INITIAL DECISION FILED:
June 27, 2002

UNITED !STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	
SCHERING-PLOUGH CORPORATION, a corporation,	PUBLIC RECORD VERSION
UPSHER-SMITH LABORATORIES, a corporation,	Docket No. 9297
and	
AMERICAN HOME PRODUCTS CORPORATION, a corporation.	

INITIAL DECISION

By: D. Michael Chappell, Administrative Law Judge

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I. INTRODUCTION

A. Federal Trade Commission Complaint

The Federal Trade Commission issued its Complaint in this matter on March 30, 2001. The Complaint charges that Respondents Schering-Plough Corporation (Schering), Upsher-Smith Laboratories, Inc. (Upsher-Smith), and American Home Products Corporation (AHP) engaged in conduct that violates Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. The Complaint alleges that Respondents entered into unlawful agreements to delay entry of low-cost generic competition to Schering's prescription drug K-Dur 20. Before detailing the findings of fact and conclusions of law, the following overview is provided.

Schering manufactures and markets two extended-release microencapsulated potassium chloride products: K-Dur 20 and K-Dur 10, both of which are covered by a formulation patent owned by Schering, patent number 4,863,743 (the "'743 patent"), which expires on September 5, 2006. On August 6, 1995, Upsher-Smith filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") to market Klor Con M20, a generic version of Schering's K-Dur 20. Upsher-Smith submitted a certification to the FDA, known as a Paragraph IV Certification, with this ANDA certifying that its product, Klor Con M20, did not infringe Schering's K-Dur 20 and, on November 3, 1995, Upsher-Smith notified Schering of its Paragraph IV Certification and ANDA.

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. On June 17, 1997, Schering and Upsher-Smith agreed to settle their patent litigation. The Complaint alleges that through this settlement agreement, 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, 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. Complaint at ¶ 44.

On December 29, 1995, ESI Lederle, Incorporated ("ESI"), a division of AHP, 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. 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. The Complaint alleges that Schering and AHP reached an agreement in principle settling their litigation in January 1998, and they executed a final settlement agreement on June 19, 1998. Complaint at ¶ 54. AHP agreed that its ESI division would not market any generic version of Schering's K-Dur 20 until January 2004, would not market more than one generic version of Schering's K-Dur 20 between January 2004 and September 2006, and would not support any study of the

bioequivalence or therapeutic equivalence of a product to K-Dur 20 until September 5, 2006. Complaint at ¶ 55. AHP received a payment from Schering of $5 million, and an additional payment of $10 million when its generic product received FDA approval in 1999. Complaint at ¶ 55.

The Complaint alleges that the agreements between Schering and Upsher-Smith, and between Schering and AHP, were agreements not to compete that unreasonably restrained commerce in violation of Section 5 of the FTC Act. Complaint at ¶¶ 68, 69.

The Complaint further alleges that Schering had 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 that monopoly power, in violation of Section 5 of the FTC Act. Complaint at ¶ 70. And, the Complaint alleges that Schering conspired separately with Upsher-Smith and with AHP to monopolize the manufacture and sale of potassium chloride supplements approved by the FDA and narrower markets contained therein, in violation of Section 5 of the FTC Act. Complaint at ¶ 71.

B. Respondents' Answers

In answers filed April 23, 2001, Schering, Upsher-Smith and AHP denied that the agreements were unlawful, and offered a number of affirmative defenses. Upsher-Smith's answer asserted that its patent settlement agreement with Schering was lawful, reasonable, procompetitive and in the public interest.

In its answer, Schering asserted that its settlement agreement with Upsher-Smith allowed Upsher-Smith to bring its product to market in September 2001, five years before patent expiration. Schering asserted its settlement agreement with ESI was forged under active judicial supervision and allowed ESI to bring its potassium chloride product to market over two years before Schering's patent expired. Schering further asserted that the Complaint fails to acknowledge that Schering has a valid patent giving it a right to exclude infringing products, the Complaint fails to allege that the procompetitive efficiencies of the settlement do not outweigh any actual or potential anticompetitive effects, and that the relief sought by the Complaint is contrary to public policy because it interferes with settlement of patent infringement litigation.

C. Procedural History

On October 12, 2001, the Complaint against AHP was withdrawn from adjudication for the Commission to consider a proposed consent agreement. The Commission approved the final consent order on April 2, 2002. Although AHP is no longer a party to the case, the legality of the Schering/AHP agreement remains at issue with respect to Schering.

Trial commenced on January 23, 2002 and ended on March 28, 2002, covering 8629 pages of transcript, with 41 witnesses testifying, and thousands of exhibits admitted into evidence. Closing arguments were heard on May 1, 2002.

On February 12, 2002, Upsher-Smith moved to dismiss the Complaint due to Complaint Counsel's failure to establish a prima facie case. Pursuant to Commission Rule 3.22(e), the ruling on the motion to dismiss was deferred until all evidence was received. In a ruling from the bench on March 22, 2002, Upsher-Smith's motion was denied on the grounds that the evidence presented created factual issues of dispute sufficient to defeat the motion to dismiss.

On March 6, 2002, the parties filed a joint motion to extend the deadline for filing the initial decision. By Order dated March 14, 2002, extraordinary circumstances were found to exist sufficient to extend the deadline for filing the Initial Decision by 60 days until May 31, 2002. The record was closed on March 28, 2002. By Order dated May 29, 2002, continuing extraordinary circumstances were found to exist and the deadline was extended an additional 60 days. This initial decision is filed within 90 days of the close of the record.

D. Evidence

The Initial Decision is based on the transcript of the testimony, the exhibits properly admitted in evidence, and proposed findings of fact and conclusions of law and replies thereto filed by the parties. Numerous exhibits were conditionally admitted. Evidence, including transcripts from investigational hearings, which was conditionally admitted, was considered even though Complaint Counsel failed to properly connect up the evidence against all parties, and was found not to be dispositive to the determination of any material issue in the case.

The parties submitted extensive post-trial briefs and reply briefs. The Initial Decision contains only the material issues of fact and law. Proposed findings of facts not included in the Initial Decision were rejected either because they were not supported by the evidence or because they were not dispositive to the determination of the allegations of the Complaint.

Many of the documents and testimony were received into the record *in camera*. Where an entire document was given *in camera* treatment, but the portion of the document relied upon in this Initial Decision does not rise to the level necessary for *in camera* treatment, such information is disclosed in the public version of this Initial Decision, pursuant to 16 C.F.R. § 3.45(a) (the ALJ may disclose such *in camera* material to the extent necessary for the proper disposition of the proceeding).

E. Summary

Based upon the theories advanced by Complaint Counsel, for Complaint Counsel to prove that the agreements to settle the patent litigation between Schering and Upsher-Smith and between Schering and ESI were anticompetitive requires a presumption that the '743 patent was not valid or that Upsher-Smith's and ESI's products did not infringe the '743 patent. There is no basis in law or fact to make that presumption. In addition, Complaint Counsel has failed to meet its burden of proving the relevant product market or that Schering maintained an illegal monopoly within that market. Despite the emotional appeal which may exist for Complaint Counsel's position, an initial decision must be based on substantial, reliable evidence and well reasoned legal analysis. For the reasons set forth below, the violations alleged in the Complaint have not been proven and the Complaint will be dismissed.

II. FINDINGS OF FACT

A. Respondents

1. Schering-Plough Corporation

1. Schering-Plough Corporation ("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 Answer at ¶ 3; CX 174 at FTC 0022249-50 (Schering 12/31/99 Form 10K)).

2. Key Pharmaceuticals, Inc. ("Key"), a Florida corporation, is a subsidiary of Schering. (CX 174 at FTC 0022315). It produces K- Dur 20, a 20 milliequivalent potassium chloride supplement, and holds the patent on that product. Schering Answer at ¶ 34. Warrick Pharmaceuticals Corporation ("Warrick"), a Delaware corporation, is a subsidiary of Schering. CX 174 at FTC 0022318. It produces generic pharmaceutical products, and in some situations, produces generic versions of Schering's patented products once another generic has entered the market. (Russo, Tr. 3429-30).

3. Schering is a corporation, as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44. (Schering Answer at ¶ 7).

4. Schering's acts and practices, including the acts and practices alleged in the Complaint, are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S. C. § 44. (Schering Answer at ¶ 8).

2. Upsher-Smith Laboratories, Inc.

5. Upsher-Smith Laboratories, Inc. ("Upsher-Smith") is a business corporation organized under the laws of the state of Minnesota that has issued shares of common stock. (CX 1 (Upsher-Smith Articles of Incorporation); Upsher-Smith First Admissions, Nos. 1, 2. Its principal place of business is Plymouth, Minnesota. (Troup, Tr. 5397). Upsher-Smith is a privately-held company. (Troup, Tr.5398).

6. Upsher-Smith is incorporated, has shares of capital or capital stock, and is authorized to carry on business for its own profit, and is, therefore, a corporation, as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

7. Upsher-Smith manufactures pharmaceutical products at its facilities in Minnesota and ships products to the other 49 states of the United States. It purchases pharmaceutical ingredients for its pharmaceutical products from suppliers located outside Minnesota, and transfers funds across state lines in exchange for those ingredients. Upsher-Smith First Admissions, Nos. 12, 13, 14, 15, 16, 17, 18, 19, 20 and 21.

8. Upsher-Smith markets its products to retail, chain, and hospital pharmacies, and to key physician groups, primarily by means of wholesale and drug chain distribution channels throughout the United States. (CX 317 at USL 01643 (Upsher-Smith Financial Statements, 1/3/99 and 1/4/98)).

9. Upsher-Smith's business activities are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

3. American Home Products Corporation

10. American Home Products Corporation ("AHP") is a corporation organized and existing under the laws of Delaware, with its principal place of business at Five Giralda Farms, Madison, New Jersey. It engages in the discovery, development and marketing of brand name and generic drugs, as well as "over the counter" medications. AHP Answer at ¶ 5; CX 484 at 05 00052.

11. Wyeth-Ayerst Pharmaceuticals, Inc. ("Wyeth"), is a subsidiary of AHP. ESI Lederle, Inc. ("ESI"), is a business unit of Wyeth. ESI engages in research, manufacture and sale primarily of generic drugs. AHP Answer at ¶ 6.

12. On October 10, 2001, Complaint Counsel and counsel for AHP filed a Joint Motion to Withdraw Respondent American Home Products from Adjudication in order for the Commission to consider an executed proposed consent agreement. On October 12, 2001, the Commission issued an Order Withdrawing Matter from Adjudication as to Respondent

American Home Products Corporation. The Commission approved the final consent order April 2, 2002.

B. The Pharmaceutical Industry

13. Newly developed prescription drugs are sometimes referred to as "pioneer" or "innovator" or "branded" drugs. (Hoffman, Tr. 2206-07; Dritsas, Tr. 4621). Approval for an innovator drug is sought by filing a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA"). (Hoffman, Tr. 2207).

14. Newly developed prescription drugs are often protected by patents. (Hoffman, Tr. 2215). A patent is granted by the federal government to the patent holder giving the holder exclusive rights to make, use, vend and to import the subject matter covered by the patent claims. (Miller, Tr. 3310-11:2; O'Shaughnessy, Tr. 7064-65).

15. A generic drug contains the same active ingredient as the branded or innovator drug, but not necessarily the same inactive ingredients. (Hoffman, Tr. 2207; Levy, Tr. 2186). Approval for a generic drug may be sought by filing an Abbreviated New Drug Application ("ANDA") with the FDA. (Hoffman, Tr. 2209; Troup, Tr. 5403). The ANDA applicant must demonstrate, among other things, that the generic drug is bioequivalent to the brand-name drug that it references. (Hoffman, Tr. 2208; Troup, Tr. 5403).

16. When a brand-name prescription drug is protected by one or more patents, an ANDA applicant that intends to market its generic prescription 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 version does not infringe the patents on the brand-name drug or (2) the patents are invalid. (Hoffman, Tr. 2215-16; Troup, Tr. 5404). This is known as a "Paragraph IV Certification." (Hoffman, Tr. 2216; Troup, Tr. 5404).

17. A bioequivalent drug contains the same active ingredient as the reference drug and is absorbed into the bloodstream at the same rate and extent, and remains at certain levels for the same period of time as the reference drug. (Hoffman, Tr. 2208).

18. Generic drugs that are AB-rated to a reference drug are considered by the FDA to be therapeutically equivalent to, and substitutable for, the reference drug. (Hoffman, Tr. 2278).

19. Generic drugs can offer price competition to the branded drug. The generic enters the market at a lower price than that of the branded drug. (Teagarden, Tr. 210-11; Goldberg, Tr. 137-38; Dritsas, Tr. 4743, 4904-05).

20. The price of generic drugs falls even further as additional generic versions of the same branded drug enter the market. (Schering Answer at ¶ 17; Goldberg, Tr. 120-21; Rosenthal, Tr. 1543).

21. Sales of the branded product decrease after generic entry because generics are substituted for the branded product. (Rosenthal, Tr.1538; Bresnahan, Tr. 462-63).

22. In most states, a pharmacist is permitted to substitute an AB-rated generic product for a brand name drug, unless the physician directs otherwise. (Hoffman, Tr. 2278; Teagarden, Tr. 197-98; CX 1493 at 81 (Dolan Dep.); Schering Answer at ¶ 18). A pharmacist cannot substitute a generic that is not AB-rated for a branded drug without the physician's approval. (Bresnahan, Tr. 491; Russo, Tr. 3468).

23. In some states, pharmacists are required to substitute an AB-rated generic unless the physician directs otherwise. (Bresnahan, Tr. 1178; Addanki, Tr. 5998).

24. In addition to state mandatory substitution laws, Medicaid policies and managed care plans also tend to encourage generic substitution. (CX 18 at SP 23 00044 (1997 K-Dur Marketing Plan); Bresnahan, Tr. 491-93).

C. Geographic Market

25. The geographic market is the United States. (F. 26-28).

26. Purchasers of potassium chloride supplements in the United States can purchase these products only from manufacturers who market in the United States, and whose products have been approved for sale in the United States by the FDA. (Hoffman, Tr. at 2206).

27. Schering has FDA approval to sell its K-Dur extended release potassium chloride tablets. (Kerr, Tr. 6561). Schering sells K-Dur throughout the United States. (CX 18 at SP 23 00044). Of the $290 million in K-Dur 20 sales in 2000, Schering made $287 million of those sales in the U.S., and $3 million worth internationally in 2000. (Audibert, Tr. 4212-13).

28. Upsher-Smith has FDA approval to sell its Klor-Con M extended release potassium chloride tablets. (CX 59; Hoffman, Tr. 2273-74). Since Upsher-Smith began Klor Con M20 in September 2001, Upsher-Smith has been shipping it to all the major wholesalers and chain distribution centers throughout the United States. (Kralovec, Tr. 5076-77). Upsher-Smith does not sell Klor-Con M20 outside of the United States. (Dritsas, Tr. 4620).

D. Relevant Product Market

29. The relevant product market is all oral potassium supplements that can be prescribed by a physician for a patient in need of a potassium supplement. (F. 31-118).

30. Professor Bresnahan incorrectly defined the relevant product market as K-Dur 20 mEq. (F. 31-118).

1. K-Dur 20 is one of many potassium chloride products on the market

31. K-Dur is a potassium chloride product marketed by Schering. (Russo, Tr. 3410-11). K-Dur is primarily used to treat potassium depletion in coronary artery disease patients. (Russo, Tr. 3410-11). To treat a patient's coronary artery disease, physicians often prescribe products that are also diuretics, causing a depletion in potassium, referred to as hypokalemia. (Russo, Tr. 3410-11; Goldberg, Tr. 125-26).

32. K-Dur is marketed in 10 mEq and 20 mEq dosage strengths. (Russo, Tr. 3411). The 10 mEq and 20 mEq labels denote the amount of potassium within the tablet. (Russo, Tr. 3415).

33. There are at least 23 potassium supplements on the market. (Russo, Tr. 3414; SPX 2209-31; CX 17).

34. Reports from the IMS database reflect that the potassium chloride supplement category includes a number of products, including K-Dur 10 and 20, Micro K, Micro K 10, Slow K, K-Tab, Klor Con 8, Klor Con 10, Klor Con M10, Klor Con M20, as well as other general tablet/capsules and generic forms of potassium chloride. (USX 1010; Bresnahan, Tr. 889-90).

35. Managed health care offers many choices of oral potassium chloride supplements. There were at least 24 different combinations of brand and generic potassium chloride products listed on the 2001 United Healthcare Preferred Drug List. (Goldberg, Tr. 154; USX 277).

36. As of 2001, there were numerous branded and generic potassium chloride products on Merck-Medco's formulary. (Teagarden, Tr. 207, 216-17; CX 56; CX 57). A formulary is a list of drugs that the physicians keep on hand to determine what products and what portion of the cost the managed care organization will reimburse to the patient. Dritsas, Tr. 4648.

37. Medco, a pharmacy benefit manager and Merck-Medco's predecessor, regards 10 mEq and 20 mEq potassium chloride products to be "competing." (Teagarden, Tr. 226; USX 131 at Merck-Medco 000206).

2. Potassium chloride products are therapeutically equivalent

38. The demand for a potassium supplement "begins when a patient goes in to a physician and they're treated for hypokalemia, so the doctor would write a prescription for KCl." (Dritsas, Tr. 4644; Bresnahan, Tr. 696).

39. If a physician prescribes a specific amount of potassium, any potassium chloride product would be effective. (Freese, Tr. 4951-52). A prescription for 20 mEq of potassium could be satisfied with a potassium chloride powder, effervescent, or liquid. (Freese, Tr. 4953-54; USX 410 at 190301). Because potassium products are all therapeutically interchangeable, a pharmacist could dispense 20 mEq of potassium chloride in whatever product form is appropriate for the patient. (Freese, Tr. 4956).

40. At maintenance, a physician will typically prescribe approximately 40 mEqs of potassium per day. (Russo, Tr. 3423). If a doctor writes a prescription for K-Dur 20, a patient will take two tablets (one tablet two times a day, with meals). (Russo, Tr. 3423-24). If a patient's prescription is written for a 10 mEq product, the patient will have to take four 10 mEq tablets, likely two in the morning and two in the evening. (Russo, Tr. 3424).

41. Just because a potassium chloride product is not AB-rated to K-Dur 20 does not mean that it is not therapeutically interchangeable for K-Dur 20. (Dritsas, Tr. 4689-90; CX 740).

42. The FDA's designation of a generic pharmaceutical as "AB-rated," rated or bioequivalent, to a pioneer drug does not necessarily define the product market for antitrust purposes. (Addanki, Tr. 5684). Professor Bresnahan incorrectly defined the relevant market as consisting of 20 mEq tablets and capsules; and a 20 mEq tablet is not bioequivalent to a 20 mEq capsule. (Addanki, Tr. 5684; Bresnahan, Tr. 675; CX 1586). An AB-rated generic is substitutable for the branded product, but that does not mean that the AB-rated generic is the only potential substitute for the branded product. (Addanki, Tr. 5684).

43. K-Dur 20's 20 mEq dosage does not give it a therapeutic advantage over other potassium chloride products. (Russo, Tr. 3421).

44. K-Dur 20 is therapeutically interchangeable with two Klor Con 10s. (Dritsas, Tr. 4655-56). There is no category of patients who can only take K-Dur 20 and not two Klor Con 10s. (Dritsas, Tr. 4661).

45. Two 10 mEq tablets would effectively release in a patient's stomach at approximately the same rate as one 20 mEq tablet. (Goldberg, Tr. 174-75). If a pharmacist were to give a patient two Klor Con 10 tablets, rather than a K-Dur 20, the patient would simply take the two Klor Con tablets at the time that he was supposed to take the one K-Dur 20 tablet. (Dritsas, Tr. 4660-61).

46. Upsher-Smith's 1996 marketing plan for its Klor-Con potassium products shows that the various release mechanisms for different potassium chloride products all delivered potassium, and therefore were therapeutically equivalent and comparable. (Dritsas, Tr. 4693-94; USX 1549; USL 13859).

47. Dr. Addanki looked at whether there were side effect differences between different potassium chloride products that affected their substitutability for each other. (Addanki, Tr. 5693). The primary side effect associated with potassium chloride products is the possibility of gastrointestinal (GI) irritation. (Addanki, Tr. 5693-95). Gastrointestinal irritation is not a substantial problem, however, as its incidence is low for all oral potassium chloride supplements. (Addanki, Tr. 6163). K-Dur 20 does not eliminate this potential GI side effect. (Addanki, Tr. 5693-95). Thus, potential side effect issues do not affect the substitutability of other potassium chloride products for K-Dur 20. (Addanki, Tr. 5695).

48. Although Schering's marketing strategy for its K-Dur 20 product was to emphasize that it could increase patient compliance, there is no significant difference in patient compliance between K-Dur 20 and Klor Con 10. (Dritsas, Tr. 4662).

3. Customers viewed K-Dur 20 and other potassium chloride products as interchangeable

49. According to Complaint Counsel's witnesses, oral potassium chloride products are therapeutically equivalent.

50. Dean Goldberg of United HealthCare ("UHC") testified that there is a substantial "degree of choice" in the potassium chloride market. Goldberg, Tr. 126-27. Goldberg testified that most, if not all, potassium chloride products are therapeutically equivalent. Goldberg, Tr. 144 (discussing USX 277, United HealthCare's Preferred Drug List). Goldberg also confirmed that reasonable substitutes exist to the 20 mEq sustained release potassium chloride product and, that physicians consistently prescribe those products. Goldberg, Tr. 144.

51. Russell Teagarden, a licensed pharmacist, of Merck-Medco, the nation's largest Physician Benefits Manager ("PBM") testified that there is no separate listing for 20 mEq potassium chloride products on its formulary. Teagarden, Tr. 234 (discussing USX 125); Tr.

240 (discussing USX 127). He also testified that at many times, for example in 1993, 1994, and 1995-96, Merck-Medco did not even list K-Dur 20 as a prescription drug on its formulary. Teagarden Tr. 239-44. Instead, Merck-Medco's formularies at those times simply listed other potassium supplements sold by other pharmaceutical companies. USX 127 at 176; USX 128 at 186.

52. Merck-Medco has consistently regarded potassium chloride products with different delivery systems as clinically equivalent and therefore interchangeable. (Teagarden, Tr. 249-50; (USX 123; USX 124; USX 125).

53. Merck-Medco equates microencapsulated tablets and capsules with wax matrix potassium chloride products. (Teagarden, Tr. 232, 247-48, 250; USX 123-25). Merck-Medco views branded and generic liquids, sustained release tablets and capsules, effervescent tablets, and powder potassium chloride supplements as alternative products substitutable for one another. (Teagarden, Tr. 233-34, 237-38, 240, 243, 255-56; USX 125; USX 127; USX 128; USX 126; USX 690). In addition, 8 mEq and 10 mEq products consistently are listed as substitutable alternatives on Merck-Medco's formularies. (Teagarden, Tr. 234, 240, 243-44, 256; USX 125; USX 127; USX 128; USX 690).

54. All the potassium chloride products on Merck-Medco's 2001 formulary are listed in the same therapeutical class. (Teagarden, Tr. 223-24; USX 131).

55. All the oral potassium chloride products on United Healthcare's Preferred Drug List are therapeutically equivalent. (Goldberg, Tr. 144-45).

56. Decision-makers at HMOs do not place a premium on K-Dur's delivery system or dosage form. (CX 13 at SP 003045; Addanki, Tr. 5691).

57. Physicians viewed K-Dur 20 as a product for which there were numerous other alternatives. (Dritsas, Tr. 4834). In 1995, 71 percent of the prescriptions for potassium chloride supplementation were being written for products other than K-Dur 20. (Addanki, Tr. 6174; CX 13). As of August 1997, 6 out of 10 potassium chloride prescriptions were for something other than K-Dur 20. (Bresnahan, Tr. 1279).

58. A company could compete with K-Dur 20 simply by convincing a physician to change his prescribing habits. (Dritsas, Tr. 4690).

59. There was significant substitution back and forth between Klor Con 10 and K-Dur 20. (Dritsas, Tr. 4752; Addanki, Tr. 5702). Pharmacists were substituting two Klor Con 10s for one K-Dur 20. (Dritsas, Tr. 4834).

4. Schering viewed K-Dur 20 as competing in the same market as other potassium chloride products

60. Schering measures the sales performance of K-Dur 20 against the entire potassium chloride supplement market, including other products such as 10 mEq potassium chloride products as competitors to K-Dur 20. (Russo, Tr. 3420; CX 18 at 23 000041; CX 17 at 003951, 003954; CX 20 at 00434). Schering's marketing plans indicate that there are over 20 different potassium chloride supplements, all competing in the same market. (Russo Tr. 3414-15; SPX 2209-2231; CX 17). Professor Bresnahan relied on Schering business documents that combined K-Dur 10 and K-Dur 20 in the same charts and business plans. (Bresnahan, Tr. 816). Bresnahan did not consider key portions of Schering's documents that show Schering considered K-Dur to be a part of a larger potassium chloride market. (Bresnahan 709-13, 721, 814-17, 824-25).

61. A 1996 Schering marketing backgrounder states that "K-Dur competes in a crowded $264 million potassium market which continues to grow. . . ." (Russo, Tr. 3412; CX 17, CX 746; Bresnahan, Tr. 720-21).

