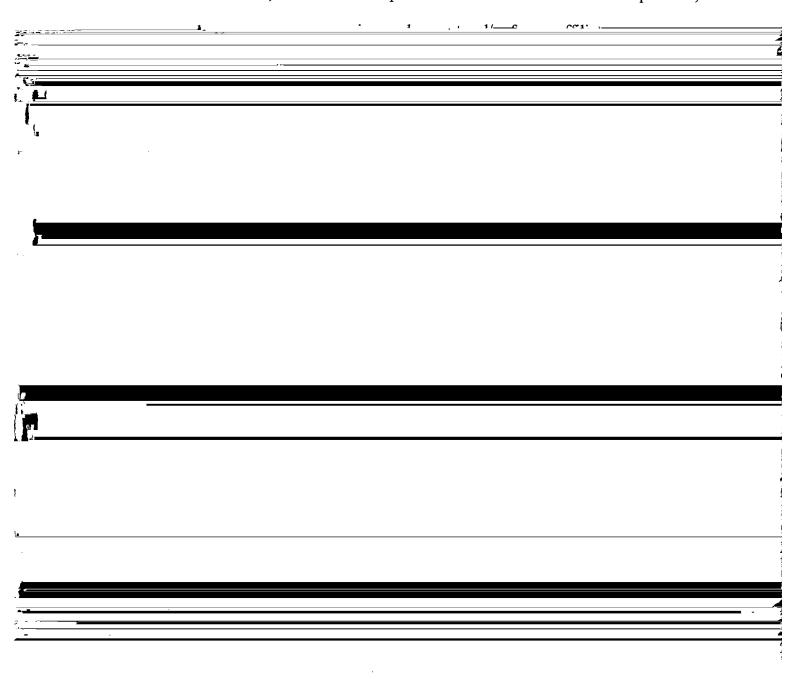


attorneys, consultants, representatives, officers, and all other persons acting on its behalf.

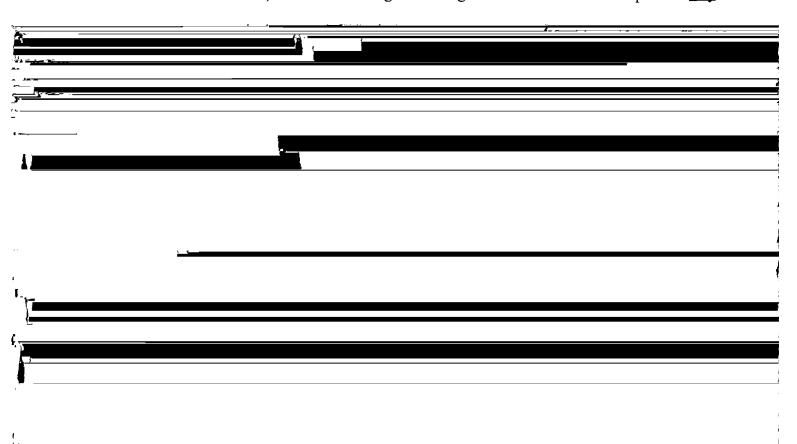
R	As used herein,	"AHP"	means re	espondent.	American	Home	Products	Cornoration	n ita
IJ.	I ID UDOU HOLVIII	7 11 11	miculio i c		1 miloriomi	TIOHIO	I I O U U C U	Corporation	J. ILI



parents, divisions, or subsidiaries, and any of their respective officers, directors, employees, partners, agents, attorneys, or any person acting on their behalf.

C. As used herein, "ESI" means the corporate entity that was organized under the laws of the state of Delaware and which had its principal place of business in St. David's

- G. As used herein, "Complaint" means the administrative complaint issued by the Federal Trade Commission on March 30, 2001, Docket No. 9297, styled <u>In the Matter of Schering-Plough Corporation</u>, et al.
- H. As used herein, the "'743 patent" means U.S. Patent No. 4,863,743 issued to Key Pharmaceuticals, Inc. on September 5, 1989.
- I. As used herein, "K-Dur 20" means the 20 milliequivalent (20 mEq) potassium chloride supplement sold under that brand name by respondent Schering-Plough
- J. As used herein, "FDA" means the United States Food and Drug Administration, including without limitation its employees, scientists, technicians, agents, examiners and laboratories.
- K. As used herein, "the Patent Infringement Litigation" means the action captioned Key



