/Key's lawsuit triggered the statutory waiting period of up to 30 months for FDA approval of the ESI product. 21 U.S.C. § 355 (j)(5)(B)(iii).

56. By the end of January 1998, Schering, Key, AHP, and ESI had reached an agreement in principle to settle the patent litigation. On June 19, 1998, Schering, Key, AHP and ESI executed the final Schering/Key-AHP/ESI Agreement. The patent litigation had previously been dismissed by agreement without prejudice.

57. Pursuant to the Schering/Key-AHP/ESI Agreement, Schering agreed to pay AHP/ESI up to $30 million in exchange for AHP's and ESI's promises to refrain from marketing the allegedly infringing generic competitor drug to K-Dur 20 or any other generic competitor drug to K-Dur 20, regardless of whether such product would infringe Key's

patents, until January 2004. AHP and ESI further agreed to refrain from marketing more than one generic competitor drug to K-Dur 20 between January 2004 and September 2006, and they agreed not to conduct, sponsor, file or support a study of the bioequivalence of any product similar to K-Dur 20 prior to September 2006, when the K-Dur 20 patent will expire.

58. The $30 million under the Schering/Key-AHP/ESI Agreement was broken down into the following components. Schering agreed to pay ESI $5 million up front with an additional $10 million if ESI could demonstrate that its generic competitor drug to K-Dur 20 could be approved by the FDA under an ANDA on or before June 30, 1999. Schering paid another $15 million purportedly for licenses of two generic products that ESI was developing. The payments allegedly for the licenses included $5 million to be paid within 10 days of execution of the Schering/Key-AHP/ESI Agreement, plus $10 million to be paid in annual installments over seven years.

59. ESI received tentative approval of its ANDA from the FDA on May 11, 1999, but is not eligible for final approval until March 2002, the date Upsher's 180-day Exclusivity Period expires.

60. Schering has made no sales to date of the two products licensed from ESI.

61. Instead of being based on the value of the licensed products, the $15 million payment is based on ESI and AHP's agreement to refrain from competition with Schering's K-Dur 20 product.

62. Upon information and belief, Schering has paid ESI more than $20 million and continues to make annual payments to ESI under the terms of the Schering/Key-AHP/ESI Agreement.

D. Other Potential Generic Competition Has Also Been Restrained

63. Andrx Corporation ("Andrx") filed an ANDA for a generic competitor of Schering's K-Dur 20 on June 2, 1999. Neither Schering nor Key has sued Andrx for infringement of the 743 Patent. Andrx cannot market its generic product until March 2002.

E. Market Power

64. Schering's products represent approximately 69% of the sales of all potassium chloride supplements in the United States, indicating that substitution for K-Dur products with other kinds of potassium chloride supplements does not serve as a meaningful limit on the price of K-Dur products.

65. Sales of Schering's K-Dur 20 represent 100% of the market 20 milliequivalent dosage extended-release potassium chloride tablets and capsules in the United States.

66. At all times relevant hereto, entry into the relevant 20 milliequivalent extended release market was restricted and unlikely to diminish Schering's market share. Before entry could occur, potential entrants were required to, among other things, file an NDA or an ANDA with the FDA, and obtain FDA final approval. At all times relevant hereto, only one NDA for a new potassium chloride supplement was pending before the FDA. The NDA, for a powder form of potassium chloride, has not been approved. Even if this NDA were approved, because of the disadvantages of potassium chloride powders as 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.

67. At all times relevant hereto, FDA final approval of an ANDA for a generic competitor drug to K-Dur 20 for anyone other than Upsher was and is effectively blocked. Pursuant to the Hatch-Waxman Act, Upsher was eligible for the right to a 180-day Exclusivity Period for the sale of a generic competitor drug to K-Dur 20. As a result, no company could obtain final FDA approval of an ANDA to market or sell a generic competitor drug to K-Dur 20 until at least March 2002.

VIII.

LACK OF PRO-COMPETITIVE JUSTIFICATION

68. The Agreements, and Defendants' other conduct intended to restrict the market to Schering for 20 milliequivalent extended release potassium chloride tablets and capsules in the United States as alleged herein, lack any legitimate business or pro-competitive justification. Moreover, any justification that may exist does not outweigh the substantial anti-competitive effects of Defendants' conduct.