62. Schering's 1997 K-Dur Marketing Plan lists competing potassium chloride tablets and capsules. (SPX 977 at SP003849).

63. Schering perceived that K-Dur's major competitors were Klor Con and generic potassium chloride. (CX 20; Bresnahan, Tr. 827). A number of Schering documents characterize generic 10 mEq forms of potassium chloride as Schering's "major competitors." (Bresnahan, Tr. 1170).

5. Upsher-Smith viewed its potassium chloride products as competing in the same market as the other potassium chloride products

64. Upsher-Smith believed it was competing against everyone selling potassium chloride, including K-Tab, Micro-K, Ethex, K-Dur, and Slow K. (Addanki, Tr. 5711; SPX 1050). Upsher-Smith focused on the entire potassium chloride market and did not differentiate between dosage strengths. (Dritsas, Tr. 4692).

65. Upsher-Smith's documents indicate that it was looking at the entire potassium chloride market in positioning its Klor Con 10 potassium chloride product. (Dritsas, Tr. 4692; Addanki, Tr. 5711).

66. In its 1996 market share projections, Upsher-Smith assumed that the potassium market, which included K-Dur 10, K-Dur 20 and all other potassium products, was a $218

million market. (Dritsas, Tr. 4700; USX 1549 at USL 13858).

67. A 1996 marketing plan for Klor Con tablets indicates that the major competitors to Klor Con 8 and 10 were K-Tab, Micro-K 10, Ethex and K-Dur 20. (Dritsas, Tr. 4691-92, 4696; USX 1549 at USL 13858).

68. An Upsher-Smith training manual, dated June 3, 1997, listed a variety of 10 mEq products competing in the potassium market, including Klor Con 10, K-Tab 10, Klotrix 10, Kaon-Cl, Apothecon's product Micro-K 10, ESI, Medeva, Ethex, K-Dur 10, K-Dur 20 and K-Plus 10. (Dritsas, Tr. 4738-39; USX 630 at USL 15331). The manual listed a number of 8 mEq potassium products in the market, including Klor Con 8, Slow K, Copley 8, Warner Chilcott 8, Kaon-Cl 8, Abbott 8, Micro-K 8, and K-Plus 8. (Dritsas, Tr. 4739; USX 630 at USL 15332). Potassium powders in the market were Klor Con 20, Klor Con 25, K-Lor powder, Kay Ciel powder and Klor-vess powder 20. (Dritsas, Tr. 4739; USX 630 at USL 15333). K-Lor powder is marketed by Abbott Laboratories, a major, multi-billion dollar pharmaceutical company. (Dritsas, Tr. 4739-40). Finally, at least two effervescent tablet products were in the potassium market, Klor Con/EF and K-Lyte. (Dritsas, Tr. 4740; USX 630 at USL 15333).

69. Upsher-Smith's marketing documents reflect the fact that K-Dur 20 "competes directly against the 8 and 10 mEq strengths" of Upsher-Smith's Klor Con. (Bresnahan, Tr. 845; Dritsas, Tr. 4689, 4696; CX 740).

6. The substantial substitutability among potassium chloride products was reflected in actual competition between them

(a) Upsher-Smith directly targeted K-Dur 20 by emphasizing the substitutability of Upsher-Smith's Klor Con 10 mEq product

70. Upsher-Smith built demand for its Klor Con potassium chloride products based on therapeutic substitution. (Dritsas, Tr. 4653).

71. In order to compete against Schering's K-Dur 20, Upsher-Smith's sales representatives informed physicians and managed care organizations that they could more cheaply substitute two Klor Con 10 tablets for one K-Dur 20 tablet. (Dritsas, Tr. 4622-23).

72. In August 1999, Upsher-Smith employed a tactic to encourage high prescribers of K-Dur 20 to prescribe two 10 mEq tablets instead of one K-Dur 20. (Dritsas, Tr. 4765-66; USX 484 at USL 03330).

73. K-Dur 20 tablets are scored, making them easier to break in half. (Freese, Tr. 4955). Because many patients had to break the large K-Dur 20 tablet in half to swallow it anyway, patients could save money by taking two Klor Con 10s instead of one K-Dur 20. (Dritsas, Tr. 4622-23). Upsher-Smith's Klor Con 10 wax matrix tablet was about the same size as half a K-Dur 20 tablet. (Dritsas, Tr. 4624; Freese, Tr. 4955). Klor Con 10 was easier to swallow, though, because a halved K-Dur 20 tablet was bulky with rough edges. (Dritsas, Tr. 4624). Klor Con 10 was round and aqueous coated, a good alternative for patients complaining about swallowing a big tablet. (Dritsas, Tr. 4624).

74. Upsher-Smith implemented therapeutic switch incentive programs through its telephone sales force by targeting high volume K-Dur pharmacies, through visits to the headquarters of chains, wholesalers and managed care organizations, and by targeting long term care and select chains. (Dritsas, Tr. 4754-56; USX 1551 at USL 13795). Upsher-Smith also sent direct mail to high K-Dur prescribers about the cost savings of using two Klor Con 10s instead of one K-Dur 20. (Dritsas, Tr. 4756-58; USX 1551 at USL 13795).

75. Direct mailings emphasized the quality of Klor Con and the 56 percent savings. (Dritsas, Tr. 4766; USX 484 at USL 03328). These mailings continued through November 1999. (Dritsas, Tr. 4766-67; USX 484 at USL 03331).

(b) Schering competed against other potassium chloride products

76. During the 1996 -1997 period, Klor Con 10 sales increased 33 percent, moving from 12 percent of total prescriptions to 16 percent. (Bresnahan, Tr. 831). Generic potassium chloride sales increased during the same period, moving from 29 percent to 30 percent of total prescriptions by 1997. (Bresnahan, Tr. 832).

77. This growth was coming at K-Dur 20's expense. (CX 746 at SP 23 00039; Bresnahan, Tr. 743-45, 477; CX 18; SPX 901). Generic competition was growing at K-Dur 20's expense, in part because of the generics' price advantage, in part because of efforts to substitute two 10 mEq tablets for one K-Dur 20, and also because of managed care's role in requiring the use of generics. (Addanki, Tr. 5708, 5732-33; SPX 993 at SP 290039; CX 20 at SP 004040).

78. Schering expected that losses to 10 mEq generics would worsen over time. "As physicians change their prescribing habits and as the senior population moves into the managed care setting, the branded portion of the market will decrease and the potential for K-Dur volume growth will be limited." (CX 13 at SP 003046). Documents from the March 1995 time frame reflect concerns that staff HMO "decision makers do not place a premium on K-Dur's unique delivery system and dosage form." (CX 13 at SP 003047; Bresnahan, Tr. 717).

79. In 1995, Schering developed a marketing strategy to address competition from generic 10 mEq products. (CX 13 at SP 003046; Bresnahan, Tr. 715-16). Schering sought to develop brand awareness of, and brand allegiance to, the K-Dur brand to prevent an anticipated loss of market share to generic competition. (Bresnahan, Tr. 714-715; CX 13 at SP 003044- 48).

80. As of July 1996, Schering was aggressively marketing K-Dur to gain sales from generic potassium chloride products. (CX 718 at SP 23 00039; Bresnahan, Tr. 742). Schering began a targeted mail series to promote K-Dur 20 in an effort to "blunt the continued growth of generic potassium usage." (CX 718 at SP 23 00054); Bresnahan, Tr. 758; CX 18 at SP 23 00039). Schering ran a significant number of promotional programs over a ten-year period that heavily promoted and marketed both its K-Dur products. (Russo, Tr. 3418-19).

7. *Brown Shoe* factors not addressed in the preceding sections

a. No industry or public recognition of distinct markets

81. Complaint Counsel's expert, Dr. Bresnahan, admitted that he could not cite any pharmaceutical trade periodicals that treat K-Dur 20 as a product that has unique features. (Bresnahan, Tr. 711-12; 1271-72).

82. No studies exist comparing patient compliance for K-Dur 20 and the Klor Con 8 mEq and 10 mEq wax matrix products. (Dritsas, Tr. 4662; Kerr, Tr. 6907-08).

83. IMS, the authoritative industry data source, lists a number of products and manufacturers under its single potassium supplement category numbered 60110. (Dritsas, Tr. 4709-12; 4800-01; USX 619 at 14884-996; USX 822 at 1-12). Schering's K-Dur 20 product is included in the IMS listing with all of the other potassium products. (Dritsas, Tr. 4709; USX 822 at 1). Professor Bresnahan concedes that "all economic researchers . . . working in this industry use" IMS data. (Bresnahan, Tr. 471). In fact, Bresnahan himself relied on IMS data for the graph in CX 1596. (Bresnahan, Tr. 735).

b. No peculiar characteristics and uses

84. There are no peculiar characteristics or uses for K-Dur 20. (F. 38-59).

c. No unique production facilities

85. The K-Dur 10 and K-Dur 20 mEq products are produced in the same Schering facility. (Bresnahan, Tr. 1272).

86. Upsher-Smith purchases from Reheis, the same company that supplies the active ingredient for both the wax matrix Klor Con 8 and 10 and sustained release Klor Con M10 and M20. (CX 263 at 170356.).

d. No distinct customers

87. There is no distinctive class of customers based on "demographics or other classification criteria" that prefer K-Dur 20. (Bresnahan, Tr. 707). K-Dur 20, Klor Con 8 and 10, Micro-K, K-Tab, Slow K, K-Lyte, Klotrix, Apothecon KCL and Ethex potassium chloride products are all prescribed for the same purpose of treating potassium deficiency. (Bresnahan, Tr.1271; Dritsas, Tr. 4662).

88. There is no special group of patients that can only take K-Dur 20 and can not take other potassium products such as Klor Con. (Dritsas, Tr. 4661).

e. No distinct prices

89. In 1997, K-Dur had the same relative price as other potassium chloride supplements. (Teagarden, Tr. 224, 215, 218). During this time period, branded potassium products had "comparable" prices to K-Dur 20. (Bresnahan, Tr. 730). K-Dur and other potassium chloride supplements have "approximately the same" price. (Russo, Tr. 3426).

90. Dr. Bresnahan presented no statistical pricing study (Bresnahan, Tr. 1274), and did not even have pricing data for K-Dur 20, K-Dur 10, Klor Con 10 or for any other competitors (Bresnahan, Tr. 834-35. 867). During 1997, some potassium chloride products were more expensive than K-Dur 20. (Addanki, Tr. 5741-42; SPX 2069 at 1).

91. Dr. Bresnahan conceded that a pricing difference alone does not suffice to prove a separate product market. (Bresnahan, Tr. 1002). Prices of products that compete in a relevant market need not be close to one another because competition can occur in other dimensions. (Addanki, Tr. 6198).

92. Professor Bresnahan did not conduct the analysis necessary to determine the degree of price sensitivity between 20 mEq sustained-release products and other potassium products. (Bresnahan, Tr. 689-90, 810).

93. Professor Bresnahan did not study the price trend of K-Dur 20 since September 1, 2001, when new entry occurred in the market. (Bresnahan, Tr. 1003).

94. Upsher-Smith launched Klor Con M10 on September 1, 2001. (Dritsas, Tr. 4827).

95. Upsher-Smith launched Klor Con M10 aggressively against K-Dur 10 simultaneously with the launch of Klor Con M20 against K-Dur 20. (Troup, Tr. 5486-88).

96. Just prior to the launch of Klor Con M10, K-Dur 10 sales began to fall dramatically beginning in the summer of 2001 and continuing through November 2001. (Dritsas, Tr. 4827; USX 1557). K-Dur 20 sales followed the same trend in the summer of 2001 and continued though November 2001. (Dritsas, Tr. 4823; USX 1586).

97. Upsher-Smith launched Klor Con M10 in the midst of K-Dur supply problems that began earlier in the summer of 2001, just prior to the launch of Klor Con M10. (Troup, Tr. 5488-89). Due to the lack of availability of K-Dur, Upsher's potassium chloride sales were already on the rise, when Klor Con M10 and M20 were launched into the market. (Troup, Tr. 5488-89).

98. Upon its entry into the market with Klor Con M10, Upsher-Smith had a significant sales increase in its potassium chloride products. (Troup, Tr. 5489-90). Upsher-Smith had record sales of wax-matrix potassium chloride products in the year 2001 as well. (Troup, Tr. 5490).

99. While Upsher-Smith enjoyed strong sales for its Klor Con M10 product, this was due partially to the supply shortages Schering faced for both K-Dur 20 and K-Dur 10, due to FDA compliance issues that arose during the summer of 2001. (Dritsas, Tr. 4682, 4825).

100. Upon the launch of Klor Con M10 as a generic substitute to K-Dur 10, mandated state substitution for low cost generic alternatives took effect in several states. (Dritsas, Tr. 4824-25). These laws frequently block the prescribed branded product from being dispensed when a generic alternative is available, and thus prevent competition from the branded product completely. (Addanki, Tr. 5748-49; Dritsas, Tr. 4824-25). Similarly, in the K-Dur 20 market, state substitution laws that mandated substitution by a generic alternative negatively affected Schering's sales. (Dritsas, Tr. 4682, 4825).

101. K-Dur 10 in June 1997 amounted to 5% of the total prescriptions for potassium chloride in the United States. (CX 62 at SP 089326-27). K-Dur 10 sales performed just as Schering's K-Dur 20 performed. Despite the price increases for K-Dur 10, K-Dur 10's sales rose and in fact rose faster than K-Dur 20's sales. (CX 62-65).

102. Professor Bresnahan incorrectly asserts that K-Dur 20 is a monopoly (Bresnahan, Tr. 8147), but he concedes that K-Dur 10 was not a monopoly. (Bresnahan, Tr. 8146-47; Addanki, Tr. 5740).

103. While K-Dur 10 was not a monopoly product, K-Dur 10 sales fell just as dramatically as K-Dur 20, when Klor Con M10 became available on September 1, 2001. (Addanki, Tr. 5739-40; Dritsas, Tr. 4823-28; USX 1586; USX 1557).

f. Price sensitivity

104. Price is a major competitive factor in the potassium supplement market. (Dritsas, Tr. 4715-16; USX 626 at 15228).

105. Generic potassium products competed vigorously on price with branded potassium products, taking away sales and market share. (Dritsas, Tr. 4715-18, 4724-25, 4752-53, 4770-72; USX 626 at 15228; USX 1551 at 13791; USX 425 at 1002952).

106. K-Dur 20 lost some market share to other potassium chloride products. (CX 18 at 23 00045, CX 20 at 004040; Dritsas, Tr. 4717-18, 4752-53). K-Dur 20 also took market share and sales from other potassium products. (Dritsas, Tr. 4719-20, 4724-25, 4742, 4752, 4841; CX 19 at 15228).

107. Generic manufacturers, such as Apothecon, increased their sales of potassium supplements with lower prices, suggesting price sensitivity and an ability to gain share at the expense of other products in the market with lower prices. (Dritsas, Tr. 4763-64, 4770-72, 4909-10; Addanki, Tr. 6176-79; CX 50 at 13474; USX 380 at 142328; USX 425 at 1002952.).

108. Upsher-Smith's Dolan wrote that a firm may have a gain in sales after cutting prices. Slow-K, for example, showed a unit increase of 41% from 1994 to 1995 while their dollar share continued to decline. (Addanki, Tr. 6181).

(i). Schering K-Dur prices were sensitive to other potassium supplement prices

109. According to Schering, the pricing of K-Dur 20 was depressed due to generic potassium competition. (Russo, Tr. 3416).

110. The 30% price difference between K-Dur 20 and the unbranded generic

potassium products caused the sales of the generic products to rise, as noted in the 1998 K-DUR Marketing Plan. (CX 20 at 4040).

111. Schering's price for K-Dur 20 was not the highest for potassium chloride supplements during this time – other products were both lower and higher than K-Dur 20 for a 20 mEq dose. (Addanki, Tr. 5741; SPX 2069). IMS data shows that in 1997, K-Tab 10 was the highest priced potassium chloride product. (Addanki, Tr. 5742; SPX 2069). Between 1996 and 2000, K-Dur 20 was never the highest priced potassium chloride supplement. (Addanki, Tr. 5743; SPX 2068). Schering's K-Dur 20 competed on price with other potassium chloride products by using discounts and rebate programs. (Addanki, Tr. 6172-73).

112. Professor Bresnahan testified that he did not compare Schering's prices against other potassium products' pricing in forming his opinion as to the relevant market in this litigation. (Bresnahan, Tr. 725, 867).

113. Professor Bresnahan also did not measure the cross-elasticity of demand between competing potassium products in conducting his analysis of the potassium market and K-Dur 20. (Bresnahan, Tr. 810).

(ii.) Schering paid large rebates

114. The annual rebates Schering-Plough paid to its customers for K-Dur for 1995 were $21.005 million. (CX 695 at SP 020696). The annual rebates Schering-Plough paid to its customers for K-Dur for 1996 were $28.659 million. (CX 695 at SP 020696). The annual rebates Schering-Plough paid to its customers for K-Dur for 1997 were $17.593 million. The annual rebates Schering-Plough paid to its customers for K-Dur for 1998 were $34.565 million. (CX 695 at SP 020699). The annual rebates Schering-Plough paid to its customers for K-Dur for 1999 were $37.602 million. (CX 695 at SP 020700-701). The annual rebates Schering-Plough paid to its customers for K-Dur for 2000 were $35.214 million. (CX 695 at SP 020701). These rebates were "significant" and were "more than 10 percent of the gross sales of K-Dur" in 2000. (Addanki, Tr. 6173-74). In the first six calendar months of 2001, Schering-Plough paid its K-Dur customers $23.530 million in rebates for K-Dur. (CX 695 at SP 020702).

115. From October 1, 1997 to June 30, 2001, Schering-Plough paid its K-Dur customers a total of $136.566 million in rebates related to its K-Dur product. (CX 695 at SP 020698-0702).

116. The rebates that Schering-Plough paid its K-Dur customers after the June 1997 Agreement with Upsher-Smith demonstrate that Schering-Plough "[was] competing on price through rebates" (Addanki, Tr. 6173). The tens of millions of dollars paid to K-Dur customers

in rebates is inconsistent with the theory that Schering-Plough was a monopolist in the sale of its potassium products during this time period. (Addanki, Tr. 6173).

117. Professor Bresnahan did not study Schering's rebates at all in connection with his work in this case. (Bresnahan, Tr. 702). Nor did Professor Bresnahan study Upsher-Smith's rebate programs. (Bresnahan, Tr. 702). Further, Professor Bresnahan did not compare the two firms' relative level of rebate spending on potassium chloride (Bresnahan, Tr. 702).

g. No specialized vendors for various potassium products

118. No specialized vendors serve only K-Dur 20 — both Klor Con and K-Dur 20 are dispensed by pharmacies in response to prescriptions written by doctors. (Bresnahan, Tr. 695-96). Both drugs are prescription medications for potassium. (Bresnahan, Tr. 696-97). Patients who are hypokalemic receive prescriptions for a potassium supplement when they visit the doctor. (Bresnahan, Tr. 696). Demand for both products begins when a patient presents himself to a doctor. (Bresnahan, Tr. 696). Prescriptions are dispensed for both products at pharmacies. (Bresnahan, Tr. 697-99).

E. The '743 Patent and Schering's K-Dur Products

119. Potassium chloride supplements are prescription drugs used to treat potassium deficiency (known as "hypokalemia"), a condition that often arises among individuals who take diuretic medications used to treat high blood pressure or congestive heart disease. (Goldberg, Tr. 125-26; CX 3 at FTC 190286-89; CX 19 at USL 15229). Potassium deficiency can cause muscle weakness and life-threatening cardiac conditions. (CX 3 at FTC 190286-88; CX 26 at USL 07336; Goldberg, Tr. 125-26; Schering's Answer at ¶ 22; Banker, Tr. 2950).

120. Potassium chloride, the active ingredient in potassium chloride supplements, including K-Dur 20, is not patented. (Schering Answer at ¶ 33; Banker, Tr. 3251).

121. Patent number 4,863,743 ('743 patent) claims a "pharmaceutical dosage unit in tablet form for oral administration of potassium chloride" containing potassium chloride crystals coated with a material comprising ethylcellulose, having a viscosity greater than 40 cp, and hydroxypropoylcellulose or polyethylene glycol. (CX 12 at FTC 0021322). The novel feature claimed in the '743 patent is the particular coating applied to the potassium chloride crystals. The active ingredient, potassium chloride, was a known compound. The coating allows for sustained-release delivery of the potassium chloride. (CX 12 at FTC 0021319-20). Thus, the '743 patent relates primarily to the sustained-release formulation and does not cover the active ingredient itself. (Banker, Tr. 2947; Horvitz, Tr. 3625-27).

122. Key Pharmaceuticals, a division of Schering, owns the '743 patent. The '743

patent, issued on September 5, 1989, covers K-Dur 20 (as well as K-Dur 10, a 10 mEq version of the product) and expires on September 5, 2006. (Schering Answer at ¶ 34; CX 12 at FTC 0021318).

123. K-Dur 20 is a controlled release, microencapsulated, potassium chloride product developed by Key Pharmaceuticals in the 1980s and approved by the FDA in 1986. (Kerr, Tr. 7561). The "20" in K-Dur 20 refers to 20 mEq (milliequivalent), the amount of potassium contained in the 20 mEq dosage form. (Bresnahan, Tr. 489).

124. Complaint Counsel's expert witnesses did not reach an opinion as to whether the '743 patent is invalid or infringed by Upsher-Smith's or AHP's products. (Bresnahan, Tr. 670; Bazerman, Tr. 8568; Hoffman, Tr. 2351).

F. Upsher-Smith's Potassium Products and Patent Litigation

1. Upsher-Smith's ANDA and the initiation of patent litigation

125. On August 8, 1995, Upsher-Smith filed an ANDA with the FDA to market Klor-Con M in two dosage forms, 10 mEq and 20 mEq, as bioequivalent versions of Schering's K-Dur products. (USX 695). Upsher-Smith subsequently amended its ANDA submission to remove the 10 mEq dosage form from consideration, due to the FDA's initial rejection of a biowaiver for the 10 mEq dosage form. (CX 255). The FDA determined that no ANDA filer was eligible to have exclusivity for any 10 mEq dosage form of any generic version of K-Dur. (USX 345).

126. At the time of its ANDA submission, Upsher-Smith was not aware that it was the first ANDA filing referencing K-Dur 20. (Troup, Tr. 5491; Dritsas, Tr. 4666). After amending its ANDA to remove the 10 mEq dosage form, Upsher-Smith submitted a Paragraph IV Certification. (CX 224). On November 3, 1995, Upsher-Smith notified Schering of its ANDA filing and Paragraph IV Certification with respect to the 20 mEq dosage form. (CX 224; Troup, Tr. 5404).

127. On December 15, 1995, pursuant to the time period set forth in the Hatch-Waxman Act, Schering sued Upsher-Smith for patent infringement in the U.S. District Court for the District of New Jersey, alleging that Upsher-Smith's Klor Con M infringed Schering's '743 patent. (USX 677; Kralovec, Tr. 5032; Troup, Tr. 5404). Trial of the patent case was scheduled to begin on June 18 or 19, 1997. (Hoffman, Tr. 3549).

128. No testimony or evidence was offered to show that Schering's filing of the patent litigation against Upsher-Smith was not initiated for the legitimate purpose of defending its patent.

2. Settlement discussions between Schering and Upsher-Smith

129. In the patent litigation, Schering alleged that Upsher-Smith's Klor Con M20 product infringed the '743 patent because **[redacted] [redacted] [redacted]** *(Banker, Tr. 5254-55*; *SPX 2258*; *SPX 2259)*. Schering also asserted that **[redacted] [redacted] [redacted]** [(*Banker, Tr. 5257-59:16; SPX 2258; SPX 2260)*.

130. In its answer to Schering's complaint, dated January 29, 1996, Upsher-Smith denied that its product infringed "any claim of the '743 patent," and asserted, as affirmative defenses, that the claims of the '743 patent were invalid and that the '743 patent was unenforceable. (CX 226 at SP 08 00039-41). Upsher-Smith also filed a counterclaim for declaratory judgment that its product did not infringe the '743 patent and that the '743 patent was invalid and unenforceable. Upsher-Smith asserted that Schering brought its case with the intention of "trying to delay Upsher-Smith's FDA approval and thereby put off for as long as possible the time when it must face competition from Upsher-Smith's product." (CX 226 at SP 08 00041-42).

131. The patent infringement litigation between Upsher-Smith and Schering was vigorously contested from the outset. (Cannella, Tr. 3815; Kralovec, Tr. 5033; Troup, Tr. 5405-06). As the patent litigation continued through the spring of 1997, Mr. Ian Troup, Upsher-Smith's President and Chief Operating Officer, became increasingly concerned about the toll it was taking on Upsher-Smith. (Troup, Tr. 5405-06). The litigation was taking longer than Upsher-Smith had anticipated and was particularly rancorous. (Troup, Tr. 5405-07).

132. In April or May 1997, Troup first approached Schering about a possible settlement of the litigation. (Troup, Tr. 5397, 5408-09). The parties held a series of meetings over the course of the month before trial in an attempt to reach a settlement of the patent litigation. (F. 129-62).

133. The initial settlement meeting took place between Mr. Martin Driscoll, Vice President of Sales and Marketing for Key, and Troup at Schering's office in Kenilworth, NJ on May 21, 1997. (Troup, Tr. 5409). Troup stated that he wanted to obtain through settlement the earliest possible date to launch Klor-Con M20 without incurring the damages that could arise from patent infringement. (Troup, Tr. 5411-12). Troup suggested to Driscoll that they settle the litigation by setting a date certain for Upsher-Smith to enter the market with its Klor Con M products sometime before September 2006, the expiration date of Schering's K-Dur patent. (Troup, Tr. 5410-11).