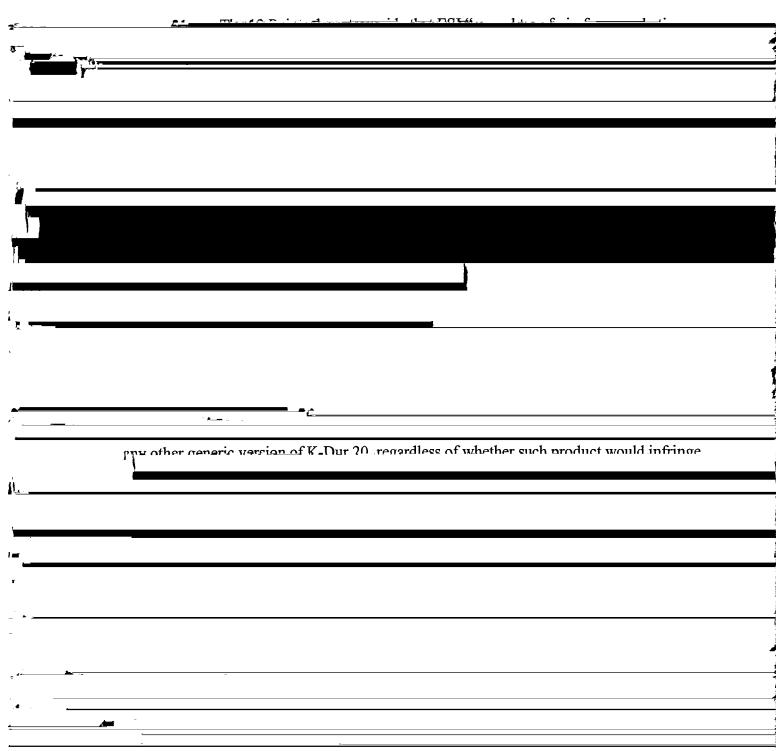
- O. As used herein, "person" means any natural person, firm, partnership, corporation, incorporated association, organization, joint venture, cooperative, governmental body or other form of legal entity.
- P. As used herein, "NDA" mean an application submitted to the United States Food and



REQUESTS FOR ADMISSIONS

	1. The "agreement in principle" referenced in paragraph 54 of the Complaint refers to the 13 Points.
	2. The 13 points were agreed to during a court-ordered settlement conference, held on January 23, 1998, during the Patent Infringement Litigation.
X	2 Marietrata Lidas Dauter was present during the court ardered settlement
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4 -	conference that took place on January 23, 1998 in the Patent Infringement Litigation.
	4. Magistrate Judge Reuter presided over the court-ordered settlement conference that took place on January 23, 1998 in the Patent Infringement Litigation.
	5. On January 23, 1998, the date of the 13 Points. FSI was a cornoration
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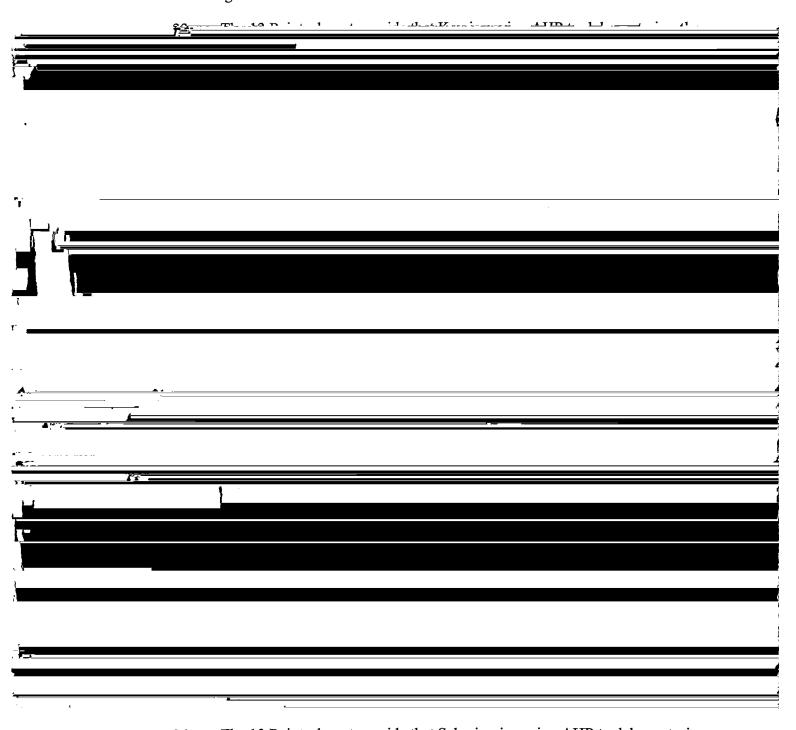
- 19. The "products" referenced in paragraph XI of the 13 Points are enalapril and buspirone.
- 20. The 13 Points do not provide that AHP "agreed to refrain from marketing . . . any other generic version of K-Dur 20, regardless of whether such product would infringe Schering's patents, until January 2004."