IX.

EFFECTS

69. The acts and practices of the Defendants as herein alleged have had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition within the Commonwealth of Pennsylvania in the following ways, among others:

(a) restraining competition in the market for extended release potassium chloride tablets and capsules;

(b) stabilizing or otherwise maintaining monopoly pricing of extended release potassium chloride tablets and capsules;

(c) restricting and allocating the market for extended release potassium chloride tablets and capsules; and

(d) depriving the Commonwealth and its departments, bureaus and agencies of the benefits of competition among generic pharmaceutical manufacturers and entry generic from new competitors.

X.

INJURY

70. As a direct and proximate result of the unlawful conduct alleged above, the Commonwealth was not and is not able to purchase or reimburse the purchase of extended release potassium chloride tablets and capsules at prices determined by free and open competition, and consequently has been injured in its business and property. The Commonwealth has and continues to pay and reimburse more money for extended release potassium chloride tablets and capsules than the Commonwealth would have paid in a free and competitive market.

71. As a direct and proximate result of the unlawful conduct alleged above, the general economy of the Commonwealth has sustained injury, and is threatened with further injury to its business and property unless the Defendants are enjoined from their unlawful conduct.

72. As a direct and proximate result of the unlawful conduct alleged above, the Defendants have unjustly profited through inflated profit margins and have thus far retained the illegally obtained profits.

73. Defendants' unlawful conduct is continuing and will continue unless the injunctive and equitable relief request is granted. The Commonwealth does not have a fully adequate remedy at law.

XI.
FRAUDULENT CONCEALMENT

74. At all times material hereto, Defendants and their co-conspirators effectively, affirmatively, and fraudulently concealed their unlawful conduct from the Commonwealth.

75. Defendants and their co-conspirators engaged in a successful, illegal fraud, combination, conspiracy and concerted action that by its nature was inherently self-concealing.

76. Defendants' wrongful conduct as alleged in this Complaint was carried out in part through means and methods which were designed and intended to avoid detection, and which in fact successfully precluded detection. Although the Commonwealth exercised due diligence, it could not have discovered Defendants' unlawful conduct, scheme and conspiracy at any earlier date, because of Defendants' effective, affirmative, and fraudulent concealment of their activities.

77. One method by which Defendants fraudulently concealed their wrongful conduct from the Commonwealth was by requiring that the record of their conduct in the patent litigation and the eventual Agreements reached to settle such litigation be sealed. Indeed, the Agreements were never disclosed to the courts in either of the two patent lawsuits.

78. Although the Commonwealth exercised all due diligence, it had no knowledge of Defendants' unlawful conduct until it was publicly announced that the government was investigating Defendants' conduct in the market for K-Dur 20.

79. Although the Commonwealth exercised due diligence, it could not possibly have discovered Defendants' unlawful conduct, scheme and conspiracy such public disclosure of the government investigation because of the successful deceptive practices and techniques of secrecy employed by Defendants and their co-conspirators to avoid detection of, and to affirmatively and fraudulently conceal, their wrongful conduct.

80. By virtue of the fraudulent concealment of their wrongful conduct by Defendants and their co-conspirators, the running of any statute of limitations has been tolled and suspended with respect to any claims and rights of action that the Commonwealth has as a result of the unlawful conduct, scheme and conspiracy alleged in this Complaint.

XII.

FIRST CAUSE OF ACTION

AGREEMENT IN RESTRAINT OF TRADE

81. Plaintiff realleges and incorporates by reference Paragraphs 1 through 80.

82. Beginning on or about June 17, 1997, and continuing to the present, Schering, Key, and Upsher engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to, among other things: (a) allocate all sales of 20 milliequivalent dosage extended-release potassium chloride tablets and capsules in the United States to Schering; (b) prevent the sale of generic 20 milliequivalent dosage extended-release potassium chloride tablets and capsules in the United States, thereby protecting K-Dur 20 from any generic competition; and (c) fix the price that purchasers would pay for K-Dur 20 at the higher, brand name drug price.

83. Beginning no later than January 1998 and continuing to the present, AHP and ESI joined the continuing illegal contract, combination and conspiracy in restraint of trade, which was expanded for the purpose, and with the effect, of preventing competition between Schering and AHP/ESI, thereby further protecting K-Dur 20 from any generic competition.