134. At this settlement meeting or the next, Driscoll and Troup discussed the possibility that Schering might permit Upsher-Smith's generic version of K-Dur to come to market in late 2005 or early 2006, before the expiration of Schering's patent. (Troup, Tr. 5412). Troup stated that Upsher-Smith wanted to be on the market at an earlier date and that it would have problems with money and cash flow if its entry was delayed until 2005. (Troup, Tr. 5413).

135. The parties met again at Upsher-Smith's offices in Plymouth, Minnesota, on May 28 and June 3, 1997. Mr. Driscoll and Mr. Raman Kapur, President of Schering's Warrick subsidiary, attended these meetings on behalf of Schering. Mr. Troup and consultant Andrew Hirschberg attended on behalf of Upsher-Smith. (Troup, Tr. 5417; CX 1511 at 8-10 (Kapur Dep.); Schering First Admissions Nos. 7-9, 11-12; Upsher-Smith Second Admissions Nos. 9-10, 13-14, 22). At the May 28, 1997 meeting, Kapur indicated he was interested in the possibility of licensing some of Upsher-Smith's products. (Troup, Tr. 5420).

136. During the course of the May 28 and June 3, 1997 meetings, Troup again suggested that Schering make a payment in connection with a settlement of the patent suit. (CX 1511 at 18-19 (Kapur Dep.)). Troup stressed Upsher-Smith's need to replace its lost revenue from not having a generic K-Dur 20 product on the market. (Hoffman, Tr. 3568; CX 1511 at 18-19 (Kapur Dep.)).

137. During the course of the May 28 and June 3, 1997 meetings, the parties discussed various dates for Upsher-Smith's entry into the K-Dur 20 market. (CX 1511 at 22-23 (Kapur Dep)). The parties decided to approach settlement by splitting the remaining life on Schering's K-Dur patent. (Troup, Tr. 5424-26). Mr. Troup preferred an earlier date. (CX 1511 at 23-24 (Kapur Dep.)). Mr. Driscoll told Upsher-Smith that the earliest date he could offer for Upsher-Smith's entry was September 2001. (CX 1511 at 23 (Kapur Dep.)). Schering never suggested that it would consider an entry date earlier than September 1, 2001. (Troup, Tr. 5500).

138. At the May 28 and June 3, 1997 meetings, the parties discussed several possibilities for business opportunities, such as a co-marketing arrangement with respect to Schering's K-Dur or a joint venture for Upsher-Smith research and development. (CX 1511 at 14-15 (Kapur Dep.); Troup, Tr. 5433-34). They also discussed the possibility that Schering might license one or more Upsher-Smith products, including cholestyramine, pentoxifylline and Upsher-Smith's sustained release niacin product, Niacor-SR. (CX 1511 at 14, CX 1495 at 62 (Kapur Dep.); SPX 1242 at 16 (Kapur Dep.); Troup, Tr. 5420, 5430-34). Upsher-Smith described the expected clinical benefits of Niacor-SR, and Schering was aware of the market opportunity for Niacor-SR because it had been involved in evaluating the market for other, nearly identical projects. (CX 1495 at 70-71; SPX 1265 at 73 (Driscoll Dep.)). Troup was

willing to consider the possibility of licensing Niacor-SR to Schering outside the United States, as Upsher-Smith had no presence in Europe or elsewhere internationally. (Troup, Tr. 5432).

139. Prior to the parties' next face-to-face negotiation session, Mr. John Hoffman, Schering's General Counsel, spoke to, Mr. Nick Cannella, Upsher-Smith's outside counsel, on or about June 10, 1997, to discuss logistics and ground rules for the upcoming meeting. (Cannella, Tr. 3824-25). Hoffman told Cannella that Schering viewed the upcoming meeting as an opportunity to discuss potential business opportunities between Schering and Upsher-Smith, not as an occasion to debate the merits of the underlying patent case. (Cannella, Tr. 3826; Hoffman, Tr. 3541). Hoffman stated that Schering "was not going to be paying Upsher-Smith to stay off the market." (Hoffman, Tr. 3541).

140. Prior to the parties' next face-to-face negotiation session, Troup and Hirschberg discussed what Upsher-Smith should ask for in exchange for a license to Niacor-SR. (Troup, Tr. 5448). Hirschberg recommended that Mr. Troup ask for $100 million for a Niacor-SR license. (Troup, Tr. 5448).

141. Upsher-Smith representatives, Troup, Cannella and Hirschberg, and Schering representatives, Hoffman, Kapur, and Jeffrey Wasserstein, Vice President of Business Development, met in Kenilworth, N.J. on June 12, 1997. (Troup, Tr. 5436-38; Hoffman, Tr. 3539, 3541-42). Troup again raised his desire to gain an entry date earlier than September 1, 2001, for Upsher-Smith's generic version of K-Dur. (Troup, Tr. 5439). Mr. Troup stated at the June 12 meeting that Upsher-Smith still had "cash needs" because all of the company's cash was tied up in two products in development, Upsher-Smith's generic version of K-Dur and its sustained release niacin product, Niacor-SR. (Hoffman, Tr. 3543).

142. Hoffman stated to Troup that the September 1, 2001 entry had already been negotiated, and that Schering wanted to discuss licensing opportunities. (CX 1509 at 49 (Hoffman Dep.); Troup, Tr. 5439-40). Mr. Hoffman told Mr. Troup that Schering would be "willing to do arm's length business deals that stand on their own two feet, and that's what we're here to discuss." (Hoffman, Tr. 3544).

143. Before the June 12, 1997 meeting Upsher-Smith required Schering to sign a confidentiality agreement regarding Upsher-Smith Niacor-SR product information. (CX 1041). Troup brought to the meeting a confidential printed presentation about Upsher-Smith's Niacor-SR product. (Troup, Tr. 5436-37; CX 1041). This presentation was similar to the presentations Upsher-Smith provided to Searle and the European companies interested in licensing Niacor-SR. (USX 538; CX 1023). Troup also provided Schering with two draft protocols for conducting post-market studies for Niacor-SR. (CX 714; CX 1043).

144. Troup confirmed that Upsher-Smith's offer of a Niacor-SR license extended

only to non-NAFTA territories. (Hoffman, Tr. 3545; Troup, Tr. 5440-41). Schering was disappointed that Upsher-Smith would not consider a partnership for Niacor-SR in the United States (CX 1511 at 26-27 (Kapur Dep.)), but remained interested in the opportunity to market the product internationally. (Troup, Tr. 5443-44). Kapur also expressed his continued interest in Upsher-Smith's cholestyramine and pentoxifyilline products. (Hoffman, Tr. 3545).

145. The parties discussed the market potential for Niacor-SR. (Hoffman, Tr. 3547-48; Troup, Tr. 5441-43; Cannella, Tr. 3868). Upsher-Smith told Schering that late-stage clinical work on Niacor-SR was finished and that Schering would be able to get on the European market with Niacor-SR soon. (Troup, Tr. 5441-43). Schering and Upsher-Smith discussed niacin combination therapy, the advantages of Niacor-SR versus immediate release niacin, the flushing side effects and Niacor-SR's effects on Lp(a). (Troup, Tr. 5583-87). Troup referred to Kos Pharmaceutical's niaspan product, and Kos's market capitalization, to show that Upsher-Smith's Niacor-SR niacin product had tremendous potential. (Troup, Tr. 5583-87; Cannella, Tr. 3829-30).

146. The June 12, 1997 meeting included a preliminary discussion concerning the price of the Niacor-SR product. Troup asked for $70-80 million in his first offer to Schering. (Troup, Tr. 5449; Hoffman, Tr. 3545; SPX 1242 at 44-45 (Kapur Dep.); Cannella, Tr. 3830). Schering told Upsher-Smith it would continue to analyze the issues and the clinical data for Niacor-SR and would get back to Upsher-Smith about its interest in pursuing a deal for Niacor-SR. (Hoffman, Tr. 3545-46; Cannella, Tr. 3832). The parties also discussed the potential licensing of other Upsher-Smith products, including Prevalite and Pentoxifylline. (Troup, Tr. 5445-46; Hoffman, Tr. 3544-45).

147. Shortly before or after the June 12, 1997 meeting with Upsher-Smith in Kenilworth, Kapur and Driscoll briefed Mr. Raul Cesan, Schering's president of pharmaceuticals worldwide, on the Upsher-Smith negotiations. (CX 1510 at 66-67; SPX 1242 at 29-30 (Kapur Dep.)). Driscoll and Kapur told Cesan that they had discussed with Troup whether there were any potential business opportunities that would be valuable to both Schering and Upsher-Smith, and that Troup had suggested a possible deal for Niacor-SR in markets outside of the United States. (SPX 1242 at 30 (Kapur Dep.)). Cesan asked Kapur to contact Mr. Tom Lauda, Schering's Vice President of Global Marketing, to see if Lauda would be interested in marketing Niacor-SR internationally. (SPX 1242 at 30-31 (Kapur Dep.); CX 1489 at 14 (Cesan Dep.)).

148. Following Cesan's instructions, Kapur telephoned Lauda and told him that Schering was considering a licensing opportunity for Upsher-Smith's sustained-release niacin product, that the opportunity would cost Schering approximately $60 million, and asked if Global Marketing would perform an assessment of the product to see if it would be worth $60 million to Schering. (Lauda, Tr. 4342-43). Kapur did not tell Lauda that this licensing

opportunity was connected to patent litigation. (Lauda, Tr. 4344).

149. Lauda asked Mr. Jim Audibert, head of Schering's Global Marketing's cardiovascular unit, to perform an assessment of Upsher-Smith's Niacor-SR product. (Lauda, Tr. 4344). Lauda told Audibert that a packet of information about the product would be delivered and Kapur was available to answer any questions that Audibert may have had. (Lauda, Tr. 4404). Lauda did not tell Audibert any amount that Schering expected to pay for the license, and Audibert was unaware that the Niacor opportunity had any connection to a patent suit. (Audibert, Tr. 4113).

150. Kapur sent Upsher-Smith's Niacor-SR data package to Audibert after receiving it from Troup. (CX 1511 at 40 (Kapur Dep.)). Audibert did not recall Lauda specifying a deadline for his review of Niacor-SR, but he knew from past experiences with similar requests that Lauda usually wanted the assessment to be completed quickly. (Audibert, Tr. 4112-13).

151. Audibert provided a formal written assessment of the commercial value of Niacor-SR, dated June 17, 1997. (SPX 2). Although Audibert did not complete his written assessment until June 17, 1997, Audibert and Lauda discussed Audibert's assessment before Audibert completed it. (Lauda, Tr. 4345; CX 1483 at 30 (Audibert I.H.)). In summary, Audibert concluded that Niacor-SR offers a $100+ million sales opportunity for Schering. (SPX 2, at SP 1600045.) Annual dollar sales projections, in millions, were $45 (1999), $70 (2000), $114 (2001), $126 (2002). (SPX2, at SP 1600046-47). Detailed findings on Audibert's analysis and conclusions are set forth at F. 243-57.

152. The next meeting between Schering and Upsher-Smith took place on June 16, 1997, in Upsher-Smith's office in Plymouth, Minnesota. (Troup, Tr. 5452; Hoffman, Tr. 3550). Kapur, Hoffman, Wasserstein and Schering's in-house attorney Paul Thompson attended for Schering; Troup, Hirschberg, and Cannella (via telephone) participated on behalf of Upsher-Smith. (Hoffman, Tr. 3546; Troup, Tr. 5452; Cannella, Tr. 3834). Discussion at the June 16 meeting focused on the valuation of the package of Upsher-Smith products, including Niacor-SR and pentoxifylline for the ex-NAFTA countries and cholestyramine worldwide. (Troup, Tr. 5453). Over the course of the meeting, Upsher-Smith offered to license to Schering for the ex-NAFTA countries its wax matrix 8 and 10 mEq products and Klor Con M20. (Troup, Tr. 5453). Troup still wanted $80 million and talked again about the fact that Kos' market capitalization was $400 million based on the strength of Kos' similar niacin product, for which Kos had projected annual sales of $250 million by the third year. (Troup, Tr. 5455; Hoffman, Tr. 3547; Cannella, Tr. 3835). Schering made a counter-offer of $60 million, which was accepted by Upsher-Smith. (Cannela, Tr. 3835; Troup, Tr. 5458).

153. The parties discussed, either at the June 16 meeting or shortly thereafter, that the $60 million would be paid in installments. (Troup, Tr. 5459-60; Hoffman, Tr. 3547; CX 1511

at 74-75 (Kapur Dep.)). To bridge the gap between Upsher-Smith's asking price and Schering's counter-offer, the parties negotiated milestone payments for launch of Niacor-SR in nine different countries throughout the world, including $2 million for Japan and $1 million each for eight other countries, totaling $10 million in milestones. (CX 1511 at 72-73 (Kapur Dep.); Cannella, Tr 3836; Hoffman, Tr. 3547; Troup, Tr. 5458-59). Troup also asked for two different levels of royalties on Niacor-SR: a 10% royalty on annual net sales up to $50 million and a 15% royalty on annual net sales in excess of $50 million. (Troup, Tr. 5459; CX 347 at SP 12 00195).

3. Final negotiations and the June 17, 1997 Agreement

154. Following the June 16, 1997 meeting, the parties' first efforts to create a written agreement produced competing drafts. (Cannella, Tr. 3842-44). The final details of the agreement, including the amounts of the installment payments that would make up the $60 million in up-front royalties, were worked out in a series of telephone calls between the parties over the next 24 hours. (CX 1511 at 74-76 (Kapur Dep.); Hoffman, Tr. 3548-50; Troup, Tr. 5459-60, 5464; Cannella, Tr. 3843-44).

155. After the conference calls to fine-tune the agreement, the agreement was memorialized in writing in an initial fax copy in the early hours of June 18, 1997. (Troup, Tr. 5464; Hoffman, Tr. 3549-50). The settlement agreement, CX 347, bears the date of June 17, 1997. (CX 347; Hoffman, Tr. 3550). However, it was actually signed at 2:00 or 3:00 a.m. on June 18, 1997. (Hoffman, Tr. 3550; Troup, Tr. 5467). Troup signed a fax copy on June 18 (Troup, Tr. 5467), and a hard copy of the final version on June 19, after returning to the office from a business trip. (Troup, Tr. 5465, 5467-68; CX 348).

156. The critical terms of the June 17, 1997 Agreement (CX 348) are set forth below:

> IX. This Agreement constitutes a binding agreement between the Parties with respect to the subject matter set forth herein, conditioned solely upon the approval of the Board of Directors of Schering-Plough Corporation (the "Board"). This Agreement will be presented to the Board at its regularly scheduled meeting to occur on June 24, 1997.
>
> X. Failure of any party to perform its obligations under the Agreement (except the obligation to make payments when properly due) shall not subject such party to any liability or place them in breach of any term or condition of the Agreement to the other party if such failure is due to any cause beyond the reasonable control of such non-performing party ("force majeure"), unless conclusive evidence to the contrary is

provided. Causes of non-performance constituting force majeure shall include, without limitation, acts of God, fire, explosion, flood, drought, war, riot, sabotage, embargo, strikes or other labor trouble, failure in whole or in part of suppliers to deliver on schedule material, equipment or machinery, interruption of or delay in transportation, a national health emergency or compliance with any order or regulation of any government entity acting with color of right. . . .

¶ 3 Upsher-Smith agrees that it will not market in the United States its KLOR CON M 20 potassium chloride product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001. Effective as of September 2001, Upsher-Smith shall have a non-royalty bearing non-exclusive license under the '743 patent to make, have made, import, export, use, offer for sale and sell its, KLOR CON M 20 and KLOR CON M 10 potassium chloride tablets in the United States. . . .

¶ 4 Each of Upsher-Smith and Schering shall stipulate to the dismissal without prejudice of the action known as Key Pharmaceuticals, Inc. v. Upsher-Smith Laboratories, Inc., U.S.D.C., D.N.J. (Civil Action No. 956281 (WHW)).

Paragraphs 7, 8, 9, and 10 grant Schering or its designated affiliates, the "SP Licensee," exclusive licenses for NIACOR-SR, KLOR CON 8, KLOR CON 10, KLOR CON M20, PREVALITE, and Pentoxifylline. For each of the drugs except PREVALITE, the territories of the exclusive licenses are all countries other than Canada, the United States, and Mexico. For PREVALITE, the territories are all countries other than Canada and Mexico (and in different packaging in the U.S.)

¶ 11 In consideration for the licenses, rights and obligations described in paragraphs 1 though 10 above, the SP Licensee shall make the following payments to Upsher-Smith:

(i) An up-front royalty payment of twenty-eight million dollars ($28,000,000) within forty-eight (48) hours of the date on which the Agreement is approved by the Schering-Plough Corporation's Board of Directors (the "Approval Date").

(ii) An up-front royalty payment of twenty million dollars ($20,000,000) on the first anniversary of the Approval Date.

(iii) An up-front royalty payment of twelve million dollars ($12,000,000) on the second anniversary of the Approval Date.

(iv) Milestone payments due within ten (10) days of the first commercial sale of NIACOR-SR by the SP Licensee or its sublicensee in each of the following countries. . . .

¶ 12 In the event that any court or governmental authority or agency rules that the licenses granted to the SP Licensee are void or invalid, then all such rights which are ruled to be invalid shall terminate and Upsher-Smith shall have the right, at its sole discretion, to purchase back, for nominal consideration, all such terminated rights. Any of Schering's payment obligations under the Detailed Agreement relating to such invalidated rights which have not become due and payable prior to the date of such ruling shall thereupon terminate.

157. The June 17, 1997 agreement achieved two purposes: (1) a settlement agreement of the patent infringement litigation whereby Schering agreed to grant Upsher-Smith a royalty-free license to enter the market with Klor Con M20 and Klor Con M10 on September 1, 2001 (five years before the expiration of Schering's patent on its K-Dur products) (Troup, Tr. 5461–63; Hoffman, Tr. 3548; CX 348); and (2) a license agreement for six separate products, and a related supply agreement for each of the six licensed products. (Troup, Tr. 5509, 5461-63; CX 348).

158. Paragraph 3 states that "Upsher-Smith agrees that it will not market in the United States its Klor Con M 20 potassium chloride product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001." (CX 348; Troup, Tr. 5469). The language "or any other sustained release microencapsulated potassium chloride tablet" was added so that Upsher-Smith could continue to market its Klor Con 8 and Klor Con 10 wax matrix tablets without any restrictions. (Troup, Tr. 5469-70). Schering wanted to prevent Upsher-Smith from simply renaming its Klor Con M 20 product to get around the language and intent of the settlement agreement. (Troup, Tr. 5470). No other restrictions on any of Upsher-Smith's other products were intended by the settlement agreement. (Troup, Tr. 5470; Cannella, Tr. 3849-50).

159. The license from Schering to Upsher-Smith for the '743 patent covers the marketing and sale of both Klor Con M20 and Klor Con M10 in the United States, even though Klor Con M10 was not a subject of the patent infringement lawsuit or a part of Upsher-Smith's ANDA filing. (Troup, Tr. 5470-72; Kerr, Tr. 6253-54; CX 348).

160. Paragraph 11 of the settlement agreement discusses royalty payments, which

refers to the licenses for the six products: Niacor-SR, cholestyramine, Pentoxifylline, and the three potassium products. (Troup, Tr. 5473-74, 5631-33).

161. Paragraph 11 contains a reference that payment was in consideration of licenses, rights, and obligations described in paragraphs 1-10 of the entire agreement. (Troup, Tr. 5473-74; CX 348). The term "SP Licensee," by whom consideration was paid, only appears in Paragraphs 7 through 10 of the settlement agreement dealing with licenses, and not in Paragraphs 1 through 6, which involve only the settlement of the patent infringement litigation. (Troup, Tr. 5472-73, 5631-33).

162. No fact witness testified that the payments provided for in the June 17, 1997 agreement were not for Niacor-SR and the other products Schering licensed from Upsher-Smith.

4. Schering's Board of Directors approves the June 17, 1997 Agreement

163. The June 17, 1997 agreement was contingent on approval by the Schering Board of Directors. (Cannella, Tr. 3855-56; CX 347 at SP 12 00190). The presentation to Schering's Board sought authorization to enter into the license agreement with Upsher-Smith. (CX 338). It states that, during the course of Schering's discussions with Upsher-Smith, Upsher-Smith "indicated that a prerequisite of any deal would be to provide them with a guaranteed income stream for the next twenty four months to make up for the income that they had projected to earn from sales of Klor-Con had they been successful in their suit." (CX 338 at SP 12 00270). The Board was informed that Schering had made it clear to Upsher-Smith that any such deal would have "to stand on its own merit, independent of the settlement." (CX 338 at SP 12 00268). One Schering Board member testified that "it was made very clear to the directors that we were looking at this license agreement which had to stand on the merits of the license agreement." (SPX 1225 at 30 (Becherer Dep.)). Another Board member explained that "the licensing agreement that was being proposed would have to stand on its own merits," so that it "would be an agreement that would make sense in and of itself independent of anything else." (CX 1526 at 24-25 (Russo Dep.)).

164. The Board presentation provided sales projections for Niacor-SR of $100 million plus in annual sales. (CX 338 at SP 12 00268). The presentation showed a net present value of $225-265 million for the Niacor license. (CX 338 at SP 12 00275).

165. The Board presentation provided sales forecasts for sales of prevalite, pentoxifylline, and Klor-Con 8, 10 and M 20 "to be $8 million a year in the first full year of launch, growing to $12 million a year in the second full year, and then gradually declining in year four and thereafter. Net margins on the products are expected to be between 35% and 50%."

(CX 338 at SP 12 00271).

166. A Board member testified that "[t]he focus of this proposal was a licensing agreement for four products in a space that Schering was interested in for a $60 million investment and a $225 million plus economic value return. So, from the Board's standpoint, there was nothing about this that would cause any questions." (CX 1526 at 51 (Russo Dep.)). Based on the information presented to them and their understanding that the payments were for the licensed products, the Board approved the license deal. (CX 340 at SP 07 00003).

5. The "any other sustained release microencapsulated potassium chloride tablet" clause was necessary and narrowly constructed to fully settle the litigation

167. Paragraph 3 of the settlement agreement states that "Upsher-Smith agrees that it will not market in the United States its Klor Con M 20 potassium chloride product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001." (CX 348; Troup, Tr. 5469). The language "or any other sustained release microencapsulated potassium chloride tablet" was added after some discussion between the parties so that Upsher-Smith could continue to market its Klor Con 8 and Klor Con 10 wax matrix tablets without any restrictions. (Troup,Tr. 5469-70). Schering wanted to prevent Upsher-Smith from simply renaming its Klor Con M 20 product to get around the language and intent of the settlement agreement. (Troup, Tr. 5470).

168. A narrowly-constructed restriction like the one in the first sentence of paragraph 3 of the agreement is necessary in a patent settlement, as "it's essential to describe what it is that the parties can and can't do." (Kerr, Tr. 6334, 6336, 6338-39). In the pharmaceutical industry, settlement agreements necessitate narrowly-constructed clauses limiting the production of specific compounds, as generics need to be as similar as possible to the branded products and hence defy limitation by general language. (Kerr, Tr. 6338-39).

169. Professor Bresnahan has not identified any other product that was blocked by the language in the June 17, 1997 agreement that allegedly barred Upsher-Smith from marketing "any other sustained release microencapsulated potassium chloride tablet." (Bresnahan, Tr. 984). Nor is Professor Bresnahan aware that either Upsher-Smith or Schering had any product in mind other than the Klor Con M20 product when they drafted their agreement. (Bresnahan, Tr. 984).

170. Upsher-Smith's witnesses verified that no other products in Upsher-Smith's pipeline were bottlenecked by the limiting clause in paragraph 3. (Dritsas Tr., 4836).

171. Professor Bresnahan conceded that "if the contract were otherwise pro-competitive," it would be reasonable to read the language of the agreement as ruling out a "me-too product that is simply introduced under another name other than Klor Con M20 but is, in fact, Klor Con M20." (Bresnahan, Tr. 985). Such a provision would not be anticompetitive. (Bresnahan, Tr. 987-88, 990-91).

G. Whether the $60 Million Dollars Was a Payment For Fair Value of Niacor-SR

172. Complaint Counsel's expert witness economist, Professor Timothy F. Bresnahan testified that a side deal at fair value did not raise competitive concerns. (Bresnahan, Tr. 932-33.) Professor Bresnahan confirmed that the determination of fair value was a subjective standard measured at the time of the transaction: "if Schering-Plough had made a stand-alone determination that it was getting as much in return from those products as it was paying, then I would infer that they were not paying for delay." (Bresnahan, Tr. 964-65. *See also* Tr. 660-61; 989-90.)

1. The market for cholesterol reducing drugs

173. In the mid-1990s, pharmaceutical companies were interested in the market for reducing cholesterol-reducing drugs. (Horovitz, Tr. 3623-60). The worldwide market for cholesterol lowering drugs had grown to become the seventh best selling drug class in the world. (SPX 235 at SP 16 00001). In 1997, the global market for cholesterol-reducing drugs was estimated at $6-7 billion. (Kerr, Tr. 6871-72; SPX 225 at 3; Levy, Tr. 1763-64; Kerr, Tr. 6876). Forecasts in 1997 for the cholesterol-reducing drug market indicated that by the year 2000, the world market could total $11 billion. (Kerr, Tr. 6875-76; SPX 225 at 3).