Schering's patents, until January 2004."

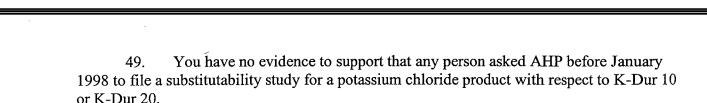
22. The 13 Points do not provide that AHP "agreed to refrain from marketing

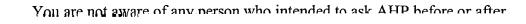
32. The 13 Points do not provide that Schering is paying ESI to delay entering the market with its generic version of K-Dur 20.



- 34. The 13 Points do not provide that Schering is paying AHP to delay entering the market with its generic version of K-Dur 20.
- 35. In the 13 Points, Key agreed to grant ESI a royalty free, non-exclusive license under the '743 Patent beginning on January 1, 2004.

- 45. You are not aware of any person who intended to ask AHP before or after January 1998 to sponsor a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20, but who did not do so because of the Settlement Agreement.
- 46. You have no evidence to support that any person intended to ask AHP before or after January 1998 to sponsor a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20, but did not do so because of the Settlement Agreement.
- 47. You are not aware of any person who intended to ask AHP before or after January 1998 to sponsor a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20, but who did not do so because of the 13 Points.
- 48. You have no evidence to support that any person intended to ask AHP before or after January 1998 to sponsor a substitutability study for a potassium chloride product with respect to K. Dur 10 or K. Dur 20, but did not do so because of the 13 Points.





January 1998 to file a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20, but who did not do so because of the Settlement Agreement.

- 51. You have no evidence to support that any person intended to ask AHP before or after January 1998 to file a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20, but did not do so because of the Settlement Agreement.
- 52. You are not aware of any person who intended to ask AHP before or after January 1998 to file a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20, but who did not do so because of the 13 Points

- 57. You are not aware of any person who intended to ask AHP before or after January 1998 to support a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20, but who did not do so because of the 13 Points.
- 58. You have no evidence to support that any person intended to ask AHP before or after January 1998 to support a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20, but did not do so because of the 13 Points.
 - 59 You have no evidence to support that if any person had asked AHP before or

after January 1998 to conduct, sponsor, support or file a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20, AHP would have done so in the absence of the Settlement Agreement.

- 60. You have no evidence to support that if any person had asked AHP before or after January 1998 to conduct, sponsor, support or file a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20, AHP would have done so in the absence of the 13 Points.
- 61. You have no evidence to support that any person asked AHP before January 1998 to conduct a study of the bioequivalence or therapeutic equivalence of a potassium chloride product to K-Dur 10 or K-Dur 20.
- 62. You are not aware of any person who intended to ask AHP before or after January 1998 to conduct a study of the bioequivalence or therapeutic equivalence of a potassium chloride product to K-Dur 10 or K-Dur 20, but who did not do so because of the Settlement Agreement.
- 63. You have no evidence to support that any person intended to ask AHP before or after January 1998 to conduct a study of the bioequivalence or therapeutic equivalence of a potassium chloride product to K-Dur 10 or K-Dur 20, but who did not do so because of the Settlement Agreement.
- 64. You are not aware of any person who intended to ask AHP before or after January 1998 to conduct a study of the bioequivalence or therapeutic equivalence of a potassium chloride product to K-Dur 10 or K-Dur 20, but did not do so because of the 13 Points.
- 65. You have no evidence to support that any person intended to ask AHP before or after January 1998 to conduct a study of the bioequivalence or therapeutic equivalence of

You have no evidence to support that any person asked AHP before January 1998 to sponsor a study of the bioequivalence or therapeutic equivalence of a potassium chloride product to K-Dur 10 or K-Dur 20. You are not aware of any person who intended to ask AHP before or after 68.

	notassium ch	bloride product to K-Dur 10 or K-Dur 20. but did not do so because of the 13
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~ <u>#</u> .	Points.	•
	78.	No person asked AHP before January 1998 to file a study of the
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Dur 20.