84. By entering into this unlawful conspiracy, Defendants have unlawfully conspired in restraint of trade and committed a *per se* violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. Defendants' Agreements constitute horizontal market allocation and price fixing agreements between actual or potential competitors.

85. In the alternative, by entering into this conspiracy, Defendants have unlawfully conspired to unreasonably restrain trade and have committed violation of Section 1 of the Sherman Act, 15 U.S.C. § 1 pursuant to an analysis under the rule of reason. Defendants' Agreements constitute horizontal market allocation and price fixing agreements between actual or potential competitors.

XII.

SECOND CAUSE OF ACTION

MONOPOLIZATION OF 20 MILLEQUIVALENT DOSAGE EXTENDED RELEASE POTASSIUM CHLORIDE SUPPLEMENT MARKET

86. Plaintiff realleges and incorporates by reference Paragraphs 1 - 85.

87. Defendant Schering has, by its illegal acts described previously in this Complaint, acquired, maintained and unlawfully exercised its monopoly power in the 20

milliequivalent dosage extended release potassium chloride supplement market, the relevant market. Defendant Schering's conduct is and has been anti-competitive.

88. Defendant Schering committed said illegal acts with the specific intent of acquiring, maintaining, and unlawfully exercising its monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

89. Defendant Schering has controlled and continues to control a substantial percentage of the relevant market, and thereby has and does possess monopoly power in the relevant market.

XIII.

THIRD CAUSE OF ACTION

ATTEMPTED MONOPOLIZATION OF 20 MILLIEQUIVALENT DOSAGE EXTENDED RELEASE POTASSIUM CHLORIDE SUPPLEMENT MARKET

90. Plaintiff realleges and incorporates by reference Paragraphs 1 - 89.

91. Schering has committed the above-described unlawful conduct with the specific intent to monopolize the relevant market, and has engaged in said anti-competitive conduct with an attendant dangerous probability of success in achieving a monopoly in the relevant market thereby attempting to monopolize the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

XIV.

FOURTH CAUSE OF ACTION

CONSPIRACY TO MONOPOLIZE 20 MILLIEQUIVALENT DOSAGE EXTENDED RELEASE POTASSIUM CHLORIDE SUPPLEMENT MARKET

92. Plaintiff realleges and incorporates by reference Paragraphs 1 - 91.

93. Schering, Key, Upsher, AHP, and ESI conspired to act together to obtain monopoly power for Schering in the 20 milliequivalent dosage extended release potassium chloride supplement market in the United States in violation of Section 2 of the Sherman Act, 15. U.S.C. § 2.

94. Actions taken in furtherance of their conspiracy include, but are not limited to, Schering's payments to Upsher, AHP, and ESI under the Agreements and Upsher's forbearance from marketing its generic equivalent despite its ANDA being approved and the expiration of the 30-month waiting period under the Hatch-Waxman Act.

XV.

SIXTH CAUSE OF ACTION

BREACH OF CONTRACT

95. Plaintiff realleges and incorporates by reference each of the preceding paragraphs as if set forth in full herein.

96. The Commonwealth and Defendant, Schering entered into a contractual agreement regarding the Commonwealth's purchase of K-Dur 20 from Schering ("the Contract"). Defendant Schering was contractually obligated to deal fairly and honestly with the Commonwealth.

97. Despite its legal and contractual obligation to do so, Defendant Schering, by its conduct complained of herein, has failed to deal fairly and honestly in the course of the Contract with the Commonwealth.

98. As a direct and proximate result of Defendant Schering's breach of its contract with the Commonwealth as set forth above, the Commonwealth has suffered substantial economic harm and damages for which it is entitled to recover.

99. All conditions precedent under the Contract which were the obligation of the Commonwealth have been performed or have occurred. Defendant Schering's breach is without justification or privilege.

100. The Commonwealth has necessarily engaged the undersigned attorneys to prosecute this action, thus incurring reasonable attorneys' fees and costs. Plaintiff is entitled to recovery of its reasonable and necessary attorneys' fees incurred in connection with the lawsuit.

XVIII.