174. Documents available to Schering in June 1997 showed that the market for cholesterol lowering drugs outside the U.S., Canada, and Mexico ("worldwide Ex-NAFTA") was larger than the U.S. market for cholesterol lowering drugs. (SPX 5 at SP 16 00447; CX 1042 at SP 16 00112). Complaint Counsel's pharmaceutical licensing expert, Dr. Nelson Levy estimated that in 1997, U.S. sales represented "roughly" half of worldwide sales of cholesterol lowering drugs. (Levy, Tr. 1914-15).

175. Although relatively inexpensive hyperlipidemic agents, including niacin, had been available for decades, annoying side effects interfered with patient compliance. (SPX 608 at SP 16 00344-345). In the late 1980's, however, the market for cholesterol lowering drugs began to take off with the widespread use of the newly developed and more expensive HMG-CoA reductase inhibitors, known as the statins. (SPX 608 at SP 16 00345). In the mid-1990's, there were five classes of cholesterol lowering drugs, including the statins that dominated the market, the fibrates, the bile acid sequestrants, niacin and probucol. (SPX 235 at SP 16

00001).

176. Niacin, or nicotinic acid, is a B vitamin that was first discovered to have hypolipidemic qualities in 1955. (SPX 608 at SP 16 00390). Niacin decreases LDL (known as "the bad cholesterol"), raises HDL (known as "the good cholesterol"), decreases triglycerides (TGs), and decreases lipoprotenin(a) (Lp(a)). (SPX 608 at SP 16 00390-391; Horovitz, Tr. 3620; Audibert, Tr. 4099). Niacin has a unique profile in that it is the only drug shown to alter each of these lipids in the desired direction, and is one of the most effective compounds in increasing HDL. (Halvorsen, Tr. 3903; Horovitz, Tr. 3620; Levy, Tr. 1761; CX 1042 at SP 16 00072). Niacin's effectiveness in reducing total cholesterol, LDL cholesterol and triglycerides, as well as raising HDL cholesterol, has been demonstrated in numerous independent studies over the past 30 years. (USX 21 at 0077; USX 308 at 110462-64).

177. Niacin is also one of the only compounds known to decrease Lp(a). (SPX 608 at SP 16 00390-391; Halvorsen, Tr. 3903; SPX 235 at SP 16 00002). Prior to 1997, several studies had associated Lp(a) with atherosclerosis and CAD, and treatment of Lp(a) was considered by European and U.S. experts to be one of the major unmet needs. (SPX 608 at SP 16 000362; SPX 235 at SP 16 00003; SPX 924 at SP 002780; CX 1042 at SP 16 00068-69).

178. In addition to its known efficacy profile when used as monotherapy, niacin had also been shown prior to 1997 to be an effective agent when used in combination with other cholesterol lowering drugs, such as statins. (SPX 608 at SP 16 00382, 391; Freese, Tr. 4962-64, 4989; SPX 52 at FTC 110463-110464; USX 141 at Moreton 00082; CX 1042 at SP 16 00074). As a result, physicians also prescribe niacin in combination with statins. (Horovitz, Tr. Tr. 3670; Brown, Tr. 3146-47; Freese, Tr. 4989).

179. Despite niacin's known profile as an effective cholesterol reducing agent, the immediate release formulations of the drug were not widely used prior to 1997 due to a side effect known as flushing. (Horovitz, Tr. 3620-21, 3625-26; USX 141 at Moreton 00082; SPX 924 at SP 002781; Audibert, Tr. 4100). Flushing is a result of increased blood flow near the skin, which causes redness, tingling and itching in almost all patients who use niacin. (Horovitz, Tr. 3625-26; Halvorsen, Tr. 3906; Brown, Tr. 3150). Although flushing does not present a safety risk, it is a nuisance side effect that significantly reduces patient compliance. (Halvorsen, Tr. 3906; Horovitz, Tr. 3620-21, 3625-26; Audibert, Tr. 4105). This flushing side effect prevented widespread use of what was recognized in the pharmaceutical industry as an otherwise effective cholesterol lowering agent. (Horovitz, Tr. 3620-21; Audibert, Tr. 4099-100).

2. Upsher-Smith's Niacor-SR and other products relevant to the settlement agreement

a. Development and testing of Niacor-SR

180. Upsher-Smith began the Niacor-SR (Sustained Release) development program in 1991. (Kralovec, Tr. 5010). Niacor-SR is a sustained-release formulation of niacin, meaning that it releases niacin gradually over a period of time. (Halvorsen, Tr. 3901; Horovitz, Tr. 3624). The purpose of sustained-release niacin is to eliminate flushing. (Halvorsen, Tr, 3905-06).

181. In 1997, both Upsher-Smith and another pharmaceutical company, Kos Pharmaceuticals, were each involved in the advanced stages of development for obtaining FDA approval of their own sustained-release niacin products. (Troup, Tr. 5474-75; USX 21 at 76-77). Upsher-Smith's Niacor-SR product presented an opportunity for Upsher-Smith to expand its sales in an extremely large market of cholesterol-reducing drugs. (Halvorsen, Tr. 3902-03).

182. By spring 1997, Upsher-Smith believed that it had completed all of the clinical development work on Niacor-SR, and was preparing to file its NDA for Niacor-SR. (Troup, Tr. 5474-75). As early as 1995, Upsher-Smith had conducted and completed the patient phase of two Phase III pivotal studies -- the last phase of clinical development for gaining approval of a drug product by the FDA with over 900 patients. (Halvorsen, Tr. 3907). By July of 1996, the last of 300 patients had completed testing in two additional longer-term Phase III follow-on studies. (Halvorsen, Tr. 3911; CX 1019 at 175679). By June 1997, Upsher-Smith was in the process of developing and performing a short, 17-day, 38-healthy-volunteer pharmacokinetic study on Niacor-SR and was finalizing an individual and integrated study report so that Upsher-Smith could file its NDA. (Halvorsen, Tr. 3907).

183. As part of its Phase III testing for Niacor-SR, Upsher-Smith conducted two pivotal studies, as required by the FDA, the 920115 and 900221 studies. (Halvorsen, Tr. 3907-08). Upsher-Smith also conducted two longer term follow-on studies – the 920944 and 900837 studies. (Halvorsen, Tr. 3907-08). The last patient in the last of the four studies, the 920944 study, completed treatment in July 1996. (Halvorsen, Tr. 3909). The results of the Phase III studies available in June 1997 confirmed the safety and efficacy of Niacor-SR as a cholesterol-reducing drug. (Horovitz, Tr. 3641-42, 3658).

184. In addition to clinical safety and efficacy tests, the FDA requires a pharmacokinetic test ("PK test") for approval of an NDA submission. (Halvorsen, Tr. 3937). This test measures how a drug is absorbed and eliminated in the human body. (Halvorsen, Tr, 3936-37, 3939). The subject is dosed and then serial blood draws or urine samples are taken over time, for example hourly, with the purpose of plotting the concentration of the drug in the plasma or urine over time. (Halvorsen, Tr. 3936-37). In March 1997, the FDA ultimately agreed with Upsher-Smith that a multi-dose PK test was unnecessary for approval of the Niacor-SR NDA, and indicated that Upsher-Smith could seek approval based on a single-dose

urine PK test. (Halvorsen, Tr. 3938-41; CX 917 at 107426-27; USX 281).

185. As of June 1997, Niacor-SR was Upsher-Smith's primary research project and was a highly valued asset. (Troup, Tr. 5474-75). By the second quarter of 1997, Upsher-Smith had spent $13 million developing Niacor-SR – more than double all of Upsher-Smith's other projects combined. (Halvorsen, Tr. 3902; Dritsas, Tr. 4833).

186. In 1994, Upsher-Smith's market research showed a potential market for Niacor-SR of $100 to $400 million in 2000. (Kralovec, Tr. 5011-12). As of spring 1997, Upsher-Smith believed Niacor-SR had the potential to be a very successful product, with revenues of at least $50 to $100 million, and possibly as much as $250 million. (Freese, Tr. 4978, 4990; Kralovec, Tr. 5011; Dritsas, Tr. 4829, 4831-32).

b. Upsher-Smith's comparison of Niacor-SR to Kos' Niaspan and cross-license agreement with Kos

187. In the mid-1990s, Kos Pharmaceuticals ("Kos") developed Niaspan, a sustained-release niacin product, which released niacin in a controlled dosage form for cholesterol therapy. (Patel, Tr. 7497; Halvorsen, Tr. 3945; Horovitz, Tr. 3640). Based on information available to Upsher-Smith in 1997, Niacor-SR and Niaspan were virtually the same in terms of efficacy and safety. (Halvorsen, Tr. 3947-48, 3960; Troup, Tr. 5524-25; Kerr, Tr. 6292; Horovitz, Tr. 3626, 3660; Lauda, Tr. 4351; Levy, Tr. 1315). During 1996 and 1997, Upsher-Smith's Director of Clinical and Regulatory Affairs, Dr. Mark Halvorsen continually kept track of the information on Niaspan that was publicly available. (Halvorsen, Tr. 3945-47; USX 535).

188. Comparing Kos's statements regarding Niaspan's performance on all of the lipid parameters -- Lp(a), LDL, HDL, triglycerides -- and Kos' statements regarding the safety profile of Niaspan to Niacor-SR's clinical and safety results, Dr. Halvorsen was confident in June 1997 that Niaspan and Niacor-SR were virtually identical. (Halvorsen, Tr. 3945-47; USX 535). Upsher-Smith executives believed Kos's Niaspan to be a direct and major competitor to Niacor-SR. (Kralovec, Tr. 5025; Halvorsen, Tr. 3946-47; Kerr, Tr. 6297).

189. By February 7, 1997, Kos and Upsher-Smith had negotiated and agreed on a cross-license under which **[redacted] [redacted] [redacted]** *(Kralovec, Tr. 5022-23; Halvorsen, Tr. 3948; CX 568 at 145288-9).* **[redacted]** *(Kralovec, Tr. 5022-23; Halvorsen, Tr. 3948; CX 568 at 145288-9).*

190. This agreement did not affect Upsher-Smith's ability to license its Niacor-SR

product for sales outside of the United States. (Kralovec, Tr. 5027-28; Troup, Tr. 5479-80). In fact, the agreement explicitly allowed Upsher-Smith to license its extra-U.S. rights under the patent to third parties. (Troup, Tr. 5655-56; Kerr, Tr. 6462; CX 568 at 145288).

191. The financial market expected Kos' Niaspan product to be very successful. (Kerr, Tr. 6292-93; USX 1606). On April 21, 1997, investment firm Dillon Reed forecast that Niaspan sales would reach $250 million by 2001 --roughly the same amount that Upsher-Smith had estimated for its sales of Niacor-SR. (Kralovec, Tr. 5025-26; USX 535 at USL 11515; SPX 225 at 2). In May 1997, analysts at Dillon Reed estimated product revenues for Niaspan of $17.3 million for 1998, growing to $242.8 million in 2001. (Kerr, Tr. 6827-28; 6832-33; USX 239). Other investment reports at that time forecast Niaspan sales of $20 million in 1997, growing to $250 million in 2000. (Kerr, Tr. 6876-77; SPX 225).

192. The investment community's valuation of Kos Pharmaceuticals in the first half of 1997 bolstered Upsher-Smith's expectations for Niacor-SR. (Kralovec, Tr. 5025-26; Troup, Tr. 5441-43; USX 535).

c. Upsher-Smith's efforts to license Niacor-SR

193. In order to reach the maximum level of sales for Niacor-SR, Upsher-Smith believed that it would have to spend $15-20 million to develop an effective sales force. (Kralovec, Tr. 5012-13).

194. Upsher-Smith saw great potential for Niacor-SR outside the U.S. market, but lacked a sales or marketing representative outside of North America. (USX 154-55; Freese, Tr. 4978; Kralovec, Tr. 5016; Troup, Tr. 5476; Halvorsen, Tr. 3970-71). By mid-1996, Upsher-Smith began actively looking for a Niacor-SR licensing partner for the European market. (Kralovec, Tr. 5028-29; Troup, Tr. 5476; Halvorsen, Tr. 3965). Upsher-Smith planned to market Niacor-SR in North America on its own and so did not discuss U.S. licensing of Niacor-SR with potential licensees. (Freese, Tr. 4977-78; Kralovec, Tr. 5016; Troup, Tr. 5431-33, 5440-41).

195. By the end of May 1997, Upsher-Smith's efforts to find a European partner for Niacor-SR had progressed to the point where Upsher-Smith representatives were holding face-to-face meetings with potential licensees to discuss licensing opportunities. (Freese, Tr. 4976-77; Halvorsen, Tr. 3965; Troup, Tr. 5475-76; Kralovec, Tr. 5020-21; USX 596-98; CX 880). These Upsher-Smith representatives reported to senior management that they were enthusiastic about finding a licensing partner. (Kralovec, Tr. 5020-21).

196. In the first week of June 1997, Upsher-Smith executives were in Europe meeting with four potential licensing partners for Niacor-SR: Servier, Pierre Fabre, Esteve, and Lacer.

(Halvorsen, Tr. 3871, 3967, 4026; Kralovec, Tr. 5028-29; Troup, Tr. 5476; Horovitz 3767; USX 596-98; CX 880). Upsher-Smith executives believed that potential European licensing partners were showing "strong interest" in Niacor-SR and that a substantial up-front payment was warranted. (Kralovec, Tr. 5017-18; 5020-21). As of June 1997, none of the four potential licensing partners for Niacor-SR had turned down Niacor-SR. (USX 596; USX 1523 at 58-59 (O'Neill Dep.); Kerr, Tr. 6321, 6818, 6815-16).

d. Other Upsher-Smith products relevant to the June 17, 1997 Agreement

197. In 1997, in addition to its niacin and potassium supplement families of products, Upsher-Smith had several other drugs on the market, or near market stage, including Pentoxifylline, Prevalite and Pacerone. (Dritsas, Tr. 4618-19, 4832-33; Troup, Tr. 5420-21, 5445). Although Upsher-Smith had plans for marketing these products in the United States, it lacked the presence and resources to market the drugs outside of North America. (Dritsas, Tr. 4636, 4833; Troup, Tr. 5431-32).

198. Prevalite, a bile acid sequestrant called cholestyramine, was another cholesterol fighting drug sold by Upsher-Smith. (Dritsas, Tr. 4618-19). Prevalite was a branded generic similar to Bristol-Myers Squibb's branded product Questran/Questran Light. (Dritsas, Tr. 4813-18; USX 591; USX 660). In 1996, Upsher-Smith had sales for Prevalite of $7 million, with 1997 projected sales at $8.8 million. (Dritsas, Tr. 4804-05, 4812-13; USX 591; USX 440; USX 627 at 15277).

199. Pentoxil, Upsher-Smith's trade name for Pentoxifylline, was another generic drug that was under development at Upsher-Smith in 1997. (Halvorsen, Tr. 3981). Pentoxifylline is used to treat peripheral intermittent claudication. Pentoxifylline allows red blood cells to be more flexible so that they may pass into blood vessels that have decreased in size and deliver oxygen. (Halvorsen, Tr. 3981). By June of 1997, Upsher-Smith had completed and submitted to the FDA all the clinical studies required for approval of its ANDA for Pentoxifylline as a generic form of the Trental brand of Pentoxifylline. (Halvorsen, Tr. 3981082). In 1997 alone, Trental sales were $153 million. (Rosenthal, Tr. 1740). Trental's Pentoxifylline patent was set to expire in July 1997, and in June 1997, Upsher-Smith expected to be among the first generics approved to enter the market after the expiration of the patent. (Halvorsen, Tr. 3983). At that time, Upsher-Smith's internal market projections estimated that Upsher-Smith's Pentoxifylline would realize $4.4 million sales in 1998. (USX 668 at 20666).

200. Pacerone, Upsher-Smith's trade name for an amiodarone product, was under development at Upsher-Smith in 1997. Pacerone is used to treat ventricular tachycardia, or rhythm management for the heart. (Dritsas, Tr. 4637-38, 4833). In June of 1997, Upsher-Smith believed that Pacerone was an important product and estimated first year sales of

Pacerone would be $10 million. (Troup, Tr. 5446).

3. Schering's interest in and valuation of Niacor-SR

a. Schering's interest in Kos' sustained release niacin product, Niaspan

i. Schering's negotiations with Kos

201. Kos filed an NDA for Niaspan with the FDA in May 1996. (SPX 18). Schering was interested in Niaspan in early 1997. Schering believed that a sustained release niacin product that solved flushing caused by immediate release niacins and did not elevate liver enzymes to the degree that some over-the-counter sustained release niacins had done could be commercially successful. (CX 1494 at 85; CX 1495 at 73 (Driscoll Dep.); SPX 1265 at 73 (Driscoll Dep.); Audibert, Tr. 4116-17).

202. Schering was interested in Niaspan not only as a late stage product that could generate revenues in the near term, but also because it presented an opportunity for Schering to enter the cholesterol lowering market in advance of its launch of ezetimibe, a drug that Schering was developing for the cholesterol market. (Audibert, Tr. 4108-11; Russo, Tr. 3437-38; SPX 21 at 002771).

203. In 1997, Mr. Raymond Russo was Key's marketing director for cardiovascular products in the United States. (Audibert, Tr. 4110; Russo, Tr. 3433-34). Russo participated in the negotiations with Kos regarding its Niaspan product. (Russo, Tr. 3449). James Audibert was Ray Russo's counterpart responsible for territories outside the United States and was for a time involved in the negotiations with Kos regarding Niaspan. (SPX 1224 at 77 (Audibert Dep.); CX 1484 at 132 (Audibert Dep.); Audibert, Tr. 2450, 2452, 4109; Russo, Tr. 3439).

204. By the time of Schering's discussions with Kos, the FDA had completed its medical review of Niaspan, and was discussing labeling with Kos. (Russo, Tr. 3445; CX 543; Audibert, 4102, 4105). The fact that the medical review had been completed meant that the FDA had judged the product to be safe and efficacious, and that it was just a matter of finalizing the actual labeling on the product before approval by the FDA. (Audibert, Tr. 4105-06).

205. During the first half of 1997, Kos was seeking a co-promotion arrangement for Niaspan, meaning that both parties to the deal would be involved in the sales and marketing of the Niaspan product. (Russo, Tr. 3449). Under a co-promotion arrangement, the parties would split efforts in the field force and divide the cost of the marketing. (Russo, Tr. 3449). A co-promotion arrangement differs from a license, in which the company licensing the product would retain all control and all sales proceeds after royalties are paid. (Russo, Tr. 3449-50).

Also, in a license arrangement, the licensee alone would be responsible for all the expenditures, investment and strategic direction associated with the product. (Russo, Tr. 3449).

206. Martin Driscoll, Schering's Vice President of Sales and Marketing for Schering's Key division, thought Kos' product labeling looked interesting. (CX 1495 at 96 (Driscoll Dep.); Driscoll, Tr. 1420, 2702). Schering asked Kos for more information, including Niaspan's clinical results supporting the labeling. (CX 1495 at 96 (Driscoll Dep.)). Kos was not forthcoming with additional information. (CX 1495 at 97-98 (Driscoll Dep.); SPX 1265 at 97-99 (Driscoll Dep)).

207. Kos wanted to maintain control over Niaspan's marketing and strategic positioning, while its partner gave Niaspan primary promotional positioning. (SPX 18). Kos wanted to have Niaspan promoted by Schering's sales representatives in the "primary position," meaning that it would be the first product a sales representative would discuss in a doctor's office. (Audibert, Tr. 4106). Schering explained that it could not guarantee that Niaspan would always be in the primary position because Schering had its own products, such as Claritin, that would be detailed first during particular seasons. (Audibert, Tr. 4107). Kos also wanted guarantees with respect to the level of call activity, asking for specific numbers of specific types of calls through the launch period. (Russo, Tr. 3451). Schering did not feel that it could accommodate the level of call activity that Kos wanted. (Russo, Tr. 3451). Schering would be more comfortable with secondary detailing. (Patel, Tr. 7555). Kos wanted "absolute maximum commitment from Schering in the form of first line details." (Patel, Tr. 7555). And, Kos also was demanding strategic control over the marketing and promotion of Niaspan. (Driscoll, Tr. 1423; Patel, Tr. 7557). Schering and Kos also discussed the issue of who would "book" sales. (Patel, Tr. 7556). Booking sales refers to which company records the sales that have been made. (Patel, Tr. 7556). Kos wanted to record, or "book," Niaspan's sales to show significant sales as a company. (Patel, Tr. 7556).

208. Audibert viewed Kos' demands as "unrealistic in terms of what their expectations were from us" regarding co-promotion activity. (Audibert, Tr. 2448). Audibert viewed Kos' demands for support from Schering's sales force as irrational, and very difficult for Schering to agree to. (Audibert, Tr. 4106).

ii. Schering's evaluation, market research, and forecasts for Niaspan

209. On February 11, 1997, the information about Niaspan that Schering had been able to obtain from Kos was sent to Schering's cardiovascular licensing group, which includes Audibert. (Audibert, Tr. 4102; SPX 924). Audibert was asked to evaluate a Niaspan co-promotion deal, in which Schering would be promoting the product along with Kos, from the perspective of Global Marketing. (Audibert, Tr. 4100-01).

210. In his discussions with Kos and evaluation of Kos' materials, Audibert learned that it was possible to develop a sustained-release niacin product that was both safe and effective. (CX 1484 at 132 (Audibert Dep.); Audibert, Tr. 2452-53; SPX 18; SPX 21). For Audibert, Niaspan proved that the concept of a sustained release niacin that reduced flushing and solved liver toxicity issues could work. (CX 1484 at 132 (Audibert Dep.); Audibert, Tr. 2454, Tr. 4115-16). Kos told Schering that Niaspan had a very low incidence of elevated liver enzymes. (Audibert, Tr. 4105). Kos referenced a study by Dr. McKinney using a particular sustained release niacin on the market at that time. (SPX 18; Audibert, Tr. 4104).

211. Schering performed market research in the United States to determine doctors' interest in sustained release niacin. (Audibert, Tr. 2393-94; Russo, Tr. 3447-48, 3501-02; CX 576). The market research included telephone interviews with ten prominent lipidologists who had attended Schering's recent meetings in New York concerning ezetimibe, another drug of Schering. (Audibert, Tr. 2393-94; Russo, Tr. 3447-48, 3501-02; CX 576). Schering found that doctors would welcome a sustained release niacin product that reduced flushing and avoided liver toxicity issues, but would want more evidence that the product met those needs. (Russo, Tr. 3532; CX 576).

212. Schering was hopeful that Niaspan's delivery system would overcome the experts' reservations regarding sustained release niacin and flushing, liver toxicity and diminished efficacy. (Russo, Tr. 3503, 3509). Accordingly, Schering wanted to see the rest of the NDA filing for Niaspan for additional data that would support Kos' representations. (Russo, Tr. 3511). Schering also wanted to see the final labeling submitted to the FDA for Niaspan because Schering believed that if it showed no contraindications and a better side effect profile than other niacin products, Niaspan would be a very good product for Schering. (Russo, Tr. 3511-12).

213. Following the April 9, 1997 meeting with Kos, Schering worked to put together broad deal terms that it ultimately would present to Kos. (Russo, Tr. 3455). Part of that process involved an assessment of the product's value to Schering and the preparation of sales forecasts. (Russo, Tr. 3455). Russo forecasted as his "base case scenario II" what he thought was the most realistic projection of Niaspan sales in the United States. (Russo, Tr. 3459, 3461-63, 3472); CX 550 at SP 002743; CX 551, at SP 002731). Under this scenario, Russo projected that Schering could achieve $134 million in sales in 2002, rising thereafter to $193 million. (Russo, Tr. 3461, 3529; CX 550 at SP 002743).

iii. Schering's offer to Kos for Niaspan

214. On May 15, 1997, Schering provided a written proposal to Kos for a co-promotion of Niaspan. (Russo, Tr. 3463-64; CX 554; SPX 619). Schering is the only company that gave Kos a written proposal before Niaspan was launched. (Patel, Tr. 7543).

215. **[redacted] [redacted]** *(Russo, Tr. 3589; CX 554).* **[redacted] [redacted] [redacted]** *(Russo, Tr. 3590; CX 554; Patel, Tr. 7666).* **[redacted] [redacted] [redacted]** *(Russo, Tr. 3590).* **[redacted]** *(Russo, Tr. 3589, 3590; CX 554; Patel, Tr. 7665; SPX 6190).* **[redacted redacted]** *(Russo, Tr. 3589-90*; *CX 554).* **[redacted]** *(Russo, Tr. 3589, 3590*; CX 554; *Patel, Tr. 7665*; *SPX 619).* **[redacted redacted redacted]** *(Russo, Tr. 3589; CX 554; Patel, Tr. 7665; SPX 619).* **[redacted redacted redacted redacted]** *Patel, Tr. 7666*).