- 79. You have no evidence to support that any person asked AHP before January 1998 to support a study of the bioequivalence or therapeutic equivalence of a potassium chloride product to K-Dur 10 or K-Dur 20.
- 80. You are not aware of any person who intended to ask AHP before or after January 1998 to support a study of the bioequivalence or therapeutic equivalence of a potassium chloride product to K-Dur 10 or K-Dur 20, but who did not do so because of the Settlement Agreement.
 - 81. You have no evidence to support that any person intended to ask AHP before

- 88. You have no evidence to support that any person that would have sought FDA approval to market a generic version of K-Dur 20 did not do so because of the 13 Points.
- 89. No person that would have sought FDA approval to market a generic version of K-Dur 20 did not do so because of the Settlement Agreement.
- 90. No person that would have sought FDA approval to market a generic version of K-Dur 20 did not do so because of the 13 Points.
 - 91 Wyeth-Averst Lahoratories Division of American Home Products and Wyeth-

Ayerst Pharmaceuticals, Inc. (hereafter, collectively "Wyeth"), divisions of AHP, entered into a Consent Decree of Condemnation and Permanent Injunction ("Consent Decree") with

FDA on October 4, 2000.

- 92. Among other things, the Consent Decree requires Wyeth to take a number of actions with respect to manufacturing drug products at its Pearl River facility in New York State and authorizes the FDA to order Wyeth to cease this manufacturing or take other corrective actions if FDA determines that Wyeth has failed to comply with the Food, Drug, and Cosmetic Act, applicable regulations thereunder, or provisions of the Consent Decree.
 - 93. AHP has decided to exit the oral generic pharmaceuticals business.
- 94. The internal AHP document seeking corporate approval for the decision to exit the oral generic pharmaceuticals business states as follows: "The discontinuation of the manufacturing of the ANDA products at Pearl River is driven by the continued projection of losses for the ANDA products at Pearl River and the Consent Decree related issues and costs at Pearl River."
- 95. AHP would have to incur significant expenditures to continue manufacturing and developing existing and new oral generic pharmaceutical products at Pearl River.

	The Compleint did not motivate or influence A UD2 decision to evit the evel
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	102. You have no evidence to disprove that AHP will no longer develop, manufacture or sell oral generic pharmaceutical products.
	103. AHP has notified complaint counsel that it has no current intention of reentering the oral generic pharmaceutical products business in the future.
	104. You have no evidence to disprove that AHP has no current intention of reentering the oral generic pharmaceutical products business in the future.
	105 Admit that were believe that the fact that the Dit-Cl- Co1 state 1st t 1971 -
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agreements thus acted as corks in a bottle, precluding competition not only by the generic company that was paid not to challenge the branded pharmaceutical, but also by other notential generic competitors because the 180 day period does not begin to run until the

- 112. The Leary Speech characterized or described or reflected a view of the effect of the agreements at issue in the Hoechst/Andrx case on third parties under the Hatch Waxman Act.
- 113. The FTC Testimony characterized or described or reflected a view of the effect of the agreements at issue in the Abbott/Geneva case on third parties under the Hatch Waxman Act.
- 114. The FTC Testimony characterized or described or reflected a view of the effect of the agreements at issue in the Hoechst/Andrx case on third parties under the Hatch Waxman Act.

	11 WARRANGE 2 2 VV
	One or more of the agreements at issue in Ahhatt/Geneva ware reached in or
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- 126. The Pitofsky Speech reflects a reasonable interpretation of the law.
- 127. The Pitofsky Speech reflects an incorrect statement of the law.
- 128. The Leary Speech reflects a correct statement of the law.
- 129. The Leary Speech reflects a reasonable interpretation of the law.
- 130. The Leary Speech reflects an incorrect statement of the law.
- 131. The FTC Testimony reflects a correct statement of the law.
- 132. The FTC Testimony reflects a reasonable interpretation of the law.
- 133. The FTC Testimony reflects an incorrect statement of the law.

acts or practices affecting commerce unlawful.

- 135. The FTC would never intentionally engage in deceptive acts or practices.
- 136. Statements by the FTC and/or its Commissioners bear particular indicia of

Schering never offered to license the '743 patent to AHP on an effective date earlier than December 31, 2003.

- 144. You have no evidence that during the course of negotiations to settle the Patent Infringement Litigation Schering ever offered to license the '743 patent to AHP on an effective date earlier than December 31, 2003.
- 145. Under the terms of previous consent decrees, the Commission has permitted parties to enter into settlements of patent infringement litigation in which the patentholder provides something of value to the alleged infringer.
- 146. The Commission did not file a complaint challenging a patent settlement agreement between Abbott Laboratories and Zenith.

Respectfully submitted,

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David Orta

Barbara Wootton

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(202) 942-5000

Counsel for American Home Products Corporation

Dated: October 2, 2001

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