SEVENTH CAUSE OF ACTION

FRAUD

101. Plaintiff realleges and incorporates by reference each of the preceding paragraphs as if set forth in full herein.

102. Defendants' conduct as described herein constitutes and involves false and material misrepresentations of existing and known facts. Such misrepresentations were made by Defendants to the Commonwealth intentionally and with actual knowledge or reckless indifference to the truth, and with intent that the Commonwealth rely on them.

103. The Commonwealth justifiably relied upon Defendants' misrepresentations.

Defendants' misrepresentations were such, that the Commonwealth, in the exercise of common prudence and diligence could not have ascertained the truth. The Commonwealth has suffered substantial economic damages as a direct and proximate result of the Defendants' misrepresentations.

XVI.
EIGHTH CAUSE OF ACTION
CIVIL CONSPIRACY

104. Plaintiff realleges and incorporates by reference each of the preceding paragraphs as if set forth in full herein.

105. Beginning at least as early June, 1997, the exact date being unknown to Plaintiff and continuing thereafter until present, Defendants and their co-conspirators engaged in a continuing conspiracy to violate Federal and State laws and to defraud Plaintiff by causing Plaintiff to pay more for K-Dur 20 than it otherwise would have in the absence of Defendants' conspiracy.

106. Pursuant to such widespread conspiracy as alleged herein and in furtherance thereof, Defendants and their co-conspirators engaged in a wide range of activities, the purpose and effect of which was to defraud Plaintiff. Those activities include, but are not limited to, the crafting and entering into of agreements whereby Defendants and their co-conspirators would take actions designed to financially benefit themselves by preserving artificially high prices on K-Dur 20 by, among other things, preventing generic equivalent access to the market.

107. Defendants performed these acts complained of herein in furtherance of the common plan or design of the conspiracy with knowledge of the injury and damage it would cause Plaintiff, and with intent to cause such injuries or with reckless disregard for the consequences.

108. As a direct and proximate result of Defendants' conspiracy as alleged herein, Plaintiff has been injured and damaged, and Defendants are jointly and severally liable for such injuries and damages.

XVII.
NINTH CAUSE OF ACTION

CONCERT OF ACTION

109. Plaintiff realleges and incorporates by reference each of the preceding paragraphs as if set forth in full herein.

110. Beginning at least as early as June, 1997 the exact date being unknown to Plaintiff, and continuing thereafter until present, Defendants and their co-conspirators engaged in concerted activity and/or a concert of action with each other to commit fraud and other tortious acts on Plaintiff, causing Plaintiff to pay more for K-Dur20 than it otherwise would have for the same or equivalent drug in the absence of Defendants' concerted activity.

111. Defendants acted in concert with one another to commit fraud on Plaintiff. Moreover, defendants acted pursuant to a common design or plan with respect to the commission of such fraud.

112. As a direct and proximate result of Defendants' concerted action as alleged herein, the Commonwealth has suffered substantial economic damages, and Defendants are jointly and severally liable for such damages.

XVIII.

TENTH CAUSE OF ACTION
UNJUST ENRICHMENT/RESITUTION

113. Plaintiff realleges and incorporates by reference each of the preceding paragraphs as if set forth in full herein.

114. Defendant Schering's sale of K-Dur 20, in conjunction with its complained of actions, has resulted in substantial health care costs which have been borne by the Commonwealth through its payment of medical costs, under the Medicaid and State medical assistance programs and otherwise, as well as increased costs for State employee health insurance, and other health care costs incurred. Such costs borne by the Commonwealth were much higher due to Defendants' wrongful conduct than they would have been in the absence of such conduct.

115. Defendants' conduct, as complained of herein, allowed Defendant Schering to improperly maintain artificially high profit levels on the sale of K-Dur 20.

116. The Commonwealth has been unjustly required to pay excessive health care costs, including the purchases and reimbursement of purchases of K-Dur 20 at inflated prices, resulting from the Defendants' wrongful acts, and on the basis of equitable principles, those costs should be borne by the Defendants. The expenditures by the Commonwealth are

necessary and were not made gratuitously.

117. The Commonwealth has conferred a benefit on Defendant Schering by, among other things, bearing the costs from harm proximately caused by Defendants' wrongful conduct, thereby enabling Schering to reap substantial and unreasonable profits from the sale of K-Dur 20 in the Commonwealth.