216. Schering's proposal did not contain up-front payments to Kos or equity investments. *(Patel, Tr. 7605*; *CX 554).*

217. On May 21, 1997, one week after submitting its proposal, Schering had a conference call with Kos to discuss the written proposal. (SPX 230; SPX 35; *Patel, Tr. 7667).* Kos did not react favorably to Schering's proposal. (Russo, Tr. 3465). Mr. Dan Bell, Chief Operating Officer of Kos, told Schering that its offer was practically "insulting," and that he was "offended" by it. (SPX 230; *[Patel, Tr. 7669].*

218. **[redacted]** *(Patel, Tr. 7571].* **[redacted redacted]** *(Patel, Tr. 7531-32, 7608; CX 556; CX 769).* **[redacted redacted]** *(Russo, Tr. 3465-66).* **[redacted redacted]** *(Russo, Tr. 3465).* **[redacted redacted]** *(Russo, Tr. 3450).* **[redacted redacted]** *(Bell, Tr. 7567; Patel, Tr. 7608-09; CX 556).* **[redacted redacted redacted]** *(Patel, Tr. 7567, 7607-08; CX 556)).*

219. After receiving Kos' reaction to Schering's first proposal, Schering did not submit another proposal to Kos. (Russo, Tr. 3466, 3488; CX 558). Schering felt that Kos would be a difficult partner to deal with. (Audibert, Tr. 2450).

iv. Kos' discussions with other potential partners and subsequent sales of Niaspan

220. Kos' Niaspan entered the market in August 1997. (7 Tr. 1404 (Driscoll I.H.)). At the time of Niaspan's launch, Kos was still looking for a co-promotion partner for Niaspan in the U.S. (Patel, Tr. 7577).

221. In the fall of 1997, Kos had conversations with Searle Pharmaceuticals. (Patel, Tr. 7576; Egan, Tr. 7895-96; 7898). In early November, Searle met with Kos and the parties discussed Kos' demands for a U.S. co-promotion agreement. (CX 524). Kos demanded from Searle a large number of details for Niaspan. (Egan, Tr. 7986-88). Searle found Kos' demands unreasonable. (Egan, Tr. 7982). Kos wanted an up-front payment from Searle in the $10-20 million range. (Egan, Tr. 7982). Kos also wanted a "ridiculous" and unreasonable percentage of the profits from any co-promote arrangement. (Egan, Tr. 7984-85). Searle declined the Kos opportunity. (Egan, Tr. 7980).

222. During the summer and fall of 1997, Kos was also pursuing discussions with SmithKline Beecham concerning a co-promotion arrangement for Niaspan. In August 1997, Kos discussed with SmithKline the broad terms of a potential co-promotion partnership for Niaspan. *(Patel, Tr. 7678*; CX 508). As with Schering, Kos stated that it needed guaranteed detailing for Niaspan, that Kos wanted to book sales, and that Kos wanted the opportunity to co-promote a SmithKline product. *(Patel, Tr. 7678-79;* CX 508). SmithKline and Kos also discussed SmithKline's interest in non-U.S. rights to Niaspan. (CX 508). In November 1997, Kos announced disappointing sales results and its stock price dropped. *(Patel, Tr. 7685, Tr. 7688)*; Levy, Tr. 2076-77). Subsequently, SmithKline and Kos did not to enter into an arrangement regarding Niaspan. (Patel, Tr. 7540).

223. Kos had other discussions with potential partners about a European license for Niaspan after November 1997. (Patel, Tr. 7589). **[redacted redacted redacted]** *(Patel, Tr. 7615,* 7587). Kos did not find a European partner for its Niaspan product. (Patel, Tr. 7540).

224. Overall, Kos' Niaspan has had a spotty history in the marketplace. (Kerr, Tr. 6329). Initially, Niaspan did not achieve nearly the expected sales levels predicted and Kos' stock price plummeted. (Kerr, Tr. 6329, 6331; USX 1607).

225. In 1998, Niaspan sales were poor. Sales for the first 6 months of 1998 totaled $3.8 million and in August 1998, after being in the market one year, Niaspan's share of new prescriptions for the month was only 1.1%. (Audibert, Tr. 4159; SPX 15). Total sales for 1998 were only $15 million. (Driscoll, Tr. 1405). Two years after introduction, in 1999, Niaspan's sales were only $37 million. (Kerr, Tr. 6331; USX 1613).

226. After four years, Niaspan is now moderately successful, with last year's sales equal to about $100 million. (Kerr, Tr. 6331).

b. Schering's Evaluation of Upsher-Smith's sustained release Niacin product, Niacor-SR

227. In June 1997, Kapur telephoned Lauda and told him that Schering was considering a licensing opportunity for Upsher-Smith's sustained-release niacin product, that the opportunity would cost Schering approximately $60 million, and asked if Global Marketing would perform an assessment of the product. (Lauda, Tr. 4342-43). Lauda contacted Audibert and instructed Audibert to conduct a commercial assessment of Niacor-SR for worldwide territories, excluding the United States, Canada, and Mexico ("Worldwide EX-NAFTA"). (Lauda, Tr. 4344).

228. Audibert began his review when he received the data package regarding Niacor-SR on June 12, 1997. (Audibert, Tr. 4113; Lauda, Tr. 4344). The package included results from the two phase III pivotal clinical trials conducted by Upsher-Smith to obtain registration of Niacor-SR, referred to by their protocol numbers 920115 and 900221. (Audibert, Tr. 4113-15, 4171; CX 1042; Halvorsen, Tr. 3907-08). The package also included information regarding two draft protocols for phase III-B studies Upsher-Smith was planning to conduct once the NDA was filed. (Audibert, 4113-15; SPX 71-72; Halvorsen, Tr. 4025). Phase III-B studies are studies conducted not as part of the initial registration of a product, but to support subsequent labeling revisions. (Audibert, Tr. 4114). One protocol would evaluate the use of Niacor-SR in combination with a statin, and the other would evaluate Niacor-SR when administered as a single evening dose. (Audibert, Tr. 4115; SPX 71-72).

i. Mr. Audibert's qualifications in June 1997

A. Expertise in Sustained Release Products and Cholesterol Lowering Pharmaceutical products

229. James Audibert, who is currently employed within the Schering Plough Research Institute, was serving in June of 1997 as the Senior Director of Global Marketing for Cardiovascular Products. (Audibert, Tr. 4085, 4092). Audibert received his Bachelor of

Science in Pharmacy from Northeastern University College of Pharmacy in 1974, and received his Master of Science in Pharmacology from Northeastern University College of Pharmacy in 1982. (Audibert, Tr. 4081). From 1976 to 1987, Mr. Audibert worked for two companies, both of which specialized in the use of sustained release technology to transform old compounds into new products. (Audibert, Tr. 4082-84).

230. In mid-1986, Schering acquired Key and, in March 1987, Audibert moved to New Jersey to work for Schering's marketing department. In April 1995, Audibert went to work in Schering's Global Marketing Department. (Audibert, Tr. 4085). In this position, Audibert was in charge of cardiovascular products, including cholesterol lowering products. (Audibert, Tr. 4092-93).

231. Audibert's responsibilities included working on a cholesterol-lowering agent Schering had in development called ezetimibe. (Audibert, Tr. 4093). By early-1997, Mr. Audibert began working with the research organization to identify the patient populations in which, and products against which, ezetimibe would be tested in clinical studies. (Audibert, Tr. 4094). As part of this process, Audibert was also conducting a detailed evaluation of the market for cholesterol lowering drugs. (Audibert, Tr. 4094-95).

232. Audibert's detailed evaluation of the cholesterol lowering market included: (1) a review of secondary information and published literature regarding the market and products within the market; (2) conducting primary market research around the world, including interviewing physicians on what they perceived to be unmet needs and future trends in cholesterol management; (3) convening advisory panels to get input from experts in the cholesterol lowering area; (4) attending major cardiology meetings around the world dealing with current and future trends in cholesterol management, and the development of future cholesterol lowering products; and (5) traveling to subsidiaries around the world to meet with national experts and local opinion leaders in cholesterol management. (Audibert, Tr. 4095-96).

233. As part of this process of evaluating the cholesterol lowering market, Audibert studied the profiles of the products that were already available for the treatment of cholesterol, as well as the anticipated profiles of future products, and evaluated what unmet needs existed within the market. (Audibert, Tr. 4097-98). This included studying the major cholesterol lowering products on the market in 1997, including the statins, the fibrates, the resins, and niacin. (Audibert, Tr. 4098). Audibert also conducted a detailed evaluation of the size of the cholesterol lowering market, which included: (1) examining the current size of the worldwide market by product and geographic territory; (2) predicting the future size of the cholesterol lowering market through conversations with opinions leaders, examination of cholesterol management treatment guidelines, estimation of the impact of future products on the market, and consideration of analyst reports published by the investment community. (Audibert, Tr. 4096-97).

234. **[redacted redacted redacted]** *[(SPX 625 at SP 002914; SPX 25 at SP 002899)]*. **[redacted]** *[(SPX 625 at SP 002914; SPX 25 at SP 002899)]*.

235. **[redacted redacted redacted]** *(Audibert, Tr. 4301-02; SPX 221 at SP 002895-2898)*.**[redacted redacted]** *(Audibert, Tr. 4302-04; SPX 231 at SP 002941-2942)*. **[redacted redacted redacted]** *(Audibert, Tr. 4303; SPX 231 at SP 002944)*. **[redacted redacted redacted]** *(Audibert, Tr. 4304; SPX 231 at SP 002944)*].

236. **[redacted redacted redacted redacted]** *(Audibert, Tr. 4304)*.

237. Audibert also learned about niacin through his work on ezetimibe. (Audibert, Tr. 4098-99). Audibert was fully aware of the available scientific knowledge regarding niacin, including: the fact that niacin had been known for many years to have a positive effect on various lipid parameters that are important in cholesterol management, including lowering LDL, raising HDL, lowering triglycerides, and lowering Lp(a); the fact that niacin has been shown to be effective in long term morbidity studies; and the fact that niacin was incorporated into the NCEP treatment guidelines which recommend niacin as one of the agents for use in managing cholesterol. (Audibert, Tr. 4098-99). However, Audibert was also acutely aware of the fact that immediate release forms of niacin were limited by the side effect of flushing, and that sustained release niacin dietary supplements had been associated with substantial elevations in liver enzyme levels. (Audibert, Tr. 4100).

B. Involvement in the evaluation of Kos' Sustained Release Niacin Product in Spring 1997

238. On February 11, 1997, the information about Niaspan that Schering had

obtained from Kos was sent to Schering's cardiovascular licensing group. (Audibert, Tr. 4102; SPX 924).

239. On March 13, 1997, Audibert and Russo initiated a conference call with Kos to discuss Niaspan. (Audibert, Tr. 4103-05; SPX 18 at SP 002776). During this conversation, Audibert initiated a discussion of Niaspan's side effect profile, including in particular, the success of its sustained release formulation in: overcoming the flushing side effect of immediate release niacin, without causing the significant elevations in liver enzymes reported with over-the-counter sustained release niacin formulations. (Audibert, Tr. 4103-05; SPX 18 at SP 002776; Russo, Tr. 3443-44).

240. Kos advised Audibert that the rate of discontinuation due to flushing had been reduced to about 5% of patients. (Audibert, Tr. 4103-05; SPX 18 at SP 002776). When Audibert raised the issue of liver enzyme elevations, Kos advised Audibert that, in contrast to the McKinney study in which 50% of patients experienced liver enzyme elevations above five times the upper limit of normal, only about 1% of patients in clinical trials with Niaspan experienced elevations of three times the upper limit of normal. (Audibert, Tr. 4103-05; SPX 18 at SP 002776).

241. Kos advised Audibert that it had filed an application for regulatory approval with the United States FDA, and that the FDA had completed its medical review of Niaspan and was discussing labeling with Kos. (Audibert, Tr. 4105; SPX 18 at SP 002776). Because the FDA does not proceed to a discussion of labeling until it has determined a product is safe and effective, the fact that the FDA had completed its medical review and was discussing labeling for Niaspan indicated to Audibert that the FDA had concluded that Niaspan's sustained release formulation was indeed safe and effective. (Audibert, Tr. 4101-02, 4105-06).

242. In late-March or early-April 1997, Audibert stopped participating as the international contact in the negotiations with Kos. (Audibert, Tr. 4111-12). Kos had indicated that it was focused on co-promotion of the product in the United States and that promoting Niaspan outside the United States was not a priority. (Audibert, Tr. 4106). Audibert terminated his involvement, in part, because he believed Kos' demands were "totally irrational" and he felt that it was unlikely that the parties would reach an agreement. (Audibert, Tr. 4111-12).

ii. Mr. Audibert's evaluation of the Niacor-SR opportunity in June 1997

A. Evaluation of market opportunity and product profile

243. Audibert conducted an evaluation of Niacor-SR to determine whether its product profile satisfied the market opportunity. (Audibert, Tr. 4112). The 52-page data package provided by Upsher-Smith to Schering contained detailed summaries of the results of Niacor-SR's phase III pivotal trials, including all the information that Audibert required to conduct his evaluation of Niacor-SR's clinical profile. (Audibert, Tr. 4113-14).

244. The clinical data from Upsher-Smith's pivotal trials confirmed to Audibert that Niacor-SR was effective, and that it exceeded the regulatory hurdle of an average 15% reduction in LDL cholesterol. (Audibert, Tr. 4123; CX 1042; CX 1484 at 119-21 (Audibert Dep.)).

245. The clinical data from Upsher-Smith's pivotal trials illustrated to Audibert that Niacor-SR had significantly reduced the incidence of flushing as compared to immediate release niacin. (Audibert, Tr. 4117-19; CX 1042 at SP 16 00088-00089). As compared to immediate release niacin, Niacor-SR reduced the number of flushing occurrences more than four-fold. (Audibert, Tr. 4118-19; CX 1042 at SP 16 00089; Horovitz, Tr. 3645-46).

246. The clinical data from Upsher-Smith's pivotal trials illustrated to Audibert that Niacor-SR caused a very low incidence of liver enzyme elevations. (Audibert, Tr. 4119-20). Audibert concluded that the incidence of liver enzyme elevations in the Niacor-SR pivotal trials was consistent with that seen with cholesterol lowering drugs generally, and was substantially lower than the 66% incidence associated with prior sustained release niacin products. (Audibert, Tr. 4104-05, 4121, 4124; Horovitz, Tr. 3650-51). In his written commercial assessment, Audibert reported that the fact that some patients experienced liver enzyme elevations with Niacor-SR was consistent with the known side effect profile of the statins. (SPX 2 at SP 16 00044). Audibert's evaluation of the results of the Niacor-SR pivotal trials also revealed that the liver enzyme elevations experienced in that small percentage of patients returned to normal when the drug was discontinued. (Audibert, Tr. 4121-22; CX 1042 at SP 16 00093; Horovitz, Tr. 3649-50).

247. Based on his evaluation of the results of the pivotal trials, Audibert concluded that Niacor-SR was a safe and effective drug that satisfied the unmet need in the cholesterol lowering market that he identified in June 1997. (11 Tr. 4123-24 (Audibert Dep.)). Audibert had seen Kos' Niaspan as the "proof of concept," and he concluded based on the results of Upsher-Smith's clinical trials that Upsher-Smith had also used sustained release technology to develop a safe and effective niacin product. (11 Tr. 2453-54 (Audibert Dep.); [*Lauda, Tr. 4512-13).*].

B. Mr. Audibert's Commercial Assessment of the Niacor-SR Opportunity

248. Having determined that Niacor-SR's product profile satisfied an unmet need in the marketplace, Audibert constructed a forecast of sales based on that product profile in that market. (Audibert, Tr. 4124). The process for constructing this sales forecast included: (1) an evaluation of the current and future size of the cholesterol lowering market; (2) an evaluation of how Niacor-SR would be positioned within that market; (3) an evaluation of the price at which the product would be sold; and (4) a determination of the market share that the product would obtain given that price and product position in a market that size. (Audibert, Tr. 4124-27).

249. First, Audibert evaluated the current size of the market and made a projection of the future growth of that market for a period of ten years. (Audibert, Tr. 4124-25). Mr. Audibert used IMS data representing the current size of the cholesterol lowering market worldwide, excluding the U.S., Canada and Mexico ("worldwide Ex-NAFTA"), the territories in which the license to Niacor-SR was available. (SPX 5). The IMS data indicated that the size of the cholesterol lowering market in those territories in 1996 was $4 billion. (SPX 5). Mr. Audibert's handwritten notations on the IMS data reflect his calculation of prior growth in this market at a rate of 10%, 22% and 6% in the previous three years. (SPX 5). Audibert estimated an average annual growth 15% in 1997, 1998 and 1999, and a lower growth rate of 10% thereafter. (SPX 2 at SP 16 000046). Second, Audibert evaluated how Niacor-SR would be positioned within the cholesterol lowering market, first, as monotherapy and second, in combination with statins. (Audibert, Tr. 4125-26; [*SPX 231 at SP 002944)*]. Third, Audibert conducted an evaluation of the price at which Niacor-SR could be marketed. (Audibert, Tr. 4125-27). In making this determination, Audibert knew that Niacor-SR's position against the statins required that he be realistic in terms of pricing for Niacor-SR. (Audibert, Tr. 4126). As a result, he concluded that Niacor-SR would best be positioned as an inexpensive alternative to the statins and he selected a price of just half of atorvastatin, the generic name for Lipitor. (Audibert, Tr. 4126). Finally, Audibert projected what share of the market Niacor-SR could obtain at that price and positioning. (Audibert, Tr. 4126-27). Audibert concluded that Niacor-SR would compete as a low-priced, moderately effective product for the treatment of high cholesterol. (Audibert, Tr. 4126-27). From his experience in talking with cardiologists and health payers internationally, Audibert had learned that many countries with government funded health systems recognized the need to treat high cholesterol, but simply could not afford to treat significant portions of the population with the expensive statins. (Audibert, Tr. 4126-27).

250. Having identified the opportunity to position Niacor-SR as an inexpensive alternative to statins, Audibert still believed that Niacor-SR would only obtain an initial market share of .75%, rising for just two years to 1.5%, and then decreasing thereafter to a 1% share. (Audibert, Tr. 4127-29; SPX 2 at SP 16 00047).

251. Having estimated the overall size of the market and a market share for this product over a ten year period, Audibert used multiplication to determine projected sales. (Audibert, Tr. 4127). Audibert's formal written assessment for Niacor-SR, dated June 17,

1997, includes tables illustrating Audibert's annual projections of market size and market share, from which he calculated annual dollar sales. (Audibert, Tr. 4127-29); SPX 2 at SP 16 00046-47). The sales projected for each of these years, in millions, were:

Sales	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**
Millions	45	70	114	126	116	127	140	125	136	149

(SPX 2 at SP 16 00046-47).

252. On the basis of his sales projections, Audibert then prepared a written profit and loss analysis. (Audibert, Tr. 4138-39; SPX 6). The annual profit and loss calculations were created by deducting from his sales forecasts, an estimated 10% cost of goods, as well as the cost of selling and promoting Niacor-SR, which Audibert estimated to peak at $22.8 million in the third year of sales. (SPX 6). Because Audibert did not know what royalty rate would be negotiated, his calculations represented the annual net profit before deducting the royalties to be paid to Upsher-Smith. (Audibert, Tr. 4139).

253. Following his evaluation of the Niacor-SR opportunity, Audibert prepared a written commercial assessment, as well as a written profit and loss projection on the basis of the sales he had projected in his commercial assessment. (SPX 2; SPX 6). Audibert provided a copy of each of these documents to Lauda. (Audibert, Tr. 4138-40; Lauda, Tr. 4345-46).

254. In his assessment, Audibert provided background information regarding the cholesterol lowering market, including the competitor products in that market. (SPX 2 at SP 16 00040-45). Audibert explained the current state of knowledge regarding niacin as an effective cholesterol lowering agent, as well as the difficulties that had hampered prior immediate release niacins (flushing) and sustained release niacins (association with hepatotoxicity). (SPX 2 at SP 16 00040-45). Audibert detailed the current size of the cholesterol lowering market, recent growth experienced in that market, and provided an assessment of why the growth of that market was expected to continue. (SPX 2 at SP 16 00040-45). Audibert identified his conclusion that a product opportunity existed for Niacor-SR, and on the basis of his conclusions, he provided a summary of his sales projections for Niacor-SR. (SPX 2 at SP 16 00040-45). Audibert attached to his assessment two tables which contained his detailed financial projections of both the future growth of the cholesterol lowering market and his sales projections for Niacor-SR in that market. (SPX 2 at SP 16 00046-47). Audibert concluded that Niacor-SR offers a $100 + million sales opportunity for Schering. (SPX 2, at SP 1600045).

255. Niacor-SR also offered strategic value to Schering in June 1997. Schering was developing ezetemibe for the cholesterol market, the projected launch of which was still several years away. (Audibert, Tr. 4094, 4108-09). Because Schering was planning to launch the

largest product in company history in a market in which it had no presence, it was important for Schering to first establish a presence in that market in order to build a knowledgeable sales force capable of maximizing the launch of ezetimibe. (Audibert, Tr. 4108-11; Horovitz, Tr. 3622-23, 3659-66; Lauda, Tr. 4348-49; Russo, Tr. 3437-38).

iii. Audibert's sales projections for Niacor-SR were consistent with projections for Niaspan

256. In March 1997, Kos proceeded with an Initial Public Offering ("IPO") on the basis of projected sales of its primary product, Niaspan. (Patel, Tr. 7544; Egan, Tr. 7982; Kerr, Tr. 6982). Around the time of the IPO in the spring of 1997, several market analysts published projected U.S. sales for Niaspan reaching between $220 million and $250 million in the third year of sales. (Levy, Tr. 2072; SPX 226; Kerr, Tr. 6872-73; USX 535 at USL 11514; [*Patel, Tr. 7674-75).*]

257. In April 1997, Russo, Schering's senior director of marketing in charge of the negotiations with Kos prepared a range of forecasts of potential U.S. Niaspan sales. Russo forecasted as his "base case scenario II" what he thought was the most realistic projection of Niaspan sales in the United States. (Russo, Tr. 3459, 3461-63, 3472; CX 550 at SP 002743; CX 551 at SP 002731). Under this scenario, Russo projected that Schering could achieve $134 million in sales in 2002, rising thereafter to $193 million. (Russo, Tr. 3461, 3529; CX 550 at SP 002743).

iv. Schering determined that the value of Niacor-SR to Schering in June 1997 exceeded $60 million

258. Following Audibert's evaluation, Lauda and Audibert met to discuss the written assessment and profit and loss statement, including the projected sales that Schering could expect from Niacor-SR, its projected market share, and assumptions underlying those projections. (Lauda, Tr. 4345-46; SPX 2; SPX 6). Lauda concluded that Schering could promote Niacor-SR and "easily garner" the market share that Audibert projected. (Lauda, Tr. 4347-49).

259. Using the financial projections contained in Audibert's commercial assessment and the terms of the license agreement, including the royalty payments to Upsher-Smith called for under the agreement, Schering performed its standard calculation of the economic value for this transaction which confirmed that Niacor-SR presented an economic value to Schering of between $225 to $265 million, and an internal rate of return of 43%. (SPX 26 at SP 16 00275). None of Complaint Counsel's witnesses challenged the validity of Schering's calculation that Audibert's financial projections for Niacor-SR represented an economic value to Schering of between $225 to $265 million, and a return on its investment of 43%. (SPX 26 at

SP 16 00275).

260. Schering's expert on pharmaceuticals, Dr. Zola Horovitz, performed his own "conservative" calculations and concluded that Schering could have paid as much as $100 million and still obtained a 35% internal rate of return and an economic value of $205 million. (Horovitz, Tr. 3617-18). Upon review of the information he relied upon, Dr. Horovitz testified that, based on Schering's projections at knowledge in June 1997, the deal for Niacor-SR would be a good deal for Schering and would stand on its own two feet. (Horovitz, Tr. 3787).

261. Having concluded that the Niacor-SR opportunity presented a value to Schering in excess of $60 million, Lauda advised Kapur of his conclusion and later provided him a copy of Audibert's written assessment and profit and loss projections. (Lauda, Tr. 4349; SPX 2; SPX 6).

4. Schering's And Upsher-Smith's post-deal conduct

a. Schering's internal preparations and communications with Upsher-Smith regarding availability of Niacor-SR data

262. Shortly after Schering's Board of Directors approved the Niacor-SR license, June 24, 1997, (CX 340), Schering began to get the Niacor-SR project organized. On July 2, 1997, Kapur informed Cesan that global marketing would take responsibility for Niacor-SR, while Warrick, Schering's subsidiary, would oversee development of the generic products licensed from Upsher-Smith. (SPX 8). At the same time, Kapur notified Lauda that the Niacor-SR deal had been approved and that global marketing was to take the lead in supervising Schering's international registration and marketing of Niacor-SR. (SPX 7; Lauda, Tr. 4350).

263. Schering also contacted Upsher-Smith regarding Niacor-SR and other matters soon after the Schering Board approved the Upsher-Smith license agreement. (SPX 255; SPX 9). On June 30, 1997, Schering's in-house counsel for licensing, Paul Thompson, sent Upsher-Smith a draft of a more detailed Amendment Agreement that expanded on such issues as the supply and delivery of Niacor-SR and other licensed products. (SPX 255; Kralovec, Tr. 5050-51). On July 16, 1997, Kapur wrote to Troup regarding Schering's intention to schedule a visit to inspect Upsher-Smith's facility that manufactured cholestyramine, one of the generic products Schering had licensed from Upsher-Smith. (SPX 9).

264. Audibert attempted to arrange, through Mark Halvorsen, Upsher-Smith's Director of Clinical and Regulatory Affairs, a visit by someone from Schering's clinical research group to Upsher-Smith in order to review Upsher-Smith's data and discuss regulatory filing strategies. (SPX 241; Audibert, Tr. 4142, 4149-50). On August 21, 1997, Audibert updated

Kapur on the Niacor-SR project, explaining that his efforts to arrange this trip to Upsher-Smith had been unsuccessful because of Upsher-Smith's delays in compiling the relevant clinical data and regulatory documents. (SPX 11; Audibert, Tr. 4154-55).

265. Schering continued to communicate with Upsher-Smith regarding its desire to obtain the Niacor-SR data. (SPX 10; SPX 12). On October 21, 1997, Kapur wrote to Troup, asking whether the Niacor-SR clinical data that Schering had expected by mid-October was available and attempting once again to set up a meeting for Schering to review the information at Upsher-Smith's offices. (SPX 12 at SP 05 00014; Audibert, Tr. 4156). A November 7, 1997 memo from Mr. Kapur to Audibert indicates that Troup had agreed that Upsher-Smith would send Schering the Niacor-SR registration information in segments so that Schering would not have to wait until the full ISS/ISE (Integrated Summary of Safety and Integrated Summary of Efficacy) were completed. (SPX 12 at SP 05 00013; Audibert, Tr. 4156).

b. Upsher-Smith's internal development efforts on Niacor-SR and communications with Schering

266. After the June 17, 1997 agreements, Troup alerted the various managers of departments at Upsher-Smith about the specific products being licensed by Schering and the steps to be taken for each product under the license agreement with Schering. (Troup, Tr. 5481-83). By the end of June, Upsher-Smith and Schering had begun to negotiate and exchange drafts of a fuller Amended Agreement and a Manufacturing Agreement for the products from Upsher-Smith. (USX 732).

267. As of the summer of 1997, Upsher-Smith was going forward with its NDA and Upsher-Smith's primary activity was to complete the final study reports and the ISS/ISE. (Halvorsen, Tr. 3975). The patient phase of all four clinical studies had concluded well before June 1997 and Upsher-Smith was in the process of compiling the data. (Halvorsen, Tr. 3912).

268. In early June 1997, consistent with the FDA's agreement in March 1997 that Upsher-Smith only needed to conduct a single-dose PK test (Halvorsen, Tr. 3940-41; USX 0281). Upsher-Smith prepared a protocol for such a test and started on it immediately. (Halvorsen, Tr. 3941; SPX 331). To conduct the PK test, Upsher-Smith first had to be sure that it had validated a proper bioanalytical method for measuring the drug passed in urine. (Halvorsen, Tr. 3942-45). Upsher-Smith hired two contract research organizations ("CROs") to work separately in competition to develop a final methods validation. (Halvorsen, Tr. 3942-45; USX 562). Simultaneously, Upsher-Smith had them test the protocol with a pilot study using Slo-Niacin so that Upsher-Smith would have samples to use in developing the method for testing Niacor-SR. (Halvorsen, Tr. 3942-45).

269. Upsher-Smith continued throughout the second-half of 1997 to hold its teleconferences

with the CROs regarding the study reports, medical narratives and the accompanying medical narratives. (Halvorsen, Tr. 3975; USX 1146). Between June 20 and December 19, 1997, there were 19 more such conference calls. (USX 1146). As of July 22, 1997, the goal was to file the Niacor-SR NDA before the end of the year. (Halvorsen, Tr. 3985; USX 1188 at 093578).

270. During June and July 1997, Upsher-Smith was working on its Niacor-SR package insert to include with its NDA submission. (Freese, Tr. 4990; USX 308). By July 21, 1997, Upsher-Smith had developed a revised draft of its package insert. (Freese, Tr. 4990; USX 308). Upsher-Smith's draft package insert included annotations to over 20 different niacin studies regarding the efficacy and benefits of niacin in the treatment of hypercholesterolemia. (Freese, Tr. 4990; USX 308 at 110477-9).

271. Prior to August 14, 1997, Audibert called Halvorsen regarding Niacor-SR clinical data in the first of several communications between the two representatives. (Halvorsen, Tr. 3976-77; USX 189). During that first call, Halvorsen and Audibert discussed the four clinical studies Upsher-Smith had conducted with Niacor-SR for FDA approval — the two pivotal studies and the two follow-on studies. (Halvorsen, Tr. 3976-77; USX 189). On August 14, 1997, Audibert sent Halvorsen a fax to arrange a meeting at Upsher-Smith for the week of September 15. (USX 189).

272. In August 1997, Upsher-Smith was still planning to file its NDA for approval of Niacor-SR at the end of 1997. (Halvorsen, Tr. 3977-78). By telephone call, Halvorsen informed Audibert that he did not believe that there would be clinical data available until late October, and that what Upsher-Smith would have at that time were the final reports from the individual studies, and not the ISS/ISE. (CX 780 at 00236).

273. On August, 15, 1997, Upsher-Smith mailed copies of the four protocols --the 115, 221, 837 and 955 clinical studies --to Audibert. (Halvorsen, Tr. 3979; USX 727). Mr. Audibert then forwarded this information to Schering's research institute. (CX 780 at 00236).

274. On October 27, 1997, a Schering licensing attorney faxed to Upsher-Smith's CFO, Mr. Paul Kralovec, a copy of the Amendment Agreement with Schering's proposed revisions. (SPX 217 at 0013). On November 12, 1997, Kapur's secretary, responded to Upsher-Smith's October 31 letter regarding the need for Schering to execute a broader confidentiality agreement covering the licensed products, including Pentoxifylline. (USX 218 at 135402).

c. Kos' stock plunge preceded Upsher-Smith's and Schering's decisions not to pursue Niacor-SR projects

275. In November 1997, Kos announced its first quarterly results for Niaspan sales in the United States, which were considerably below what everyone had expected. (Audibert, Tr. 4156; Lauda, Tr. 4433; Halvorsen, Tr. 3956; Troup, Tr. 5480). The first published figures regarding Niaspan sales in November 1997 were a major disappointment to investors, and Kos' stock price, which had

peaked around $44 per share, plummeted to $5 per share. (Troup, Tr. 5480).

276. Within a few weeks after Kos released the sales information for Niaspan, Upsher-Smith had pulled back on its ANDA project because in order to successfully go forward with a generic product, the branded product must attain a certain level of sales. (Halvorsen, Tr. 3956, 3964). An NDA was equally unpromising, as Niacor-SR was a very similar product to Niaspan, which failed to achieve a large following. (Halvorsen, Tr. 3964). In December 1997, Upsher-Smith put its Niacor-SR development project "on hold status, pending evaluation of Kos marketing success." (SPX 302 at USL 16165).

277. Although Upsher-Smith decided not to go forward with its NDA for Niacor-SR in the United States, a December 16, 1997 fax reports that Halvorsen informed the Niacor-SR team that there was a possibility that the project would proceed in Europe through Schering. (USX 1226; Halvorsen, Tr. 3987-88). January 15, 1998 meeting minutes indicate that the Niacor-SR project was on hold with "only minimal activity" to continue in most departments. (CX 962 at USL 13253; Halvorsen, Tr. 4051). Halvorsen testified that Upsher-Smith's clinical department proceeded "full forward" at that point with efforts to complete the study reports. (Halvorsen, Tr. 4051). The January 15, 1998 meeting minutes indicate that this continuing work represented "a significant amount of resource hours" for Upsher-Smith. (CX 962 at USL 13252, USL 13253; Halvorsen, Tr. 4051). Upsher-Smith continued to communicate with its CROs in efforts to compile the integrated summary of safety and the draft clinical tables in January 1998. (Halvorsen, Tr. 3988-89; USX 1235).

278. Niaspan's performance in the marketplace was relevant to the Niacor-SR project because it provided a real world opportunity for Schering to test the market. (Audibert, Tr. 4144). By September 1998, Schering no longer believed that Niacor-SR would do as well as it had originally predicted. (Lauda, Tr. 4433-34; Audibert, Tr. 4143-44).

279. A subsequent discussion between Audibert, Kapur and Troup regarding Niacor-SR is summarized in a September 25, 1998 memo from Audibert to Mr. Lauda. (SPX 15). During this discussion, Troup stated that Upsher-Smith was not going forward with its NDA. (SPX 15; Audibert, Tr. 4159). Audibert's memo indicates that this raised some real issues in his mind about the potential commercial viability of Niacor-SR from his perspective. (SPX 15; Audibert, Tr. 4159). He noted that "in August 1998, after being in the market one year, Niaspan's new Rx share for the month is only 1.1 percent" and that, "judging by the response of the investment community, the prognosis of Niaspan is poor." (SPX 15). He also stated that Upsher-Smith's decision not to pursue its NDA would result in delay and a greater demand on Schering's resources if it proceeded with its European filings. (SPX 15).

280. On October 6, 1998, Kralovec confirmed in a letter to Kapur that Upsher-Smith had suspended all research on Niacor-SR. (CX 1111; Kralovec, Tr. 5058-59; Lauda, Tr. 4428-29). Upsher-Smith cited the poor performance of Kos' Niaspan as one factor in its decision (Kralovec, Tr. 5061-62), as well as the fact that the FDA had requested that Upsher-Smith conduct an additional PK

study, which would have delayed Upsher-Smith's NDA and resulted in the product coming to market two or three years behind the launch of Niaspan. (Lauda, Tr. 4429; CX 1111).

281. Schering abandoned its efforts to bring Niacor-SR to market for several reasons. (Audibert, Tr. 4144; Lauda, Tr. 4352-53). The Kos product continued to do poorly in the marketplace, telling Schering that marketing a sustained release niacin product was going to be more difficult than anticipated. (Audibert, Tr. 4144-45). Niaspan's poor performance in the United States had implications for Niacor-SR sales in Europe. (Audibert, Tr. 4145). The fact that Upsher-Smith had abandoned its pursuit of the NDA before it was ready to be filed meant that Schering would have to devote more of its own resources to putting together its international dossier than had originally been anticipated. (Audibert, Tr. 4145). Finally, even if Schering had gone forward with the work to prepare the dossier, the entry of Niacor-SR in Europe would have been much later than originally anticipated. (Audibert, Tr. 4145). As a result, Schering decided not to pursue Niacor-SR further. (Lauda, Tr. 4407).

d. Upsher-Smith continued clinical work and medical writing wrap up and continued to communicate with Schering in 1998

282. Although Upsher-Smith decided in December 1997 to put on hold its plans to obtain FDA approval for Niacor-SR, this did not affect its clinical work on behalf of Schering. (Halvorsen, Tr. 3989). Upsher-Smith continued in 1998 to finalize the clinical study reports and put them in a usable form for Schering. (Halvorsen, Tr. 3989). During 1998, Upsher-Smith remained in contact with Schering-Plough regarding the licensed products. (USX 665, SPX 251; CX 1088; CX 1111).

283. Throughout the first part of 1998, at Upsher-Smith's instruction, its CRO continued to work on the methods validation for the single-dose PK protocol. (Halvorsen, Tr. 3943-44; SPX 331). The CROs working on the reports and medical writing continued their work through March of 1998, and Upsher-Smith's research and development team continued to have their regular telephone conferences to supervise and assist that work. (Halvorsen, Tr. 3924-25:4; 3944-45; USX 1230). Between January 1, 1998 and May 1998, members of Upsher-Smith's research and development team participated in a dozen such calls. (USX 1230; USX 1232 at 903845; Halvorsen, Tr. 3988-95).

284. In a meeting in March of 1998 in the office of Upsher-Smith's president Mr. Troup, Dr. Halvorsen was informed that Schering was not going to seek European approval. (Halvorsen, Tr. 3924-25).

285. On May 13, 1998, a CRO provided to Upsher-Smith the final draft of the Niacor-SR 92044 follow-on study and the related medical narratives. (USX 1265 at 093775; CX 1019). On November 4, 1998, Upsher-Smith received from a CRO its 508-page report containing the final methods validation for the PK test required by the FDA. (Halvorsen, Tr. 3943-44; SPX 333 at 165879). The total cost to Upsher-Smith of performing this final methods validation was $400,000.

(Halvorsen, Tr. 3944). Upsher-Smith was also spending money on its multiple CROs for their clinical work in completing the final study reports, the ISS and the ISE. (Halvorsen, Tr. 3944-45).

286. All totaled, from 1991 through 1998, Upsher-Smith spent $15-16 million on developing Niacor-SR -- four times as much alone than all other product development projects, and more than 80 percent of Upsher-Smith's total research budget during that period. (Kralovec, Tr. 5010-11; Halvorsen, Tr. 3902, 3995; Troup, Tr. 5475).

287. In September 1998, Upsher-Smith's President and Warrick's President, Mr. Kapur, had a discussion regarding the status of Niacor-SR. (Troup, Tr. 5608; Audibert, Tr. 4158-59; CX 1088 at 006-7). Troup reported that Upsher-Smith was not planning to file its NDA for FDA approval. (CX 1088; CX 1111 at SP 05 006-7; Troup, Tr. 5610). Mr. Troup explained that Upsher-Smith was concerned that Kos's Niaspan product had not been successful, even though Kos had invested considerably more sales and promotion effort in the United States than Upsher-Smith planned. (CX 1088 at SP 05 006-7; Troup, Tr. 5480-81; Audibert, Tr. 4159-60).

288. Based on what he knew at the time, Troup also explained that Niaspan appeared to be marginally better than Niacor-SR. (CX 1111). Upsher-Smith believed that because Niaspan had received the results indications for arteriosclerosis and myocardial infarction and because Niacor-SR would not get those indications without further expensive and time-consuming clinical tests, Niaspan had a market advantage over Niacor-SR. (Kralovec, Tr. 5058-59; Halvorsen, Tr. 3957-60).

289. As Kapur had requested, on October 6, 1998 Paul Kralovec, Upsher-Smith's Chief Financial Officer, provided Kapur written confirmation of Upsher-Smith's decision to suspend its efforts on Niacor-SR. (CX 1111). In the letter, which was also copied to Troup, Kralovec again confirmed the reasons for Upsher-Smith's decision not to proceed with U.S. approval. (CX 1111). He again explained that based on Kos's approval, Upsher-Smith would have been two to three years behind the launch of Niaspan. (CX 1111).

5. Complaint Counsel has not demonstrated that the value of Niacor-SR and the other pharmaceutical products was not $60 million

a. Dr. Levy's criticism of the terms of the license fees

290. Dr. Levy did not prove that the terms of the deal were "grossly excessive" because he performed no quantitative analysis of the value of Niacor-SR. (*See* Levy, Tr. 2055-64). Dr. Levy rejected the standard practice of using discounted cash flows to determine the value of a drug such as Niacor-SR. (Levy, Tr. 2059). As a result, Dr. Levy could not provide testimony as to the value of Niacor-SR — he admitted he could not testify whether a license for Niacor-SR was worth zero, $10 million or $100 million. (Levy, Tr. 2063).

291. Dr. Levy conceded that he had done no quantitative analysis of Niacor-SR. (Levy, Tr. 2057-59). Dr. Levy rejected using net present value ("NPV") analysis to value license opportunities for late stage pharmaceutical products. (Levy, Tr. 2155). He described conducting NPV analysis to determine the value of a pharmaceutical drug as "guesswork" because he believed that one "does not have a clue" as to what the risk factor is and testified that "nobody is going to rely" on such NPV calculations. (Levy, Tr. 2155-57). He testified that an NPV analysis of a late-stage pharmaceutical product that was not on the market was "GIGO," which he explained meant "Garbage in, garbage out." (Levy, Tr. 2157).

292. Other witnesses who testified in relation to NPV analysis confirmed its utility in valuing licenses, including Complaint Counsel's own witnesses. Dr. Max Bazerman, Complaint Counsel's expert witness, testified that in his 15 years of meetings with pharmaceutical executives, none have ever expressed the view that "discounted cash flows are junk or garbage or worthless or words to that effect." (Bazerman, Tr. 8555). Complaint Counsel's expert Professor Bresnahan confirmed that NPV determinations are used to value a stream of payments and that NPV analysis is a common concept in economics and finance. (Bresnahan, Tr. 662). Upsher-Smith's expert Dr. William Kerr testified that NPV analysis is "the most common method for valuing intellectual property." (Kerr, Tr. 6277-78). Schering's expert Dr. Zola Horovitz explained that the purpose of a net present value analysis calculation is to determine what a project will return as far as profits and cash flow to a company. (Horovitz, Tr. 3615). Horovitz testified that he conducted an NPV analysis based on the information Upsher-Smith provided to Schering and concluded that Schering could have paid up to $100 million for the Niacor-SR license. (Horovitz, Tr. 3612-13).

293. Not only did Dr. Levy not perform a financial evaluation of Niacor-SR, he did not do a financial evaluation of any of the five other products licensed to Schering. (Levy, Tr. 2059). Dr. Levy admitted that he did not know as to each of the five other products licensed under the June 17 Agreement whether each product was worth zero, $10 million or $100 million. (Levy, Tr. 2062-63). Dr. Bresnahan concedes that each of these 5 other products had value for Schering. (Bresnahan, Tr. 951, 953, 956).

294. Dr. Levy admitted that he also did not do any valuation analysis on the production or supply rights for the six licensed products that Upsher-Smith granted to Schering in Paragraphs 7-10 of the license agreement. (Levy, Tr. 2059-63). In fact, Dr. Levy was unaware that Schering had received any production rights from Upsher-Smith under the agreement. (Levy, Tr. 2059-60).

295. Dr. Kerr, Upsher-Smith's valuation expert, performed a valuation of the drugs licensed in the June 17 Agreement other than Niacor-SR and determined that they were worth $10.1 million as of June 1997. (Kerr, Tr. 6300-02).

296. Instead of offering an opinion on the value of the license fees, Dr. Levy testified only that the fees were "grossly excessive." This conclusion was based in part on his belief that the $60 million

up-front payment was larger than any previous license fee in the history of the pharmaceutical industry. (Levy, Tr. 1329-30). A comparison of the payment terms of various deals requires more than an isolated consideration of the up-front license fees. In performing his up-front-payments-only analysis, Dr. Levy ignored provisions relating to how the parties agreed to split future revenues generated from the product and ignored Schering's consideration of its costs to bring the product to market. (Levy, Tr. 1337, [*Tr. 1464-66*]; CX 1604).

297. **[redacted redacted]** *(Levy, Tr. 1329; SPX 92 at SP 00195)*. **[redacted redacted redacted]** *(Levy, Tr. 1329)*. **[redacted redacted redacted]** *[(Lauda, Tr. 4595; CX 1402 at SP 074847)]*, **[redacted redacted]** *[(CX 1468 at SP 074431-32)]*, **[redacted redacted]** [*(CX 1468 at SP 074433)*]. **[redacted redacted]** [*(Lauda, Tr. 4450-51)*], **[redacted redacted]** [*(CX 1397 at SP 06958)*]. **[redacted]**

298. As noted by Mr. James Egan, Complaint Counsel's rebuttal witness from Searle Pharmaceuticals, there is risk involved in making a large up-front payment (Egan, Tr. 7983). **[redacted redacted redacted redacted]** [*(CX 1338 at SPCID2 ID 12723)*]. **[redacted redacted]** [*(Lauda, Tr. 4512-13)*], **[redacted redacted redacted].** [*(Lauda, Tr. 4599-4601)*].

299. In evaluating a licensing opportunity, Schering analyzes the total investment required to bring a product "to a state of registration," which includes (1) research and development expenditures required to bring a product to the approvable stage; and (2) payments that are contingent upon pre-approval events, such as successful completion of phase II studies. (Lauda, Tr. 4365-66). With the results of the Phase III clinical trials already in Schering's hands, Niacor-SR was much further along in development than most of the other Schering deals analyzed by Dr. Levy. [*(Levy, Tr. 1464-65)*]; CX 1604; [(*Lauda, Tr. 4405, 4468)*]; SPX 2267; Horovitz, Tr. 3766). **[redacted redacted redacted**

redacted] [*(Lauda, Tr. 4465-68)*];(SPX 2264).

300. Schering also regularly considers economic value when considering an in-licensing opportunity. (Lauda, Tr. 4361-63). The economic value is the estimated economic return Schering expects to realize on a project. (Lauda, Tr. 4362). **[redacted redacted redacted]** [*(Lauda, Tr. 4450-51)*], **[redacted redacted redacted]** [*(Lauda, Tr. 4479, 4481, 4483); CX 1397)*], **[redacted redacted]** [*(Lauda, Tr. 4478-79)*]. **[redacted redacted redacted redacted].** [*(CX 1397 at SP 06958)*] *(SPX 92 at SP 00195)*. [*(Lauda, Tr. 4481-83)*]; *(19 Tr. 4479-83; CX 1397 at SP 069948)*.

ii. Dr. Levy's criticism of Schering's due diligence

301. Dr. Levy testified that, in his opinion, the level of due diligence performed by Schering for Niacor-SR was "strikingly superficial." (Levy, Tr. 1341-42; CX 1597). In explaining how he reached this conclusion, Dr. Levy testified that he had put himself in Schering's position in June 1997 to "try to ascertain what I might have done had I seen what they saw." (Levy, Tr. 1342).

302. In support of his testimony that the due diligence performed for Niacor-SR was "strikingly superficial," Dr. Levy compared the volume of due diligence for Niacor-SR to the volume of due diligence from two other Schering evaluations. [*(Levy, Tr.* 1376-78, *1492, 1516, 1886-87)*]. In selecting his two yardsticks, Dr. Levy concedes that he simply selected these comparators from a "list," and that he did not review "in toto" all 33 license evaluations for which Schering produced documents to Complaint Counsel. [(*Levy, Tr. 1377, 1524)*].

303. Aside from his general criticism of the volume of due diligence performed for Niacor-SR, Dr. Levy identified two specific aspects of due diligence that he believes should have raised concerns for Schering: (1) dietary supplement forms of sustained release niacin had been associated with liver toxicity; and (2) the FDA had requested that Upsher-Smith perform an additional 17-day, single-dose pharmacokinetic ("PK") study in 30 patients. (Levy, Tr. 1317, 1388; Halvorsen, Tr. 4001-03; SPX 0331). However, the liver toxicity issue had already been specifically evaluated by Schering. (Audibert, Tr. 4119-22). Also, Dr. Levy described the requirement of a PK study as follows: "Doing a pharmacokinetic study in Schering-Plough is like falling off a log. I mean they do them routinely." (Levy, Tr. 1388). Lauda testified that the PK study was, at best, a very minor issue that would not even have "caused a blip on the radar." (Lauda, Tr. 4516-17, 4421). Moreover, at the time of the license

agreement for Niacor-SR, Upsher-Smith had already built the PK study into the December 1997 NDA filing timetable upon which Schering relied. (Horovitz, Tr. 3728, 3793-94).

304. The amount of due diligence that Schering performs in evaluating a licensing opportunity depends on the nature of the opportunity. (Russo, Tr. 3432-33; [*Lauda, Tr. 4574*]). Schering does not use any standard approach in evaluating a licensing opportunity. (Russo, Tr. 3432-33). Generally, the higher the risk involved with a particular product, the more involved Schering's review process will be. (Russo, Tr. 3432-33).

305. Unlike other products Schering has evaluated, Niacor-SR was a very straightforward product in a market with which Schering was intimately familiar. [*(Lauda, Tr. 4599-4601)*]; Audibert, Tr. 4093-98, [*4299-4304*], 4137). Niacor-SR was a late stage Phase III product, and Schering was able to conduct its evaluation on the basis of the results of the Phase III pivotal trials. (Audibert, Tr. 4113-14; [*Lauda, Tr. 4599-4600*]; Horovitz, Tr. 3682, 3717; CX 1042). Niacor-SR's active ingredient, niacin, is an old and well-known compound with an established product profile. (Audibert, Tr. 4137-38; [*Lauda, Tr. 4599-4600*]; Horovitz, Tr. 3681). Niacor-SR had "proof of principle" in that niacin has long been known to be effective in the treatment of high cholesterol, the exact indication targeted for Niacor-SR. (Audibert, Tr. 4116-17; [*Lauda, Tr. 4599-4600*]. In fact, as a result of niacin's known efficacy profile, the FDA had advised Upsher-Smith during the development of Niacor-SR that "there is no question that niacin is effective," and that "efficacy was considered almost a non-issue." (CX 1376 at Upsher-Smith FTC 127098; CX 1371). On the basis of these considerations, Dr. Horovitz testified that in evaluating a drug like Niacor-SR, he would expect that a knowledgeable person could perform the requisite due diligence more quickly than would be the case with other licensing evaluations. (Horovitz, Tr. 3682).

306. Audibert was already familiar with cholesterol lowering drugs – including niacin – as a result of his detailed evaluation of the cholesterol lowering market as part of his work on Schering's blockbuster pipeline drug, ezetimibe. (Audibert, Tr. 4095-4100). Niacor-SR was a known drug reformulated using sustained release technology to overcome a known side effect, a method of development with which Audibert had gained substantial expertise throughout his career. (Audibert, Tr. 4082-89; Horovitz, Tr. 3679-80). Audibert knew from his evaluation of Kos' Niaspan just months earlier that the FDA was on the verge of approving another sustained release niacin, and the results of the pivotal trials for Niacor-SR confirmed that Upsher-Smith had similarly succeeded in developing a safe and effective sustained release niacin. (Audibert, Tr. 2453-54 (Audibert Dep.); [*Lauda, Tr. 4512-13*]; Horovitz, Tr. 3679-80).

307. Based on Audibert's evaluation of Niacor-SR, Schering did not believe that additional due diligence was required. [*(Lauda, Tr. 4516*]; Audibert, Tr. 4137).

308. Dr. Levy was unfamiliar with the National Cholesterol Education Program ("NCEP"), which sets the nationally accepted guidelines for cholesterol lowering in the United States and which

were relied on throughout the Kos and Upsher-Smith niacin research documents and studies. (Levy, Tr. 8404-05). Dr. Levy also demonstrated his unfamiliarity with the leading studies relating to niacin. (Levy, Tr. 8401-03, 8406).