118. Defendants engaged in the wrongful conduct with knowledge that the Commonwealth would be required to bear healthcare costs attributed to such conduct. Defendants knew of, and appreciated the benefits that the Commonwealth's payment of increased health care costs conferred on them. Under these circumstances, Defendants' acceptance and retention of the benefits from their wrongful conduct would be inequitable, unconscionable, and unjust.

119. As a result of Defendants' unfair and deceptive acts or practices as alleged herein, Defendants have gained millions of dollars in unjust profits and gains from the Commonwealth, which they otherwise would not have received and which in equity they should be required to disgorge. In addition, pursuant to 73 P.S. sec. 201-4.1, this Court may, and should require Defendants to disgorge and restore to the Commonwealth all such wrongfully attained amounts as described herein, and which have resulted from Defendants' violations of the Pennsylvania Unfair Trade Practices and Consumer Protection Law as described below.

XIX.

ELEVENTH CAUSE OF ACTION

VIOLATION OF THE PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW, 73 P.S. § 201-1, *ET SEQ.*

120. Plaintiff realleges and incorporates by reference each of the preceding paragraphs as if set forth in full herein.

121. The Defendants' conduct, and conduct take in concert with each other, as alleged herein, has been undertaken in the course of trade or commerce as defined in 73 P.S. § 201-2 (3).

122. Defendants' acts, and use or employment of unconscionable commercial practices, including deception, fraud, false promises, misrepresentations and/or the knowing concealment, suppression or omission of material facts practiced with the intent that others rely on them, conducted individually, and in concert with one another, and as set forth above, constitute willful and knowing violations of the Pennsylvania Unfair Trade Practices Act, P.S. sec. Sec.201-1 *et seq.*

123. Defendants' unconscionable, illegal, commercial practices which constitute unfair methods of competition include specifically, but are not limited to, the crafting and entering into, and maintenance of, illegal, collusive agreements designed to unfairly and illegally restrain trade. Defendants' unlawful conduct is continuing and will continue unless injunctive and equitable relief is granted.

124. As a direct and proximate result of Defendants' acts complained of herein, the Commonwealth has suffered substantial economic damages for which each Defendant is individually and legally responsible.

125. The Commonwealth has been forced to engage the undersigned attorneys to protect its rights and prosecute this action, and in so doing has incurred, and continues to incur reasonable attorneys' fees and costs for which it is entitled to recovery pursuant to P.S. 73 201-9.2.

XX.

JURY TRIAL DEMAND

126. The Commonwealth demands trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil procedure, of all issues triable of right by jury.

XXII.

PRAYER FOR RELIEF

WHEREFORE, the Commonwealth prays that this Court:

(a) adjudge and decree that Defendants have engaged in conduct in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2;

(b) enjoin and restrain, pursuant to Federal law, the Defendants, their affiliates, assignees, subsidiaries, successors and transferees, and the heirs, directors, partners, agents and employees thereof, and all other persons acting or claiming to act on their behalf, or in concert with them, from continuing, maintaining or renewing the contracts, combinations or conspiracies alleged herein, or from engaging in any other contract, combination or conspiracy having a similar purpose or effect, and from adopting or following any practice, plan, program or device having a similar purpose or effect;

(c) grant any other such injunctive relief the Court deems necessary to correct, remedy and prevent the recurrence of the anti-competitive and unlawful practices alleged herein;

(d) enter judgment for Plaintiff for three (3) times the amount of damages sustained by the Commonwealth (as direct purchaser or assignees of direct purchasers) as allowed by Federal law, together with the costs of this action, including reasonable attorney's fees;

(e) enter judgment for actual and statutory damages;

(f) enter an order requiring each Defendant to discourage all profits and gains earned either in whole or in part for the unfair and/or deceptive acts or practices complained of herein;

(g) a judgment requiring each and every Defendant to be ordered to pay restitution;

(h) award Plaintiff punitive and exemplary damages against Defendants, and in an amount sufficient to punish Defendants and to deter others from similar wrong doings;

(i) award Plaintiff the costs of this action, including reasonable attorney's fees, and, where applicable, expert fees; and

(j) award such other and further relief as the court deems appropriate under the circumstances.

Respectfully submitted:

By:_____

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