309. Dr. Levy was mistaken in both his expert report and his trial testimony as to the type of PK study Upsher-Smith needed to complete to get its NDA for Niacor-SR approved — he was under the misimpression that a multiple dose PK study was required. In fact, by March 1997 the FDA had confirmed that Upsher-Smith only had to perform a single-dose PK study. (Levy, Tr. 2182-83; CX 917 at 107426; USX 281).

310. Dr. Levy admitted that he had not seen (and therefore had not considered) the 200-plus page final methods validation report for the Niacor-SR PK test that the CRO had been developing between summer 1997 and fall of 1998. (Levy, Tr. 2131; SPX 333 (methods validation report); Halvorsen, Tr. 3943-45 (describing MDS Harris work on report); USX 556 (December product update cited by Levy stating "MDS Harris will complete work through method validation")).

311. At the time he testified, Dr. Levy believed Upsher-Smith had only conducted the two Phase III pivotal clinical studies and was unaware that Upsher-Smith had also conducted the two longer term follow-on Phase III studies, the 900837 and the 920944 studies. (Levy, Tr. 2079-80).

312. When asked whether he took into account any follow-on studies, Dr. Levy indicated he had focused on the materials provided to Schering and believed he knew what Schering knew at the time about the status of Upsher-Smith's clinical studies. (Levy, Tr. 2079-80). However, all four clinical studies are referenced in the confidential presentation Upsher-Smith provided to Schering -- including the two follow-on studies -- and the presentation indicated that Upsher-Smith had completed or was completing the final study reports for all four. (CX 1042 at 0079). Dr. Levy conceded on cross-examination that all four reports were referenced in the materials Schering received. (Levy, Tr. 1830-31).

313. In his expert report, Dr. Levy stated that the elevated liver enzyme levels indicated in the package Schering received from Upsher-Smith "would have mandated a detailed examination of the effects of Niacor-SR on the liver prior to any consideration of in-licensing the drug. Such detailed examination, in my opinion, would have included at least: Examination of liver biopsies in patients treated with Niacor-SR . . ." (Levy, Tr. 1785-99). A liver biopsy is performed by inserting through the skin of the subject a seven-inch hollow needle, approximately 18-gauge, with a bore on the point that fills the bore of the needle. (Levy, Tr. 1785-99). The needle is pushed through into the liver, a chunk of the liver is removed using suction, and then the needle is removed. (Levy, Tr. 1795-96).

314. To perform such liver biopsies, Upsher-Smith would have been required to track down patients who had completed the study years earlier and re-dose those patients in an attempt to replicate those elevations, and then perform a surgical procedure to remove a piece of the patients' livers to

determine whether that re-dosing had caused liver damage. (Levy, Tr. 1786-87, 1796-97). Dr. Levy testified at his deposition that it would have been "quite reasonable" for Schering to ask Upsher-Smith to do this. (Levy, Tr. 1786-87). During cross-examination, however, Dr. Levy admitted that he "probably overstated" the opinion expressed in his expert report and deposition testimony regarding the requirement of liver biopsies. (Levy, Tr. 1790, 1793, 1798-99). Dr. Horovitz explained his experience with the clinical trials for one of the statins where a Japanese company had inquired about the possibility of taking liver biopsies of patients during the clinical trials, and the FDA considered that request "ridiculous." (Horovitz, Tr. 3708).

iii. Dr. Levy's criticism of the post deal conduct

315. Dr. Levy testified that his opinion that the "$60 million was not for Niacor-SR" rests in part on the fact that after the June 17, 1997 licensing transaction neither party showed any serious interest in marketing Niacor-SR. (Levy, Tr. 1822-23). In his report, Dr. Levy wrote that there were almost no communications between Schering and Upsher-Smith after the execution of the agreement. (Levy, Tr. 2079-80).

316. Levy's conclusion in his report and testimony that there were almost no communications between Schering and Upsher-Smith following the June 17, 1997 Agreement is contrary to the record evidence. (Levy, Tr. 2079-80). There were no fewer than 2 meetings and 21 other documented communications between Schering and Upsher-Smith in 1997 after Upsher-Smith and Schering's licensing agreement and the record indicates it is likely there were other undocumented telephone calls. The communications continued into 1998. (F. 262-65).

317. Dr. Levy admitted that in reaching his opinion regarding Upsher-Smith's post-June 1997 efforts on Niacor-SR, he had not reviewed any of the more-than 80 minutes and agendas documenting the more-than 40 teleconferences Upsher-Smith had held with the CROs between June of 1997 and May of 1998 contained in USX 1178 through USX 1266. (Levy, Tr. 2099-2102, 2127). Those minutes detail the ongoing work being done by Upsher-Smith and the CROs to finalize the individual study reports, to compile the ISS/ISE and to wrap up the project. (Levy, Tr. 2099-2102, 2127). Those ClinTrials teleconference minutes and agenda memorialize that in December of 1997, Upsher-Smith had informed ClinTrials that Upsher-Smith was not going forward with filing the NDA, but that its European partner (Schering) might be proceeding. (USX 1259 at 093868; USX 1260 at 093790).

318. Based on the mistaken belief that Upsher-Smith had stopped its clinical work on Niacor-SR, Dr. Levy testified it was his belief that the Upsher-Smith went almost a year without telling Schering that Upsher-Smith had decided not to pursue its U.S. submission -- a decision Dr. Levy found "inconceivable." (Levy, Tr. 1394). Dr. Levy admitted, however, that he had been unaware of the ClinTrials documents indicating not only that Upsher-Smith had continued the clinical work into May of 1998, but that Upsher-Smith understood in March of 1998 that Schering was not going forward with its European submission. (Levy, Tr. 2099-2102, 2127; USX 1259 at 093868; USX 1260 at 093790).

b. Professor Bresnahan

319. Complaint Counsel offered the testimony of Professor Timothy Bresnahan, Professor of Economics. Bresnahan did not perform an economic valuation of any of the drugs licensed from Upsher-Smith to Schering. (Bresnahan, Tr. 950-57). He did not do a valuation analysis of Niacor-SR, pentoxifylline, Prevalite, the Klor Con products, or the supply agreement. (Bresnahan, Tr. 950-57). Professor Bresnahan also did not challenge the Niacor-SR sales projections, estimated cost of goods sold, net profit, or the economic value of $225 - 265 million presented to Schering's Board of Directors. (Bresnahan, Tr. 975-78). Instead, Bresnahan utilized a "revealed preference" test and a market test to opine on the value of Niacor-SR. (F. 320-22).

i. The "revealed preference" test

320. Professor Bresnahan applied the "revealed preference" test to opine that the $60 million payment was not for the Niacor license. Professor Bresnahan's opinion was that Schering's decision not to pay Kos for the right to co-market Niaspan revealed that Schering would not pay $60 million for a license for any sustained-release niacin product. (Bresnahan, Tr. 582, 596-98; CX 1578).

321. Schering's decision to discontinue discussions with Kos with respect to a potential co-marketing arrangement was made for reasons that did not apply to its license transaction with Upsher-Smith. First, Schering was to receive at most half the profits from sales of Niaspan. As Professor Bresnahan conceded, this meant that the projected NPV of Schering's interest in Niaspan profits was $127 million. (Bresnahan, Tr. 1115-16; CX 558; Russo, Tr. 3529-30). On the other hand, Schering was to receive all of the Niacor-SR sales after deducting a small royalty. (Levy, Tr. 1329; SPX 92 at SP 00195). As Professor Bresnahan conceded, the projected NPV of Schering's interest in the Niacor-SR sales was $225-$265 million. (Bresnahan, Tr. 1117; [*Lauda, Tr. 4478-79*]; SPX 26 at SP 16 00275). Second, Kos' demands from a co-promotion arrangement were high. Kos insisted that under any arrangement Schering would have to guarantee a significant number of primary details for Niaspan. (Patel, Tr. 7531, 7554; CX 769). Kos also wanted guarantees with respect to the level of sales call activity. (Russo, Tr. 3451). Third, Kos wanted to retain most of the control over how the product was marketed. (Bresnahan, Tr. 1112). Fourth, Kos insisted on booking sales or making Schering pay money in order to book sales. (Patel, Tr. 7556). And fifth, the Kos people were proving to be very difficult to work with. (Bresnahan, Tr. 1122).

322. The substantial, reliable evidence presented by Schering demonstrates legitimate, credible reasons for Schering's preference of a licensing deal with Upsher-Smith over a co-marketing arrangement with Kos. (F. 217-19). This evidence refutes the conclusion Professor Bresnahan reached using his "revealed preference" test. (F. 320-21).

ii. The market test

323. Professor Bresnahan testified that he applied a "market test" to prove that the $60 million was a payment for delay, and not for Niacor-SR. Professor Bresnahan's theory was that because no other company had made Upsher-Smith an offer that included a substantial non-contingent payment for the licenses, the "market test of the $60 million payment is failed." (Bresnahan, Tr. 601-02). Bresnahan's conclusion that the Niacor-SR license was not worth $60 million was based on his application of this "market test."

324. Professor Bresnahan had never before applied this market test in the context of pharmaceutical licensing, and he did not understand, when he applied it, how Schering normally goes about deciding what to pay for a license. (Bresnahan, Tr. 1125). When applying his market test, Professor Bresnahan did not know whether Schering customarily knew or cared what other companies were bidding for a product. Lauda explained, there is never a "market price" for a licensing opportunity. Schering generally does not know what other companies are bidding, and Schering's determination of how large a bid to make is driven by the company's own internal assessments. (Lauda, Tr. 4374-75). Complaint Counsel's rebuttal witness, Egan, (Searle) testified that one company may value a licensing opportunity differently from another. (Egan, Tr. 7964). These differences in valuation are attributable to varying subjective criteria. (Egan, Tr. 7964).

325. During the 30 days preceding Schering's license of Niacor-SR, Upsher-Smith had received expressions of interest from a number of European companies. (Halvorsen, Tr. 3970-73). At the conclusions of the June meetings in Europe, those companies indicated that they would review Niacor-SR and contact Upsher-Smith, but not within the following month. (Halvorsen, Tr. 3974).

326. The substantial, reliable evidence presented by Schering demonstrates the factors Schering considered in valuing the Niacor-SR licence. (F. 243-57). The evidence presented by Schering that Niacor-SR was worth $60 million to Schering in June 1997 refutes the conclusion Professor Bresnahan reached using his market test.

H. ESI's Micro-K20 and Patent Litigation

1. ESI's ANDA and the initiation of patent litigation

327. In 1995, ESI Lederle, Incorporated ("ESI"), a division of American Home Products ("AHP") sought approval from the FDA to market Micro-K20, a generic version of Schering's sustained release potassium chloride tablet, K-Dur 20. (SPX 678; Miller, Tr. 3320). On December 22, 1995, ESI submitted an ANDA to the FDA that referenced K-Dur 20 and contained a Paragraph IV certification to Schering's '743 patent. (Schering Answer ¶ 51; AHP Answer ¶ 51).

328. On December 29, 1995, ESI notified Schering of its Paragraph IV certification containing data from a bioequivalent study demonstrating Micro-K 20's bioequivalency to Schering's

K-Dur 20 tablets. (CX 419 at SP 06 00052; Schering Answer ¶ 51). The notification letter stated that the '743 patent would not be infringed by the AHP generic product since it "[did] not contain potassium chloride crystals coated with a mixture of ethylcellulose and hydropropylcellulose or with a mixture of ethylcellulose and polyethylene glycol, as disclosed and claimed in U.S. Patent 4,863,743." (CX 419 at SP 06 00052; SPX 678 at 1).

329. On February 16, 1996, within 45 days of receiving this letter, Schering's Key Pharmaceuticals division sued ESI for "willful and deliberate" infringement of the '743 patent, as contemplated under 21 U.S.C. § 355(j)(5)(B)(iii). (Miller, Tr. 3319-20). Schering sought an injunction in the U.S. District Court for the Eastern District of Pennsylvania that would have prevented ESI from marketing its generic version of K-Dur 20 for the remaining life of the '743 patent. (Miller, Tr. 3319-21; SPX 679).

330. ESI filed an answer and counterclaim for a declaratory judgment, alleging non-infringement and invalidity of the '743 patent. (SPX 680).

331. No evidence or testimony was offered to show that Schering's filing of the patent litigation against ESI was not initiated for the legitimate purpose of defending its patent.

2. Settlement Negotiations

332. The parties first began discussing a possible settlement of the case in October 1996. (Herman, Tr. 2487). At a status conference, the presiding judge, Judge DuBois, suggested that the parties participate in a mediation session with a U.S. magistrate judge. (Herman, Tr. 2487). On October 16, 1996, both Key and ESI agreed to participate in mediation. (Herman, Tr. 2495; SPX 73). The magistrate judge appointed to participate in the mediation was Judge Rueter. (Herman, Tr. 2486). The mediation process with Judge Rueter ultimately lasted approximately 15 months. (Herman, Tr. 2486).

333. Throughout the course of the litigation between Schering and ESI, Judge DuBois made it clear that he wanted the parties to settle the case. (SPX 1222 at 53:13-25 (Alaburda I.H.)). Judge DuBois brought up settlement every time he talked to the parties, usually as the first order of business. (SPX 1222 at 73:3-16 (Alaburda I.H.)).

334. The parties participated in a settlement conference on November 19, 1996 in Judge Rueter's chambers. (Herman, Tr. 2497; SPX 77).

335. On December 10, 1996, Schering proposed to ESI that they enter into a co-promotion venture in which Schering and ESI would jointly fund and manage a third-party workforce in marketing K-Dur 20. (Herman, Tr. 2503-04; CX 1482 at 67 (Alaburda I.H.); CX 1494 at 101 (Driscoll I.H.); SPX 76).

336. ESI rejected the proposal on February 20, 1997, stating that, as a generic manufacturer, ESI did not have a sales and detail force capable of selling and marketing K-Dur 20. (Herman, Tr. 2504; CX 1482 at 70 (Alaburda I.H.); CX 1492 at 56 (Dey I.H.); CX 457).

337. Eight days later, on February 28, 1997, another mediation session took place in Judge Rueter's chambers. (Herman, Tr. 2504; SPX 1202).

338. Following the February 1997 mediation session, the parties continued to discuss settlement proposals. On March 12, 1997, Judge DuBois sent a letter to counsel stating that he understood from Judge Rueter that settlement negotiations were continuing, and expressing his hope that the parties would settle. (Herman, Tr. 2513; SPX 1198).

339. On March 19, 1997, Mr. Paul Heller, ESI's outside counsel, wrote Mr. Anthony Herman, Schering's outside counsel, a letter stating that he had been advised that Schering's copromote proposal "raises considerable antitrust risks." (Herman, Tr. 2513; CX 458). The letter noted, again, that ESI was amenable to an arrangement whereby Schering would pay ESI and ESI would receive a license to enter the market in the future. (Hoffman, Tr. 2659-60; CX 458). Schering explained to ESI that this proposal was unacceptable. (Hoffman, Tr. 2631-32).

340. On April 18, 1997, Herman sent a letter to Judge Rueter on behalf of both Schering and ESI reporting on the state of the settlement efforts as being at "a standstill." (Herman, Tr. 2514; CX 459; CX 1492 at 129 (Dey I.H.)).

341. On August 20, 1997, Judge Rueter held a third mediation session in his chambers. (Herman, Tr. 2515; SPX 552).

342. Following the August 20, 1997 mediation session, on September 24, 1997, Heller sent a letter to Herman. (Herman, Tr. 2519; SPX 94). That letter projected the amount of profits that ESI believed it would earn if it were to win the case. (Herman, Tr. 2519; SPX 94, at SP 13 00004). ESI projected that, with the simultaneous launch of three generic versions of K-Dur 20, ESI's generic would earn over $15 million in sales in the first year on the market. (SPX 94, at SP 13 00004). ESI projected that its generic version of K-Dur 20 would earn over $25 million in sales in its second year on the market, over $28 million in its third year on the market, over $24 million in its fourth year on the market, and over $23 million in its fifth year on the market. (SPX 94, at SP 13 00004).

343. Schering was willing to discuss other opportunities that were mutually beneficial to the parties apart from an outright payment to ESI. (Kapur, Tr. 1431; SPX 1242 at 125-27 (Kapur Dep.)). Mr. Martin Driscoll, then Vice President of Marketing and Sales for Key, discussed several such opportunities with ESI, including co-marketing Schering's products. (CX 1510 at 140 (Kapur I.H.); Kapur, Tr. 1431).

344. On October 14, 1997, Dr. Michael Dey, CEO of ESI, wrote a letter to Kapur, the head of Schering's generic division, to discuss a proposal for ESI to license several products to Warrick for overseas sale. (Herman, Tr. 2519; CX 465; CX 1482 at 121-24 (Alaburda (I.H.)). Those two products were enalapril and buspirone. (Herman, Tr. 2519-20; CX 1482 at 122-23 (Alaburda I.H.); SPX 1242 at 125-27 (Kapur Dep.)).

345. The next mediation session occurred on October 27, 1997 in Judge Rueter's chambers. (Herman, Tr. 2520). No settlement between the parties was reached that session. (Hoffman, Tr. 2618; Herman, Tr. 2520).

346. Another settlement conference was scheduled for November 17, 1997. (CX 468). On November 12, 1997, Herman sent Judge Rueter a letter expressing Schering's position that it would be a waste of the Court's and the parties' time to proceed with the scheduled settlement conference. (Herman, Tr. 2521; CX 468). At that point, ESI had told Schering that it was no longer interested in a co-promotion arrangement. (Herman, Tr. 2522; CX 468). This was the last time the copromote concept was raised. (Herman, Tr. 2522). The letter informed Judge Rueter that ESI had stated it was unwilling to agree to Schering's copromote proposal because of antitrust concerns. (Herman, Tr. 2522; CX 468). ESI responded that although ESI was not interested in a co-promote, the parties were considering separate licensing opportunities. (SPX 1195).

347. Herman's letter also addressed Schering's concerns that ESI lacked a potentially marketable product, informing Judge Rueter that Schering was unwilling to make another settlement offer until ESI demonstrated that it has a bona fide 20 milliequivalent potassium chloride product that, but for the lawsuit, would receive FDA approval. (Herman, Tr. 2522; CX 468).

348. The proposed November 17, 1997 settlement conference was postponed. (Herman, Tr. 2521).

349. ESI then provided Schering with information related to the current FDA approval status of ESI's proposed generic version of K-Dur. (Herman, Tr. 2523; SPX 82). On December 15, 1997, Mr. Herman summarized this information in a letter to ESI's counsel. Mr. Herman's December 15, 1997 summary noted the difficulties ESI had up to that point in trying to obtain FDA approval for its proposed generic version of K-Dur 20. The main problem ESI had involved a study included in the ANDA designed to demonstrate ESI's proposed generic was bioequivalent to K-Dur 20. (CX 469; Herman, Tr. 2523). The bioequivalence study had been performed in 1989. (CX 469; Herman, Tr. 2523-24). The FDA found five different deficiencies with regard to the study. (CX 469; Herman, Tr. 2523-24). ESI did not respond to the FDA regarding the deficiencies until May 14, 1997. (CX 469; Herman, Tr. 2524). On August 6, 1997, FDA rejected ESI's response to the five deficiencies in ESI's bioequivalence study. (CX 469; Herman, Tr. 2524). ESI began a new bioequivalence study on December 8, 1997, a week before the December 15, 1997 summary. (CX 469; Herman, Tr. 2524).

350. Two days later, in a December 17, 1997 letter from Schering to ESI, Schering proposed to settle the lawsuit by providing ESI with a license to market ESI's proposed generic version of K-Dur, effective December 31, 2003. (Hoffman, Tr. 2638-39; Herman, Tr. 2525; CX 470).

351. The December 17, 1997 letter stated:

> We propose to settle the case based on the following:
>
> (1) Schering shall grant ESI a royalty-free license under the '743 patent to make, use, offer for sale and sell its Micro-K 20 potassium chloride product in the United States effective December 31, 2003. Until that date, ESI shall not make, use, offer for sale or sell its micro-K product.
>
> (2) ESI will acknowledge infringement and validity of the '743 patent in a consent judgment.

(CX 470; Herman, Tr. 2525-26).

352. In the same December 17, 1997 letter, Schering also proposed that:

> As an additional matter, ESI shall grant Schering, including its designee, exclusive licenses for buspirone, enalapril, and three other products under development by ESI to be mutually agreed upon by the parties. . . . In exchange for the licenses described in the unnumbered paragraph above, Schering shall pay ESI an up-front payment of $5 million and a 5 percent royalty on annual sales for ten years post-approval.

(CX 470; Herman, Tr. 2526).

353. ESI responded to Schering's offer on December 22, 1997, accepting the December 31, 2003 entry date:

> The general structure of your December 17 proposal is acceptable with the following modifications. The effective date of the license under the '743 patent should be December 31, 2003, or whenever a generic is placed on the market, whichever occurs earlier. . . . ESI will be able to market in the United States if the '743 Patent is invalidated or rendered unenforceable by another party.

(CX 473; Herman, Tr. 2527; Hoffman, Tr. 2639). ESI also agreed to acknowledge validity and enforceability of the '743 patent, but would not acknowledge that its product infringed. (Herman, Tr. 2528; CX 473).

354. The date of December 31, 2003 referred to in the letters differs from the date for ESI's product entry in the final agreement by one day. (Herman, Tr. 2525; CX 470; CX 473; CX 479). In the final agreement, the date agreed upon for ESI's product entry was January 1, 2004. (Herman, Tr. 2525; CX 479).

355. ESI also agreed, in its December 22, 1997 letter, to grant licenses to Schering for buspirone, enalapril, and three other products to be agreed upon. (Herman, Tr. 2528; CX 473; CX 1509 at 70 (Hoffman Dep.)). ESI countered with an initial $5 million payment, to be followed by further payments upon the FDA's issuance of an approval letter for ESI's ANDA and thereafter for a total of $55 million on an agreed-upon time schedule. (Hoffman, Tr. 2528; CX 473). This represents a $50 million difference from Schering's offer. (Herman, Tr. 2528; CX 470; CX 473). ESI also proposed a royalty rate of 50 percent of gross profit for the licenses to Schering, as opposed to Schering's proposal of 5 percent of annual sales. (Herman, Tr. 2528-29; CX 473; CX 470).

3. Settlement agreement in principle

356. Between the time of the December 22, 1997 correspondence and January 23, 1998, the date Schering and ESI reached an agreement in principle, Schering and ESI had agreed on a January 1, 2004 date of entry for ESI. (Hoffman, Tr. 2640, 2619-20, 2638; CX 1509 at 70 (Hoffman Dep.); Herman, Tr. 2532-33). Schering told ESI that January 1, 2004 was as far as Schering would go. (CX 1482 at 99-100 (Alaburda I.H.); SPX 1222 at 101 (Alaburda I.H.); CX 1492 at 136-37 (Dey I.H.)). Schering made it very clear to ESI that "that was it. That was as far as they would go, and there wouldn't be any further negotiating on that point." (CX 1482 at 99-100 (Alaburda I.H.); SPX 1222 at 101 (Alaburda I.H.)).

357. The final mediation sessions occurred on January 22 and 23, 1998, in conjunction with a Markman hearing held on January 21 and 22, 1998. (Herman, Tr. 2529). A Markman hearing is a hearing at which evidence is taken and argument is heard so that the Court can interpret the claims of the patent at issue in the lawsuit. (Herman, Tr. 2529).

358. On January 22, 1998, the second day of the Markman hearing, the Court finished hearing evidence at around 1 p.m. (SPX 687, at ESI HRG 000126-27). The parties had another settlement conference with Judge Rueter scheduled for 2 p.m. (SPX 687, at ESI HRG 000126-27). The parties spent about three and a half hours in the January 22, 1998 settlement conference with Judge Rueter. (SPX 687, at ESI HRG 000128).

359. On January 23, 1998, the parties had another settlement conference with Judge Rueter.

(Herman, Tr. 2529). The session concluded about 11:30 p.m., when an agreement in principle was reached. (Herman, Tr. 2529, 2531-32).

360. At the January 23, 1998 meeting, for Schering, were Mr. Herman and Ms. Susan Lee, Director of Patent Litigation. For ESI, were Mr. Heller and Dr. Dey. (Herman, Tr. 2532). During the evening, there were also calls between Judge Rueter and John Hoffman of Schering, who was at home, and between Judge Rueter and Mr. Driscoll, who was on his cellular phone at a New Jersey Nets basketball game with his sons. (Hoffman, Tr. 2603, 2618-19; 2629; Herman, Tr. 2532; Driscoll, Tr. 2706).

361. Before the January 23, 1998 mediation conference, the date of market entry for ESI's generic product had been agreed to in principle as January 1, 2004. (Hoffman, Tr. 2640, 2619-20, 2638; Herman, Tr. 2532-33). The parties had also agreed in principle that Schering would license generic enalapril and buspirone from ESI for $15 million. (Herman, Tr. 2532; Hoffman, Tr. 2620).

362. During the meeting, ESI insisted on additional payments. (Herman, Tr. 2533). Mr. Herman took the position that Schering was not going to pay any more money, and that it wanted to try the case. (Herman, Tr. 2533). Schering eventually agreed to pay ESI $5 million to settle the case. (Hoffman, Tr. 2620; Herman, Tr. 2534). ESI continued to insist on another $10 million. (Herman, Tr. 2535).

363. Driscoll, testified that he came up with a concept under which Schering would not have to pay ESI any money if ESI could not obtain approval of its ANDA product. If ESI received approval for its ANDA by a date certain, Schering would make a certain payment. (Driscoll, Tr. 2712; CX 1494 at 110 (Driscoll I.H.); Hoffman, Tr. 2620-21; CX 1492 at 156-57 (Dey I.H.)). If the date was later, it would be a lesser payment. (Driscoll, Tr. 2712; CX 1494 at 110 (Driscoll I.H.); Hoffman, Tr. 2620-21). Driscoll ultimately agreed that Schering could make certain payments, consisting of $10 million if ESI's ANDA were approved by July, $5 million if it were approved 6 months later, with further decreasing payments. (Driscoll, Tr. 2712).

364. When Driscoll made this commitment, he believed that Schering would not have to pay it. (Driscoll, Tr. 2713, 2722; CX 1509 at 104 (Hoffman Dep.); CX 1482 at 109 (Alaburda I.H.)).

365. Judge Rueter asked the parties to write up the terms and initial or sign them that night. (Hoffman, Tr. 2621). In the secretarial area of Judge Rueter's chambers, Heller, counsel for ESI, hand wrote out the settlement principles with Schering's representatives. (Herman, Tr. 2537, 2488; CX 472).

366. The two-page handwritten agreement in principle, dated January 23, 1998, was signed by Mr. Heller, for ESI, and for Key by Ms. Susan Lee, who was the director of patent litigation for Schering. (Herman, Tr. 2488-89; CX 472).

367. The January 23, 1998 handwritten agreement in principle states that Schering would grant ESI a license under its K-Dur patent beginning on January 1, 2004. (CX 472).

368. The January 23, 1998 handwritten agreement, states that ESI grants to Schering the right to market ESI's generic versions of enalapril and buspirone in Europe. (CX 472). The handwritten agreement also states that Schering would provide $10 million to ESI upon the signing of the settlement agreement, and $10 million split into equal monthly installments to be paid over seven and a half years. (CX 472). In addition, the handwritten agreement states that Schering would pay ESI an amount between $625,000 and $10 million, depending on the date of FDA approval of ESI's generic version of K-Dur 20. (CX 472).

369. Immediately after the agreement in principle was reached on January 23, 1998, the district judge conditionally dismissed the case. (Hoffman, Tr. 2651-52).

4. Final settlement agreement

370. Ms. Somerville, ESI's outside counsel, later sent a more formal draft agreement to Mr. Herman, accompanied by a transmittal letter. (Herman, Tr. 2538; CX 478). That initial draft does not accurately reflect what the parties agreed to that evening with Judge Rueter. (Herman, Tr. 2539; SPX 1266 at 181-82; CX 478). Paragraph 16 of the draft characterizes all the payments as royalty payments, when only $15 million of the $30 million were royalty payments. (Herman, Tr. 2539; CX 478).

371. This error was corrected in the final drafts of the agreements. (Herman, Tr. 2539; CX 479; CX 480). The final drafts of the agreements were prepared by Schering's outside counsel, Covington & Burling. (Herman, Tr. 2539). The final agreement was reached in June 1998. (Herman, Tr. 2539; Hoffman, Tr. 2652; CX 479).

372. Under the final settlement agreement, dated June 19, 1998, Schering agreed to pay ESI a $5 million noncontingent payment and an additional $10 million contingent on ESI's FDA approval. (Hoffman, Tr. 2643; CX 479). Schering granted under the '743 patent a royalty free license to ESI effective, January 1, 2004. (Hoffman, Tr. 2643; CX 479).

373. The final settlement agreement also provides that Schering wishes to market in Europe certain pharmaceutical products for which ESI has filed ANDAs with the FDA. (CX 479).

374. As provided in the earlier handwritten agreement, Schering and ESI also entered into a contemporaneous license agreement, dated June 19, 1998, whereby AHP and ESI granted to Schering the licenses to enalpril and buspirone in exchange for $15 million. The license agreement includes a statement that the parties desire to eliminate the uncertainties and costs of the patent litigation between

Schering and ESI over the '743 patent. (CX 479).

375. Schering paid ESI $5 million ten days after the execution and delivery of the June 19, 1998 final settlement agreement. (Schering Answer at ¶ 59). Shortly before the June 1999, $10 million payment deadline, ESI received approval from the FDA. (Hoffman, Tr. 2646). Schering then paid ESI $10 million. (Hoffman, Tr. 2646).

5. Settlement language related to other products

376. The terms of the final settlement agreement that were added after the agreement in principle was reached included: (1) ESI could not market any potassium chloride product that is 'therapeutically equivalent or bioequivalent to, or otherwise substitutable on a generic basis for, K-Dur 10 or K-Dur 20" until January 1, 2004; (2) ESI cannot market more than one new potassium chloride product that is 'therapeutically equivalent or bioequivalent to, or otherwise substitutable on a generic basis for, K-Dur 10 or K-Dur 20" between January 1, 2004 and September 5, 2006; (3) ESI cannot conduct, sponsor, file, or support a bioequivalence study or a substitutability study of a potassium chloride product to K-Dur 10 or K-Dur 20 until Schering's patent expires in 2006; (4) if ESI acquires a business, the new business could not seek FDA approval for a potassium chloride product that is 'therapeutically equivalent or bioequivalent to, or otherwise substitutable on a generic basis for, K-Dur 10 or K-Dur 20" prior to September 5, 2006; and (5) ESI cannot transfer ESI's ANDA. (CX 479).

377. The inclusion of clauses in the settlement agreements that affected ESI's exploitation of products similar to K-Dur 20 for a period of time prevent ESI from making minor, insubstantial modifications to its product and filing another ANDA with an infringing product. (SPX 1228 at 159-60 (Dey I.H.)).

6. Complaint Counsel did not prove that Schering's payment to ESI was a payment to delay entry

378. Complaint Counsel introduced fact evidence only in the form of deposition and investigational hearing testimony of Schering and ESI personnel who negotiated the settlement, and a few documents relating to the settlement negotiations. It offered opinion evidence in the form of about fifteen minutes of testimony about the ESI settlement by Professor Bresnahan. (Bresnahan, Tr. 618-40).

379. Professor Bresnahan testified that to reach a conclusion that the agreement between Schering and ESI delayed competition, he relied upon what he characterized as an "assumption" that if ESI had won its patent suit, it might have been able to enter before March 2002. (Bresnahan, Tr. 620-21). This unfounded opinion, based only on speculation, does not demonstrate that the patent case would have settled any earlier for any reason.

380. Complaint Counsel offered insufficient evidence to show that the $15 million was not

paid for the licenses to enalapril and buspirone. Dr. Levy, Complaint Counsel's valuation expert, was not asked his opinion on the value of enalapril and buspirone. Complaint Counsel offered insufficient evidence of what the fair value of enalapril and buspirone was.

381. Schering has made no sales from either enalapril or buspirone. (Schering Answer at ¶ 56). Schering has been pursuing registration of both enalapril and buspirone in Europe and anticipates filing for approval in 2002. (SPX 1242 at 133-35 (Kapur Dep.)).

382. A statement made in an investigational hearing by Michael Dey, an ESI official involved in the settlement negotiations, that "if Schering had been willing to allow [ESI] onto the market before 2004," ESI "may have" been willing to settle for less money is insufficient to demonstrate that Schering paid ESI only for delay or that the case would have settled sooner for any reason. (Bresnahan, Tr. 632-33 (quoting Dey I.H.)). This is not sufficient to prove payment only for delay.

383. Complaint Counsel offered insufficient evidence to demonstrate that the patent case would have settled without the provision for the product license.

384. Schering's expert witnesses, Robert Mnookin, testified that society benefits when settlements allow the parties to conserve resources and avoid transaction costs, which may include not only legal fees, but also the time and distraction of the parties and their personnel. (Mnookin, Tr. 2675-76.) Mnookin also testified that settlements can mitigate uncertainty and allow the parties to avoid the risks of litigation, thus creating economic efficiencies. (Mnookin, Tr. 2675-76.)

I. Whether Schering's Payments to Upsher-Smith and AHP Were for Delay

385. A patent owner is given the exclusive right to preclude others from making, selling, using or vending the subject matter of the invention covered by the claim. (35 U.S.C. § 271(a); Miller, Tr. 3310-11). To enforce a patent, the patentee is given the right to sue in a federal court for patent infringement. (35 U.S.C. § 271; 28 U.S.C. § 1338; Miller, Tr. 3316).

386. The '743 patent gives Schering the right to "exclude others from making, using, offering for sale, and selling the invention throughout the United States," together with certain additional rights provided in the statute. 35 U.S.C. § 154. The '743 patent expires on September 5, 2006. (Miller, Tr. 3311; SPX 1275 at ¶ 8). Hence, Schering has the right to exclude infringing products from the market until September 5, 2006. (Miller, Tr. 3311).

387. An applicant who has filed an ANDA with a Paragraph IV certification must notify the branded drug manufacturer and the patent holder of the filing of its ANDA, and provide a detailed statement of the factual and legal bases for the ANDA filer's opinion that the patents will not be infringed or are invalid. (21 U.S.C. § 355 (j)(2)(B)(i) and (ii); Hoffman, Tr. 2217-18).

388. Under Hatch-Waxman, the branded drug manufacturer has 45 days after receiving such notice to file a patent infringement suit against the ANDA applicant in order to automatically trigger a stay of FDA approval of the ANDA. If a patent infringement suit is filed within this 45-day window, the FDA cannot give final approval for the ANDA until the earliest of: (1) the date the patent is judicially determined to be invalid or not infringed; (2) a judicial determination of the patent litigation, or (3) the expiration of an automatic 30-month waiting period, which may be extended or shortened by the court. (Hoffman, Tr. 2218; Rosenthal, Tr. 1575-76; 21 U.S.C. § 355 (j)(5)(B)(iii)).

389. The patent holder, if successful in proving that the generic product infringes his patent in the patent infringement litigation, can keep the ANDA from being approved and enjoin the marketing of the generic product until the patent expires. (Miller, Tr. 3316-17; Rosenthal, Tr. 1576).

390. A generic drug company could be involved in patent litigation with the patent holder, and at the end of the 30-month stay of FDA approval receive final approval from the FDA for its product, but still not enter the market given the risks of patent infringement and potential treble damages. (Rosenthal, Tr. 1578-81). There are numerous situations in which companies have not gone to market with their generic alternatives, even though they have FDA approval, specifically out of fear of an adverse ruling in an ongoing patent infringement suit. (Rosenthal, Tr. 1582-87; Kerr, Tr. 6259-60; 6901-02).

391. In November 1998, Upsher-Smith received final FDA approval to market its Klor Con M20 generic version of Schering's K-Dur 20. (Dritsas, Tr. 4902-03). Shortly before June 1999, ESI received approval from the FDA for its generic version of K-Dur 20. (Hoffman, Tr. 2646). However, it would be "foolhardy" for a generic to enter the market while patent litigation is pending because of the potential "very, very severe penalties." Kerr, Tr. 6738. Paul Kralovec, Upsher-Smith's CFO, testified that for Upsher-Smith to have launched Klor Con M20 while the Schering '743 patent challenge was unresolved would have been "financial suicide." (Kralovec, Tr. 5038). ("[I]f we had lost the case, it could have been significant financial obligation for us to pay as far as damages go."). Schering's lead counsel on the patent infringement case brought by Key Pharmaceuticals against ESI Lederle, Anthony Herman, a partner at the law firm of Covington & Burling, testified that in his practice he has never encountered a generic manufacturer who sought to enter the market after the 30-month stay had expired but while patent litigation was ongoing. (Herman, Tr. 2484-2568).

392. Thus, even though Upsher-Smith and ESI had final FDA approval as of November 1998 and June 1999 respectively, it is highly unlikely that either would have marketed on those dates while patent litigation was still pending. (F. 391).

393. There is no way to determine the date or the outcome of the judicial determination of the patent litigation. Schering's expert, Mr. James O'Shaughnessy, a patent trial lawyer testified that patent litigation is by its very nature unpredictable. (CCPTB at p. 71; Miller, Tr. 7065). Schering's patent expert, Mr. Charles Miller testified there is no recognized methodology for handicapping trials or for

testing the reliability of predictions of litigation outcomes. (CCPTB at p. 73; Miller, Tr. 3296). Opinions on the merits of cases that settle before the court decides them can never be tested. (CCPTB at p. 73; Miller, Tr. 3296).

394. Complaint Counsel acknowledges that the outcome of the patent litigation cannot be predicted. (CCPTB at p. 71). Complaint counsel's patent litigation expert, Professor Martin Adelman, testified that patent infringement cases can take up to five years to litigate in some federal district courts, not including appeals. (Adelman, Tr. 7773-74). Intellectual property litigation is more uncertain than other types of litigation. The Federal Circuit, which hears intellectual property appeals, has a 50 percent reversal rate, making it extremely difficult to predict the outcomes of intellectual property litigation. (O'Shaughnessy, Tr. 7065-66).

J. 180 Day Exclusivity Period

1. No firm was actually blocked from introducing a generic 20 mEq potassium chloride supplement

395. Lawrence Rosenthal, Executive Vice President of Sales and Marketing at Andrx testified that Andrx **[redacted]** *(Rosenthal, Tr. 1553, 1591, 1734-35)*. **[redacted redacted redacted]** *(Rosenthal, Tr. 1728-31)*. **[redacted redacted redacted]** *(Rosenthal, Tr. 1735)*.

396. Executives at Upsher-Smith were not aware of any other potential competitors blocked from the market. (Dritsas, Tr. 4667, 4686-87; Troup, Tr. 5494-95).

397. Professor Bresnahan testified that he is not aware of any potential competitors who were blocked from entering the alleged product market for K-Dur 20 as a result of the June 17, 1997 Agreement. (Bresnahan, Tr. 912). Despite the running of the 180-day period, Bresnahan admitted that there were currently three generic 20 mEq potassium tablet products on the market during the period: Warrick (Schering), Klor Con M20 (Upsher-Smith), and Qualitest. (Bresnahan, Tr. 929). Bresnahan also testified that the change in law regarding 180-day exclusivity was not attributable to Upsher-Smith's or Schering's conduct. (Bresnahan, Tr. 982).

398. Complaint Counsel introduced no evidence of any competitor blocked from entry into the market because of Upsher-Smith's 180 exclusivity.

2. The 180-day period was not discussed between Schering-Plough and Upsher Smith

399. The 180-day exclusivity period was never discussed during settlement negotiations between Schering Plough and Upsher-Smith. (Troup, Tr. 5492-93; Hoffman, Tr. 3550-51). Nowhere in Schering or Upsher-Smith documents or in the settlement agreement is the 180-day exclusivity mentioned as a consideration in creating the settlement agreement. (Bresnahan, Tr. 914-17); CX 348; Troup, Tr. 5493).

K. Monopolization

1. Market share

400. In March 1995, seventy-one percent of the potassium chloride prescriptions were for products other than K-Dur 20. (Bresnahan, Tr. 1275; CX 13 at SP 003044). In April 1996, sixty-eight percent of the potassium chloride prescriptions were for products other than K-Dur 20. (Bresnahan, Tr. 1276-1277; CX 746, CX 18). Of total prescriptions between 1994 and 1999, the total number of K-Dur 20 prescriptions was only slightly higher than the total number of generic prescriptions, with K-Dur 20 comprising 25.7% versus the generics' 24.1% (1994); K-Dur 20's 28.4% versus the generics' 27.4% (1995); K-Dur 20's 30.9% versus the generics' 28.9% (1996); K-Dur 20's 33.0% versus the generics' 31.1% (1997); K-Dur 20's 34.8% versus the generics' 32.7% (1998); and K-Dur 20's 35.8 % versus the generics 33.6% (1999). (CX 1389 at SP 23 00016).

401. As reflected in a July 1, 1996 Schering document entitled "K-Dur Marketing Research Backgrounder," K-Dur 20 represented 32 percent of total prescriptions. (CX 746 at SP 2300382). The 1998 K-Dur Marketing Plan represents that the market share for K-Dur 20 as of August 1997 was less than 38 percent. (Bresnahan, Tr. 1279; CX 747 at SP 23 00091).

402. The market share of generic potassium chloride rose as fast or faster than K-Dur 20 in every year from 1997 through 2000. CX 62 at SP 089326 for 1997 generic KCL growth. However, at the time relevant to the Bresnahan test, June 1997, generic potassium tablets/capsules were almost as large in market share as all of K-Dur 20, 31.0% of total potassium chloride prescriptions. (CX 62 at 089327). With K-Dur 20 at 33.0% of total potassium chloride prescriptions, *id.*, other brands of potassium chloride, such as K-Tab, Micro K, Micro-K 10, Klotrix, Kaon-Cl, Klotrix, Klor Con 8 and Klor Con 10, accounted for 27.6% of total potassium chloride prescriptions as of June 1997. Ray Russo testified that generics were a major competitor to K-Dur due to substitution. (Russo, Tr. 3421-2212).

403. Between 1995 and 1999, other Schering documents calculated the market share of K-Dur 20 at between 30 and 40 percent. (Bresnahan, Tr. 1169-70). No Schering documents gave Schering a 100% market share.

404. Schering's market share does not indicate that Schering had monopoly power. (Addanki, Tr. 5719, 5724, 6209; Bresnahan, Tr. 876).

2. Lack of entry barriers and the ability of rivals to expand output

405. Professor Bresnahan did not analyze entry into potassium chloride supplements by Ethex, Apothecon, ESI Lederle, Medeva or Biocraft in 1996 as part of his economic analysis in this case. (Bresnahan, Tr. 8185). Professor Bresnahan did not analyze how long it took these firms to begin selling potassium chloride. *[Bresnahan, Tr. 8185-86]*.

406. As of 1997, there were over 30 products competing in the potassium chloride market, all of which had entered at some point. (Addanki, Tr. 5721-22). A number of new competitors entered the market in recent years. (Addanki, Tr. 5721; Dritsas, Tr. 4715). Several companies entered the potassium chloride market in 1996, including Apothecon, ESI, Medeva and Biocraft. (Dritsas, Tr. 4717; USX 626; USL 15228). Apothecon in particular was a very low-priced competitor with a wide range of generic products, including 10 mEq potassium product. (Dritsas, Tr. 4717-18). There were at least two other products that had already been approved, K-Norm and K-Lease, that could enter the market, but which were not yet in the market. (CX 4 at 184403).

407. Firms already in the market could expand output. (Addanki, Tr. 5722-23). Apothecon's 10 mEq market grew 80 percent in 1998, which was a significant shift in sales of potassium chloride. (Addanki, Tr. 6177; CX 75 at USL 142364; CX 73 at USL 143202-03). In 1999, Ethex and Major increased their 10 mEq potassium chloride capsule sales revenue by 68.4 and 19.7 percent, respectively, and increased unit output by 56.6 and 6.1 percent, respectively. (CX 76 at 162110). Among 10 mEq wax matrix producers, K-Tab, Qualitest, Major and Apothecon increased unit sales by 17, 100, 51 and 60 percent, respectively. (CX 76 at 162109; Addanki, Tr. 6181; USL at 162109). Another product, Slow-K, showed a unit increase of 41% from 1994 to 1995. (Addanki, Tr. 6181; USX 380).

408. Complaint Counsel presented no evidence that Schering had any ability to restrict the output of the more than 20 firms selling therapeutically equivalent potassium chloride supplements.

3. Sales of K-Dur were expanding

409. Schering's documents reflect that Schering was seeking to expand sales and to engage in advertising and promotional activities that stimulate demand for the product. (Addanki, Tr. 5744). Such activities have the effect of expanding output. (Addanki, Tr. 5744). Dr. Addanki analyzed Schering's output as part of his analysis of whether Schering had monopoly power. (Addanki, Tr. 5744).

410. Schering's sales of K-Dur 20 did expand. From 1990-1996, K-Dur 20 grew more

rapidly in units than did the rest of the potassium chloride market. (CX 79 at USL 138066). Schering's sales continued to expand between 1996 and 2000. (Bresnahan, Tr. 8181). According to Professor Bresnahan, between 1997 and 2001, K-Dur output increased by one-quarter (25 percent). (Bresnahan, Tr. 8181).

411. Schering outspent all of its potassium supplement competitors combined by more than a 4 to 1 margin on advertising and physician awareness activities. Addanki, Tr. 5726-28. Schering outspent Upsher-Smith in its marketing of Klor Con 10 by a factor of 100 to 1. (Bresnahan, Tr. 734). (CX 746 at 00384 (Appendix A-5, K-Dur Marketing Research Backgrounder, July 1, 1996). This extensive advertising campaign was designed to compete against generic forms of potassium supplements. (Addanki, Tr. 5730-32).

412. Schering invested millions in promotion and field force effort, with a number of significant promotional programs over that approximate ten-year period that heavily promoted and marketed K-Dur 10 and K-Dur 20. (Russo, Tr. 3418-19, 3425-26).

413. Schering's executives recognized that marketing was a key to gaining market share from the other potassium firms: "Detailing by sales representatives is the most effective way to educate providers on the importance of K-DUR and move market share." CX 18 (1997 K-DUR Marketing Plan, Sept. 10, 1996 at SP 23 00039).

4. Bresnahan's conclusion that K-Dur 20 was a monopoly was not based on a thorough examination of the potassium supplement industry

414. Complaint Counsel's economic expert, Professor Bresnahan opined that Schering has monopoly power in the K-Dur 20 market. Under Professor Bresnahan's test, the issue of whether or not the June 1997 Settlement Agreement of the '743 patent infringement case was "anticompetitive" turns on the following three questions:

(1) Does the patent holder have monopoly power?
(2) Is there a threat to that power? The threat need not be a certainty; all that is required is that there be a probability of entry and competition.
(3) Is there a payment to the potential entrant to delay its entry? The payment can take any form, as long as it is a net positive value to the entrant.

Bresnahan, Tr. 655-58.

415. The three elements of the Bresnahan Test are to be assessed as of the date the

Agreement was entered into, June 17, 1997. Bresnahan, Tr. 659.

416. If Schering-Plough was not proven to be a monopolist in June 1997, then the first prong of Bresnahan's test would not be satisfied. Bresnahan, Tr. 660-661.

417. Bresnahan also testified that if the patent holder did not have monopoly power, then the agreement would not be anticompetitive. Bresnahan, Tr. 419 ("Only if there's some competition absent, which might happen, can you have an anti-competitive act. If rather than being products with market power or monopoly power they were products that already had enough competition to constrain them, an anti-competitive act couldn't – wouldn't do anything to harm competition.").

418. Professor Bresnahan incorrectly determined that Schering had unlawful monopoly power. (F. 30).

419. Bresnahan did not study systematically Schering's pricing of K-Dur 20, Upsher-Smith's pricing for its Klor Con 10 or Klor Con 8 potassium products, or the pricing of other potassium manufacturers' potassium products because he did not have access to a data set of such pricing data for the period 1995 to 2001. (Bresnahan, Tr. 834-35).

420. Bresnahan did not calculate the pricing differential (if any) between the various firms' potassium products and the price charged by Schering for equivalent does of K-Dur 20. (Bresnahan, Tr. 1071; USX 72).

421. Bresnahan conducted no econometric analyses comparing sales of 10 mEq tablets with sales of 20 mEq tablets or comparing the sales of 20 mEq potassium powders with 20 mEq tablets. (Bresnahan, Tr. 685-89).

422. Bresnahan did not study the cross-elasticity of demand between K-Dur 20 and other products. (Bresnahan, Tr. 810-11). Bresnahan did not study the direct price elasticity between K-Dur 20 and other potassium products.

423. Bresnahan did not attempt a study of the costs of Schering's K-Dur 20 products or the relationship between Schering's costs for producing K-Dur 20 and the price Schering charged for K-Dur 20. (Bresnahan, Tr. 834, 1274, 1003, 8148-50).

424. Bresnahan did not study the level of rebates that Schering gave back to its customers who purchased K-Dur 20 potassium products in 1995, 1996 or 1997. (Bresnahan, Tr. 702). Bresnahan conceded that there was significant promotional spending by Schering to promote its K-Dur 20 product, but he did not study this spending. (Bresnahan, Tr. 651-52, 735, 763, 1176).

425. Bresnahan did not make any formal study of the impact of Schering-Plough's marketing on the total market demand for potassium chloride products. (Bresnahan, Tr. 651-52).

426. Bresnahan did not study "first mover effects," the effects of being the first to sell a particular product – of K-Dur 20. (Bresnahan, Tr. 653).

427. Bresnahan made no analysis of promotional expenditures by Schering on K-Dur 20 in his report. (Bresnahan, Tr. 734-35). But Bresnahan acknowledged that Schering outspent Micro-K in by a factor of ten to one and outspent Upsher-Smith in its marketing of Klor Con 10 by a factor of 100 to one. (Bresnahan, Tr. 734.)

428. Bresnahan had no access to monthly sales data or pricing data from any firm aside from Respondents. (Bresnahan, Tr. 867-68).

429. Bresnahan did not review any marketing documents from other potassium supplement manufacturers. (Bresnahan, Tr. 867). Bresnahan did not systematically evaluate the levels of promotional spending by other potassium supplement firms over the period 1997 to 2001, such as the manufacturers of the branded potassium products Micro-K, Slow K, K-Tab. (Bresnahan, Tr. 8134).

430. Professor Bresnahan was unaware of clinical trials that compare patient compliance attributes of taking two 10 mEq tablets versus one 20 mEq tablet. (Bresnahan, Tr. 692).

431. Bresnahan did not evaluate or analyze the fact that four firms entered the U.S. potassium chloride market in 1996. (Bresnahan, Tr. 8184-85).